Vol.40—No.171
9–3–75
PAGES
40501–40795

federal register

WEDNESDAY, SEPTEMBER 3, 1975

highlights

PART I:

RAILWAY LABOR DISPUTE
Executive order creating an emergency board to investigate the dispute 40501

FOOD ADDITIVES
HEW/FDA notices of filed petitions for safe use of copolymers as component of certain coatings intended to contact food and as drift control agent for fungicide formulations 40568

VINYL CHLORIDE POLYMERS
HEW/FDA proposes termination of proceeding on prior-sanctioned polyvinyl chloride resin and proposes to restrict use in food-contact articles (2 documents); comments by 11–3–75 40529

NATIONAL BANKS
FRS adopt amendments dealing with additional powers of foreign branches 40506

CONTINUED INSIDE

PART II:

FEDERAL ELECTIONS
FEC issues interim guidelines and publishes requests for advisory opinions (5 documents); comments by 9–13–75 ..... 40668, 40671, 40673–40675

PART III:

ADMINISTRATIVE PRACTICES
HEW/FDA revokes previous regulations and proposes amendments regarding citizen petitions, public and regulatory hearings, standards and conduct and conflicts of interest (2 documents); comments 9–27–75 40681

PART IV:

PRIVACY ACT OF 1974
The following agencies and departments issue rules, proposals and/or notices implementing the Act:
Civil Aeronautics Board; comments by 9–27–75 40782
Commission on Civil Rights (2 documents); comments by 9–26–75 ..... 40783, 40786
Environmental Protection Agency; comments by 9–17–75 40792
National Security Council; comments by 9–15–75 40794
Federal Trade Commission; effective 10–3–75 40780

LOW INCOME HOUSING

HUD issues interim rule revising fair market rents in certain areas for new construction and substantial rehabilitation; effective 9–3–75; comments by 10–3–75 40513

FINANCIAL REPORTING

SEC issues proposal for disclosure of replacement cost data; comments by 1–31–76 40550

INSIDER TRANSACTIONS

FDIC proposes approval and recordkeeping requirements; comments by 10–31–75 40548

INVESTMENT COMPANIES

SEC proposes to permit sales load variations during periodic "open seasons"; comments by 10–15–75 40555

TRAINING GRANTS

HEW/OE issues notice of priorities regarding grants for training of teachers of the handicapped; effective 10–20–75 40568

EXCHANGE MEMBERS

SEC modifies requirement for maintenance of arrest and indictment records; effective 10–1–75 40512

SEEDS

USDA/AMS proposes amendments of standard and testing regulations; hearing: 10–7–75; comments 10–6–75 40524

MOTOR VEHICLE SAFETY STANDARDS

DOT/NHTSA issues advance proposal concerning safety of bicycle carriers; comments by 12–2–75 40537

PETROLEUM

COMMERCE/DIBA extends short supply controls throughout Third Quarter 1975 40507

PESTICIDES

EPA proposes new rules on experimental use permits and state regulations on registration to meet local needs (2 documents); comments by 10–2–75 ..... 40545, 40574

PARK PLANNING GUIDELINES

Interior/NPS solicits comments by 10–20–75 on proposed directives for the planning process of the National Park Service 40557

MEETINGS—

COMMERCE/DIBA: Numerically Controlled Machine Tool Technical Advisory Committee (2 documents), 10–6–75 ..... 40567, 40568

DOD/AIR: Historical Program Advisory Committee, 9–18 and 9–19–75 40557

EPA: Effluent Standards and Water Quality Information Advisory Committee, 9–25 and 9–26–75 40574

FEA: Consumer Affairs/Special Impact Advisory Committee, 9–18–75 40577

HEW: Secretary's Advisory Committee on Population Affairs, 10–23–75 40571

State: Inter-American Tropical Tuna Commission Advisory Committee, 9–18–75 40557

National Committee for the International Radio Consultative Committee, Study Group 2, 9–24–75 40557

The following government agencies have submitted Privacy Act documents to the Office of the Federal Register for publication. These documents are available for public inspection at the Federal Register Office, 1100 L St. NW., Rm. 8401. They will be published according to the following schedule:

Agency	*1975 Date of Issue*
Marine Mammal Commission, proposed rules & notices	Sept. 4
Dept. of Defense/Army, supplement to notices published Aug. 18	*
Community Services Administration, notices;	Sept. 4
Dept. of Interior, notices	*
Consumer Product Safety Commission, proposed rules	*
Commodity Futures Trading Commission, final rules	Sept. 4
Selective Service System, additional notices	Sept. 5
Dept. of Agriculture, proposed exemptions	Sept. 4

*Will be published as soon as possible but not yet scheduled.

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contents

list of cfr parts affected

The following numerical guide is a list of the parts of each title of the Code of Federal Regulations affected by documents published in today's issue. A cumulative list of parts affected, covering the current month to date, follows beginning with the second issue of the month.

A Cumulative List of CFR Sections Affected is published separately at the end of each month. The guide lists the parts and sections affected by documents published since the revision date of each title.

CUMULATIVE LIST OF PARTS AFFECTED—SEPTEMBER

The following numerical guide is a list of parts of each title of the Code of Federal Regulations affected by documents published to date during September.

3 CFR

EXECUTIVE ORDERS:
July 2, 1910 (See PLO 5512) 40162
MEMORANDUMS:
Memorandum of August 17, 1975 .. 40139

7 CFR

908 40505
989 40141

PROPOSED RULES:

51 40522
201 40524
910 40528
931 40170
948 40528

9 CFR

54 40505
91 40506

10 CFR

205 40141
212 40142
213 40143

11 CFR

Ch. I 40668

12 CFR

213 40506
215 40506
603 40454

PROPOSED RULES:

337 40548

15 CFR

377 40507

16 CFR

4 40780
13 ..... 40143–40154, 40508

17 CFR

200 40512
240 40512
249 40512

PROPOSED RULES:

210 40550
230 40555
270 40555

19 CFR

PROPOSED RULES:

201 40173
210 40173

20 CFR

PROPOSED RULES:

405 ..... 40171, 40537

21 CFR

Ch. I 40520

PROPOSED RULES:

1 40682
2 40682
5 40682
6 40682
8 40682
10 40682
11 40682
80 40682
90 40682
100 40682
102 40682
121 ..... 40529, 40682
202 40682
310 40682
312 40682
314 40682
328 40682
330 40682
429 40682
430 40682
431 40682
433 40682
511 40682
514 40682
601 40682
701 40682
1003 40682
1004 40682
1210 40682

22 CFR

PROPOSED RULES:

6a 40456

24 CFR

280 40261
888 40513

29 CFR

1952 40155–40157

PROPOSED RULES:

603 40537
608 40537
609 40537
687 40537
1910 40170
1926 40170

32 CFR

2102 40792

35 CFR

PROPOSED RULES:

10 40485

40 CFR

52 40158–40160
180 40161

PROPOSED RULES:

16 40792
52 40172
142 40538
162 40538
172 40545

41 CFR

14–3 40517
114–112 40517

43 CFR

PUBLIC LAND ORDERS:
4643 (Revoked in part by PLO 5511) 40162
5511 40162
5512 40162
5513 40162

45 CFR

30 40162
46 40163
169 40518

PROPOSED RULES:

704 40783

46 CFR

32 40163
35 40163
50 40163
52 40163
53 40163
54 40163
56 40164
58 40168
63 40169

47 CFR

91 40169

PROPOSED RULES:

73 40172

49 CFR

1033 ..... 40518, 40519
1306 40518

PROPOSED RULES:

171 40171
571 40537

50 CFR

32 ..... 40519, 40520

PROPOSED RULES:

17 40521

FEDERAL REGISTER

FEDERAL REGISTER PAGES AND DATES—SEPTEMBER

Pages	*Date*
40139–40500	2
40501–40795	3

reminders

(The items in this list were editorially compiled as an aid to FEDERAL REGISTER users. Inclusion or exclusion from this list has no legal significance. Since this list is intended as a reminder, it does not include effective dates that occur within 14 days of publication.)

Rules Going Into Effect Today

HEW/FDA—Food, Drug, and Cosmetic Products; Warning statements (3 documents)..... 8912; 3–3–75

Next Week's Deadlines for Comments On Proposed Rules

AGRICULTURE DEPARTMENT

Agricultural Marketing Service—

Egg research and promotion order; recommended decision; comments by 9–12–75..... 33982; 8–13–75

Handling of almonds grown in California; salable and reserve percentages for the 1975–76 crop year; comments by 9–11–75..... 37223; 8–26–75

Pears grown in Ore., Wash., and Calif.; comments by 9–9–75..... 37044; 8–25–75

Potatoes grown in Idaho and Ore.; comments by 9–9–75..... 37045; 8–25–75

Processed fruits and vegetables and related products; inspection and certification; comments by 9–8–75. 33043; 8–6–75

Tokay grapes grown in California, expenses and rate of assessment; comments by 9–12–75..... 37044; 8–25–75

Animal and Plant Health Inspection Service—

Viruses, serums, toxins, and analogous products; correction of language for scientific accuracy and clarity; comments by 9–8–75. 32753; 8–4–75

COMMERCE DEPARTMENT

Domestic and International Business Administration—

Basic rules of Defense priorities system; change in schedule II; comments by 9–12–75..... 33996; 8–13–75

COMMISSION OF FINE ARTS

Freedom of Information; comments by 9–8–75..... 30841; 7–23–75

DEFENSE DEPARTMENT

National Security Agency—

Privacy act systems of records; disclosures and amendment procedures and specific exemptions; comments by 9–12–75..... 37579; 8–26–75

ENVIRONMENTAL PROTECTION AGENCY

Interim primary drinking water regulations; proposed maximum contaminant levels for radioactivity; comments by 9–10–75..... 34324; 8–14–75

Residential, commercial and institutional solid wastes; guidelines for storage and collection; comments by 9–9–75. 29404; 7–11–75

FARM CREDIT ADMINISTRATION

Privacy Act; implementation; comments by 9–12–75..... 33832; 8–12–75

FEDERAL COMMUNICATIONS COMMISSION

Cable TV; channel capacity and access requirements; reply comments by 9–8–75..... 27250; 6–27–75

FM Broadcast stations; table of assignments (Garden City, Hinesville and Springfield, Georgia); comments by 9–8–75..... 30985; 7–24–75

FEDERAL ELECTION COMMISSION

Implementation of Privacy Act; comments by 9–10–75.... 46872; 8–22–75

Office and Franking Accounts: Excess Campaign Contributions; Notice of hearings; comments by 9–11–75. 36869; 8–22–75

FEDERAL HOME LOAN BANK BOARD

Deletion of obsolete regulations; comments by 9–8–75..... 33055; 8–6–75

District of Columbia Associations; comments by 9–8–75..... 33054; 8–6–75

FEDERAL POWER COMMISSION

Natural gas; national rates for jurisdictional sales; comments by 9–11–75. 32140; 7–31–75

Natural gas; staff rate recommendations and procedures regarding natural rates; comments by 9–5–75.... 33998; 8–13–75

Uniform System of Accounts; amendments; comments by 9–22–75. 33999; 8–13–75

FEDERAL RESERVE SYSTEM

Privacy Act regulations; comments by 9–12–75..... 39830; 8–28–75

FEDERAL TRADE COMMISSION

Advertising of children's premiums on television; comments by 9–8–75. 33832; 8–12–75

HEALTH, EDUCATION, AND WELFARE DEPARTMENT

Social and Rehabilitation Service—

Financial assistance programs; coverage and conditions of eligibility; definition of unemployed fathers; comments by 9–8–75.... 33461; 8–8–75

St. Elizabeths Hospital—

Conduct and traffic regulations; comments by 9–8–75.... 33459; 8–8–75

INTERIOR DEPARTMENT

Fish and Wildlife Service—

Endangered and threatened wildlife; reclassification of the American Alligator; comments by 9–8–75. 28712; 7–8–75

INTERNATIONAL TRADE COMMISSION

Import injury to industries from market disruption; investigations; comments by 9–12–75..... 34005; 8–13–75

LABOR DEPARTMENT

Occupational Safety and Health Administration—approved California plan; supplements; comments by 9–12–75. 33995; 8–13–75

Office of the Secretary—

Comprehensive Employment and Training Act; special Federal programs and responsibilities; comments by 9–11–75..... 33920; 8–12–75

MANAGEMENT AND BUDGET OFFICE

Privacy Act Procedures; implementation; comments by 9–12–75..... 34165; 8–14–75

NUCLEAR REGULATORY COMMISSION

Privacy Act; proposed implementation; comments by 9–12–75..... 33833; 8–12–75

SECURITIES AND EXCHANGE COMMISSION

Privacy Act of 1974; exemptions; comments by 9–12–75.... 34417; 8–15–75

Municipal securities brokers and dealers; registration; comments by 9–12–75..... 37228; 8–26–75

TRANSPORTATION DEPARTMENT

Coast Guard—

Air compressors; cargo handling room bilges on tank vessels; requirements; comments by 9–29–75. 33996; 8–13–75

Clearwater Pass, Florida; drawbridge operation; comments by 9–12–75. 33828; 8–12–75

Federal Aviation Administration—

Airworthiness review program; comments by 9–8–75..... 24801; 6–10–75

Airworthiness Review Program; amendments to aircraft certification rules related to flight and duties of type certificate holders; comments by 9–8–75..... 24663; 6–9–75

Alteration of transition area; comments by 9–8–75.... 33461; 8–8–75

Alteration of transition area; Wetumpka, Ala.; comments by 9–12–75. 33996; 8–13–75

Designation of transition area; comments by 9–8–75.... 33462; 8–8–75

Designation of transition area; Brenham, Tex.; comments by 9–12–75. 33997; 8–13–75

Designation of transition area; Carrizo Springs, Tex.; comments by 9–12–75..... 33998; 8–13–75

Designation of transition area; Conway, S.C., comments by 9–8–75. 30840; 7–23–75

Pilatus Aircraft Ltd. model PC–6 Airplanes; proposed airworthiness directives; comments by 9–8–75. 30980; 7–24–75

Pratt and Whitney aircraft Wasp Jr. and R–985 model engines; airworthiness directive; comments by 9–9–75..... 26542; 6–24–75

Special VFR operations in the Oakland, California, control zone; comments by 9–8–75..... 28629; 7–8–75

Materials Transportation Bureau—
Hazardous materials; exemption procedures; comments by 9–12–75. 32758; 8–4–75

Urban Mass Transportation Administration—
Charter and school bus operations; extension of comments period; comments by 9–11–75..... 29729; 7–15–75

Next Week's Public Hearings

FEDERAL ENERGY ADMINISTRATION
Energy Resources Council Interagency Task Force on motor vehicle goals beyond 1980; to be held in Los Angeles, Calif., on 9–9–75.. 28666; 7–8–75

Next Week's Meetings

ADMINISTRATIVE CONFERENCE OF THE UNITED STATES
Committee on Rulemaking and Public Information; to be held in Washington, D.C (open), 9–12–75..... 36614; 8–21–75

AGRICULTURE DEPARTMENT
Agricultural Research Service—
National Poultry Improvement Plan, General Conference Committee; to be held in Washington, D.C. (open); 9–9 and 9–10–75.. 36601; 8–21–75
Forest Service
Manti Division Grazing Advisory Board; to be held in Moroni, Utah (open) 9–14–75 ..... 34171; 8–14–75

AMERICAN REVOLUTION BICENTENNIAL ADMINISTRATION
American Revolution Bicentennial Advisory Council; to be held in Denver, Colorado (open, with restrictions) 9–11–75..... 30521; 7–21–75

CIVIL RIGHTS COMMISSION
Connecticut State Advisory Committee; to be held in New Haven, Conn. (open) 9–11–75..... 34449; 8–15–75
Illinois State Advisory Committee; to be held in Chicago, Ill. (open) 9–10–75. 34449; 8–15–75
Maine State Advisory Committee; to be held at Augusta, Me. (open) 9–10–75. 34449; 8–15–75

CIVIL SERVICE COMMISSION
Federal Employeees Pay Council; to be held in Wash., D.C. (closed), 9–10–75. 37081; 8–25–75

COMMERCE DEPARTMENT
Domestic and International Business Administration—
Computer Systems Technical Advisory Committee; to be held in Wash., D.C. (open), 9–10–75..... 33695; 8–11–75
Computer Systems Technical Advisory Committee; to be held in Wash., D.C. (closed), 9–10–75..... 33695; 8–11–75
Technology Transfer Subcommittee of the Computer Systems Technical Advisory Committee to be held in Washington, D.C. (closed in part), 9–9–75..... 33503; 8–8–75
National Bureau of Standards—
Federal Information Processing Standards Task Group 13 Workload Definition and Benchmarking; to be held at Gaithersburg, Maryland (open), 9–10–75..... 29749; 7–15–75
National Oceanic and Atmospheric Administration—
Coastal Zone Management Advisory Committee; to be held at Washington, D.C. (open with restrictions), 9–11 and 9–12–75.. 33481; 8–8–75

DEFENSE DEPARTMENT
Air Force Department—
Scientific Advisory Board, USAF; Aerospace Vehicles Panel Committee; to be held in Washington, D.C. (closed), 9–10–75, 9–11–75. 36394; 8–20–75
Navy Department—
Chief of Naval Operations Executive Panel Advisory Committee; to be held in Washington, D.C. (closed), 9–8 and 9–9–75.. 36580; 8–21–75
Office of the Secretary—
DOD Advisory Group on Electron Devices; to be held in New York, New York (closed), 9–10–75..... 34424; 8–15–75
DDR&E High Energy Laser Review Group (HELRG) Laser Hardened Materials and Structures Subpanel; to be held in Bedford, Mass. (closed), 9–11 and 9–12–75. 28818; 7–9–75
DDR&E High Energy Laser Review Group; to be held in Lexington, Mass. (closed), 9–9 and 9–10–75. 32766; 8–4–75
Natural Resources Advisory Committee; to be held in Washington, D.C. (open), 9–9 and 9–10–75.... 36394; 8–20–75
Joint Strategic Target Planning Staff Scientific Advisory Group, to be held in Offutt Air Force Base, Nebr. (closed), 10–7–75..... 34010; 8–13–75 8–13–75

FEDERAL COMMUNICATIONS COMMISSION
Private Land Mobile Advisory Committee; to be held in Washington, D.C. (open), 9–10–75..... 36425; 8–20–75

HEALTH, EDUCATION, AND WELFARE DEPARTMENT
Alcohol, Drug Abuse, and Mental Health Administration—
Clinical Psychopharmacology Research Review Committee, to be held in Rockville, Md. (partially open), 9–8 and 9–9–75..... 34014; 8–13–75
Epidemiologic Studies Review Committee, to be held in Arlington, Va. (partially open), 9–11 thru 9–12–75 ..... 34015; 8–13–75
Juvenile Problems Research Review Committee, to be held in Washington, D.C. (partially open), 9–11 and 9–12–75..... 34015; 8–13–75
Mental Health Services Research Review Committee, to be held in Elkridge, Md. (partially open), 9–8 thru 9–10–75..... 34015; 8–13–75
Metropolitan Mental Health Problems Review Committee, to be held in Washington, D.C. (partially open), 9–11 and 9–12–75..... 34015; 8–13–75
Neuropsychology Research Review Committee, to be held in Washington, D.C. (partially open), 9–11 thru 9–13–75..... 34015; 8–13–75
Preclinical Psychopharmacology Research Review Committee, to be held in Washington, D.C. (partially open), 9–11 and 9–12–75.. 34015; 8–13–75
Education Office—
National Advisory Council on Education Professions Development; to be held in Wash., D.C. (open), 9–11 and 9–12–75..... 33696; 8–11–75
Community Education Advisory Council; to be held in Washington, D.C. (open), 9–14, 9–15–75..... 36414; 8–20–75
Food and Drug Administration—
Clinical Chemistry Subcommittee of the In Vitro Diagnostic Products Advisory Committee; to be held in Washington, D.C. (open with restrictions), 9–8, 9–9–75..... 36404; 8–20–75
Dental Drug Products Advisory Committee; to be held in Rockville, Maryland (open with restrictions), 9–9, 9–10..... 36405; 8–20–75
Panel on Review of Ophthalmic Drugs; to be held in Rockville, Maryland (open with restrictions) 9–12, 9–13–75..... 36407; 8–20–75
Panel on Review of General Hospital and Personal Use Devices; to be held in Washington, D.C. (open with restrictions) 9–8, 9–9–75.... 36405; 8–20–75
Panel on Review of Ophthalmic Devices; to be held in Washington, D.C. (open with restrictions) 9–9, 9–10–75..... 36406; 8–20–75
Panel on Review or Oral Cavity Drug Products; to be held in Rockville, Maryland (open with restrictions) 9–9, 9–10–75..... 36406; 8–20–75
Pulmonary-Allergy and Clinical Immunology Advisory Committee; to be held in Rockville, Maryland (open with restrictions) 9–10–75. 36406; 8–20–75
Pulmonary-Allergy and Clinical Immunology Advisory Committee; to be held in Rockville, Maryland (open with restrictions) 9–10–75..... 36506; 8–20–75
Statistics Subcommittee of the Diagnostic Products Advisory Committee; to be held in Washington, D.C. (open with restrictions) 9–10, 9–11–75..... 36406; 8–20–75
Surgical Devices Subcommittee of the Panel on Review of Cardiovascular Devices; to be held in Washington, D.C. (open with restrictions) 9–12–75..... 36407; 8–20–75
Health Resources Administration—
Health Services Developmental Grants Study Section; to be held at Bethesda, Md. (open with restrictions) 9–8–75..... 33483; 8–8–75

National Institutes of Health—
National Commission on Arthritis and Related Musculoskeletal Diseases, to be held in Tucson, Ariz. (open) 9–8 thru 9–10–75 ..... 34020; 8–13–75
Diagnostic Research Advisory; to be held in Bethesda, Maryland (open) 9–9–75 ..... 36411; 8–20–75
National Commission on Diabetes; to be held in Bethesda, Maryland (open) 9–8, 9–9–75 ..... 36413; 8–20–75
National Cancer Institute; to be held in Bethesda, Maryland; 9–8, 9–9–75 ..... 36413; 8–20–75
Vision Research Program Committee, to be held in Bethesda, Md. (open with restrictions) 9–12–75. 34020; 8–13–75
Committee on Cytology Automation; to be held in Bethesda, Md. (open in part) 9–8 and 9–9–75.... 29317; 7–11–75
Tobacco Working Group; to be held in Bethesda, Md. (open) 9–9 and 9–10–75 ..... 29317; 7–11–75
Office of the Secretary—
President's Commission on Olympic Sports; to be held in Washington, D.C. (open) 9–10–75..... 36612; 8–21–75
National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, to be held in Bethesda, Md. (partially open) 9–12 thru 9–14–75. 34021; 8–13–75
Review Panel on New Drug Regulation; to be held in Washington, D.C. and Rockville, Maryland (open with restrictions) 9–8, 9–9–75. 36414; 8–20–75

INTERIOR DEPARTMENT

Bonneville Power Administration; to be held in Moore, Idaho (open) 9–8–75. 33057; 8–6–75
Bonneville Power Administration; to be held in Burley, Idaho (open) 9–9–75. 33057; 8–6–75
Bonneville Power Administration; to be held in Bonneville, Colorado (open) 9–9–75 ..... 33057; 8–6–75
Bonneville Power Administration; to be held in Sedro Woolley, Washington (open) 9–10–75..... 33057; 8–6–75
Bureau of Land Management—
National Advisory Board, to be held in Elko, Nev. (open) 9–8 and 9–10–75 ..... 34010; 8–13–75
National Park Service—
Chesapeake and Ohio Canal National Historical Park Commission; to be held in Harpers Ferry, W. Va. (open) 9–13–75..... 36600; 8–21–75
Gateway National Recreation Area Advisory Commission; to be held in Bfrooklyn, N.Y. (open) 9–10–75. 36600; 8–21–75
Historic American Buildings Survey Advisory Board; to be held in Ithaca, New York (open with restrictions) 9–12 and 9–13–75. 34431; 8–15–75
National Survey of Historic Sites and Buildings Consulting Committee; to be held in Washington, D.C. (open), 9–8 and 9–9–75 ..... 33758; 8–11–75
Rocky Mountain Regional Advisory Committee; to be held at Glacier National Park, Montana (open) 9–10 through 9–12–75..... 33480; 8–8–75
Water Research and Education Advisory Committee, to be held in Washington, D.C. (open), 9–8–75. 34012; 8–13–75

JUSTICE DEPARTMENT

Law Enforcement Assistance Administration—
National Advisory Committee on Criminal Justice Standards and Goals; to be held in Scottsdale, Ariz. (partially closed), 9–7 through 9–9–75 ..... 36581; 8–21–75

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

Evaluation of proposals for participation in the scientific definition of explorer-class payloads; to be held in Washington, D.C. (closed), 9–9–75. 36429; 8–20–75
Research and technology advisory council committee on materials and structures; to be held in California (open), 9–11, 9–12–75..... 36430; 8–20–75
Research and Technology Advisory Council, Panel on Aeronautical Operating Systems, ad hoc Panel on Terminal Configured Vehicles, to be held in Washington, D.C. (open with restrictions) 9–10 and 9–11–75. 34068; 8–13–75

NATIONAL ENDOWMENT FOR ARTS AND HUMANITIES

Public Programs Panel; to be held in Washington, D.C. (closed), 9–8 thru 9–12–75 ..... 33735; 8–11–75
Research Panel; to be held in Washington, D.C. (closed), 9–8 and 9–12–75. 33735; 8–11–75

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards; to be held in Washington, D.C. (open with restrictions) 9–9 and 9–10–75 ..... 37108; 8–25–75

PRESIDENTIAL CLEMENCY BOARD

To be held at Washington, D.C. (closed), 9–8 through 9–13–75 ..... 33498; 8–8–75

STATE DEPARTMENT

Government Advisory Committee on International Book and Library Programs, to be held in Washington, D.C. (open), 9–24–75..... 34009; 8–13–75
Study Group 2 of the National Committee for the International Telegraph and Telephone Consultative Committee (CCITT); to be held in Washington, D.C. (open), 9–11–75 ..... 30846; 7–23–75
Office of the Secretary—
Shipping Coordinating Committee; to be held in Washington, D.C. (open), 9–10–75 ..... 36393; 8–20–75

TRANSPORTATION DEPARTMENT

Federal Railroad Administration—
Railroad Operating Rules Advisory Committee; to be held in Washington, D.C. (open), 9–9 and 9–10–75 ..... 33698; 8–11–75
National Highway Traffic Safety Administration—
National Motor Vehicle Safety Advisory Council; to be held in Washington, D.C. (open), 9–9, 9–10, 9–11–75 ..... 36418; 8–20–75

VETERANS ADMINISTRATION

Advisory Committee on Cemeteries and Memorials; to be held in Washington, D.C. (open), 9–8 and 9–9–75. 34490; 8–15–75
Veterans Administration Wage Committee; to be held in Washington, D.C. (closed), 9–11–75 ..... 25525; 6–16–75
Warranty terms and conditions and settlement procedures; change in hearing location; comments by 9–8–75. 37226; 8–26–75

CIVIL RIGHTS COMMISSION

Pennsylvania State Advisory Committee; to be held in Philadelphia, Pennsylvania (open with restrictions), 9–10–75 ..... 33852; 8–12–75

COMMERCE DEPARTMENT

Domestic and International Business Administration—
Electronic Instrumentation Technical Advisory Committee; to be held in Washington, D.C. (partially open), 9–11–75..... 33847; 8–12–75
Office of the Secretary—
Commerce Technical Advisory Board; to be held in Washington, D.C. (open with restrictions), 9–10–75. 33850; 8–12–75

DEFENSE DEPARTMENT

Army Department—
Shoreline Erosion Advisory Panel; to be held in Ann Arbor, Michigan (open with restrictions), 9–10 thru 9–12–75..... 33844; 8–12–75
Office of the Secretary—
Wage Committee; to be held in Washington, D.C. (closed), 9–9–75. 33845; 8–12–75
Advisory Group on Electronic Devices; to be held in Arlington, Va. (closed), 9–11–75..... 37240; 8–26–75

ENVIRONMENTAL PROTECTION AGENCY

Interagency Committee on Federal Guidance for Occupation Exposures to Ionizing Radiation; to be held in Arlington, Va. (open), 9–10–75. 38187; 8–27–75

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Music Advisory Panel (choral), to be held in Washington, D.C. (open with restrictions), 9–12 and 9–13–75..... 39562; 8–28–75

Public Media Advisory Panel, to be held in Washington, D.C. (open with restrictions and closed), 9–13, 9–14, and 9–15–75..... 39562; 8–28–75

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards; to be held in Washington, D.C. (open with restrictions), 9–11, 9–12, and 9–13–75..... 38192; 8–27–75

STATE DEPARTMENT

Agency for International Development—
Government Advisory Committee on International Book and Library Programs; to be held in Washington, D.C. (open with restrictions), 9–11–75..... 33842; 8–12–75

Shipping Coordinating Committee; to be held in Washington, D.C. (open), 9–11–75..... 37239; 8–26–75

TRANSPORTATION DEPARTMENT

Federal Aviation Administration—
High Altitude Pollution Program Planning; to be held in Washington, D.C. (open), 9–11 and 9–12–75.. 37247; 8–26–75

presidential documents

Title 3—The President

Executive Order 11876 • September 2, 1975

Creating an Emergency Board To Investigate a Dispute Between the Carriers Represented by the National Railway Labor Conference and Certain of Their Employees

A dispute exists between the carriers represented by the National Railway Labor Conference, designated in lists attached hereto and made a part hereof, and certain of their employees represented by the Railway Employes' Department, AFL–CIO; International Brotherhood of Boilermakers, Iron Ship Builders, Blacksmiths, Forgers & Helpers; Brotherhood Railway Carmen of United States and Canada; International Brotherhood of Electrical Workers and the International Brotherhood of Firemen & Oilers;

This dispute has not heretofore been adjusted under the provisions of the Railway Labor Act, as amended; and

This dispute, in the judgment of the National Mediation Board, threatens substantially to interrupt interstate commerce to a degree such as to deprive a section of the country of essential transportation service:

NOW, THEREFORE, by virtue of the authority vested in me by Section 10 of the Railway Labor Act, as amended (45 U.S.C. 160), I hereby create a board of three members, to be appointed by me, to investigate this dispute. No member of the board shall be pecuniarily or otherwise interested in any organization of railroad employees or any carrier.

The Board shall report its finding to the President with respect to the dispute within 30 days from the date of this Order.

As provided by Section 10 of the Railway Labor Act, as amended, from this date and for 30 days after the board has made its report to the President, no change, except by agreement, shall be made by the

carriers represented by the National Railway Labor Conference, or by their employees, in the conditions out of which the dispute arose.

Gerald R. Ford

THE WHITE HOUSE,
September 2, 1975.

RAILROADS REPRESENTED BY THE NATIONAL RAILWAY LABOR CONFERENCE

Akron, Canton & Youngstown Railroad Company
Alameda Belt Line
Alton & Southern Railway Company
*Ann Arbor Railroad Company
Atchison, Topeka & Santa Fe Railway Company
Atlanta and West Point Rail Road Company, The Western Railway of Alabama
Atlanta Joint Terminals
Baltimore and Ohio Railroad Company, including The Staten Island Railroad Corporation
Baltimore and Ohio Chicago Terminal Railroad Company
Bangor and Aroostook Railroad Company
Belt Railway Company of Chicago
@Bessemer and Lake Erie Railroad Company
*Boston and Maine Corporation
Burlington Northern Inc.
Butte, Anaconda & Pacific Railway Company
Camas Prairie Railroad Company
Canadian National Railways—
Great Lakes Region, Lines in the United States
St. Lawrence Region, Lines in the United States
#Canadian Pacific Limited
Central of Georgia Railroad Company
*Central Railroad Company of New Jersey
New York and Long Branch Railroad Company
Central Vermont Railway, Inc.
Chesapeake and Ohio Railway Company
Chicago & Eastern Illinois Railroad
Chicago & Illinois Midland Railway Company
Chicago and North Western Transportation Company
Chicago and Western Indiana Railroad Company
Chicago, Milwaukee, St. Paul and Pacific Railroad Company
Chicago River and Indiana Railroad Company
*Chicago, Rock Island and Pacific Railroad Company
Chicago South Shore and South Bend Railroad
Chicago Union Station Company
Chicago, West Pullman and Southern Railroad Company
Cleveland Union Terminals Company
Clinchfield Railroad Company
Colorado & Wyoming Railway Company
Davenport, Rock Island and North Western Railway Company
Dayton Union Railway Company
Delaware and Hudson Railway Company
Denver and Rio Grande Western Railroad Company
Des Moines Union Railway Company
Detroit and Toledo Shore Line Railroad
#Detroit & Mackinac Railway
Detroit, Toledo & Ironton Railroad Company
@Duluth, Missabe and Iron Range Railway Company
Duluth, Winnipeg & Pacific Railway Company
Elgin, Joliet and Eastern Railway Company
*Erie Lackawanna Railway Company
Fort Worth and Denver Railway Company
Georgia Railroad
Grand Trunk Western Railroad Company
Green Bay and Western Railroad Company
Houston Belt & Terminal Railway Company

Illinois Central Gulf Railroad Company
Illinois Terminal Railroad Company
Indiana Harbor Belt Railroad Company
Indianapolis Union Railway Company
Jacksonville Terminal Company
Joint Texas Division of the CRI&P RR. and FW&D Ry.
Kansas City Southern Railway Company
Kansas City Terminal Railway Company
Kentucky & Indiana Terminal Railroad Company
#Lake Superior and Ishpeming Railroad
Lake Superior Terminal and Transfer Railway Company
*Lehigh and Hudson River Railway Company
Lehigh and New England Railway
*Lehigh Valley Railroad
Los Angeles Junction Railway Company
Louisiana & Arkansas Railway Company
Louisville and Nashville Railroad Company
Maine Central Railroad Company
Portland Terminal Company
Manufacturers Railway Company
#Merchants Despatch Transportation Company
Minneapolis, Northfield and Southern Railway
Minnesota Transfer Railway Company
Missouri-Kansas-Texas Railroad Company
Missouri Pacific Railroad Company
Missouri-Illinois Railroad Company
Monongahela Railway Company
Montour Railroad Company
@Newburgh and South Shore Railway Company
New Orleans Public Belt Railroad
New Orleans Union Passenger Terminal
New York, Susquehanna and Western Railroad Company
Norfolk and Portsmouth Belt Line Railroad Company
Norfolk and Western Railway Company
@Northampton and Bath Railroad Company
Northwestern Pacific Railroad Company
Oakland Terminal Railway
**Penn Central Transportation Company
Pennsylvania-Reading Seashore Lines
Peoria and Pekin Union Railway Company
Pittsburgh and Lake Erie Railroad Company
Portland Terminal Railroad Company
Port Terminal Railroad Association
Quanah, Acme and Pacific Railway Company
*Reading Company
@—Philadelphia, Reading & Pottsville Telegraph Company
Richmond, Fredericksburg and Potomac Railroad Company
River Terminal Railway Company
St. Joseph Terminal Railroad Company
St. Louis-San Francisco Railway Company
St. Louis Southwestern Railway Company
Saint Paul Union Depot Company
San Diego and Arizona Eastern Railway Company
Seaboard Coast Line Railroad Company
Soo Line Railroad Company
Southern Pacific Transportation Company—
Pacific Lines and Texas and Louisiana Lines
Southern Railway Company
Alabama Great Southern Railroad Company
Cincinnati, New Orleans & Texas Pacific Railway Company
Georgia Southern and Florida Railway Company
New Orleans Terminal Company
St. Johns River Terminal Company
Staten Island Railroad Corporation
Terminal Railroad Association of St. Louis
Texas and Pacific Railway Company
Texas Mexican Railway Company
Texas Pacific-Missouri Pacific Terminal Railroad of New Orleans

Toledo, Peoria and Western Railroad Company
Toledo Terminal Railroad Company
Union Depot Company, Columbus, Ohio
Union Pacific Railroad Company
Union Terminal Railway-St. Joseph Belt Railway
Washington Terminal Company
Western Maryland Railway Company
Western Pacific Railroad Company
#Yakima Valley Transportation Company
@Youngstown and Northern Railroad Company

NOTES:

*—Subject to the approval of the Courts.
**—Subject to the approval of the Trustees of the Property and to the approval of the Courts. The Trustees have approved.
#—Authorization covers negotiation of the organizations' Aug. 1, 1974 notice, only.
@—Authorization covers negotiation of the organizations' separate notices dated July 1, 1974, only.

[FR Doc.75-23525 Filed 9-2-75;11:20 am]

EDITORIAL NOTE: An announcement of the appointment of the members of the board will be printed in the Weekly Compilation of Presidential Documents (vol. 11, no. 36).

rules and regulations

Title 7—Agriculture

CHAPTER II—FOOD AND NUTRITION SERVICE, DEPARTMENT OF AGRICULTURE

ALTERNATE MEAL COMPONENTS IN CHILD NUTRITION PROGRAMS

Alternative Labeling Requirements

Correction

In FR Doc. 75-22352, appearing at page 37027 in the issue of Monday, August 25, 1975, the effective date note at the end of the document on page 37028 is unclear. It should be corrected to read "These amendments become effective August 25, 1975."

CHAPTER IX—AGRICULTURAL MARKETING SERVICE (MARKETING AGREEMENTS AND ORDERS; FRUITS, VEGETABLES, NUTS), DEPARTMENT OF AGRICULTURE

[Valencia Orange Reg. 512, Amdt. 1]

PART 908—VALENCIA ORANGES GROWN IN ARIZONA AND DESIGNATED PART OF CALIFORNIA

Limitation of Handling

This regulation increases the quantity of California-Arizona Valencia oranges that may be shipped to fresh market during the weekly regulation period Aug. 22-28, 1975. The quantity that may be shipped is increased due to improved market conditions for California-Arizona Valencia oranges. The regulation and this amendment are issued pursuant to the Agricultural Marketing Agreement Act of 1937, as amended, and Marketing Order No. 908.

(a) *Findings.* (1) Pursuant to the marketing agreement, as amended, and Order No. 908, as amended (7 CFR Part 908), regulating the handling of Valencia oranges grown in Arizona and designated part of California, effective under the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674) and upon the basis of the recommendation and information submitted by the Valencia Orange Administrative Committee, established under the said amended marketing agreement and order, and upon other available information, it is hereby found that the limitation of handling of such Valencia oranges, as hereinafter provided, will tend to effectuate the declared policy of the act.

(2) The need for an increase in the quantity of oranges available for handling during the current week results from changes that have taken place in the marketing situation since the issuance of Valencia Orange Regulation 512 (40 FR 36570). The marketing picture now indicates that there is a greater demand for Valencia oranges than existed when the regulation was made effective. Therefore, in order to provide an opportunity for handlers to handle a sufficient volume of Valencia oranges to fill the current demand thereby making a greater quantity of Valencia oranges available to meet such increased demand, the regulation should be amended, as hereinafter set forth.

(3) It is hereby further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rule-making procedure, and postpone the effective date of this amendment until 30 days after publication thereof in the FEDERAL REGISTER (5 U.S.C. 553) because the time intervening between the date when information upon which this amendment is based became available and the time when this amendment must become effective in order to effectuate the declared policy of the act is insufficient, and this amendment relieves restriction on the handling of Valencia oranges grown in Arizona and designated part of California.

(b) *Order, as amended.* The provisions in paragraph (b)(1) (i), and (ii) of § 908.812 (Valencia Orange Regulation 512 (40 FR 36570)) are hereby amended to read as follows:

§ 908.812 Valencia Orange Regulation 512.

* * * * *

(b) * * *

(1) * * *

(i) District 1: 225,000 cartons;

(ii) District 2: 500,000 cartons.

(Secs. 1-19, 48 Stat. 31, as amended; 7 U.S.C. 601-674)

Dated: August 27, 1975.

CHARLES R. BRADER,
Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc.75-23253 Filed 9-2-75;8:45 am]

Title 9—Animals and Animal Products

CHAPTER I—ANIMAL AND PLANT HEALTH INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE

SUBCHAPTER B—COOPERATIVE CONTROL AND ERADICATION OF LIVESTOCK OR POULTRY DISEASES

PART 54—ANIMALS DESTROYED BECAUSE OF SCRAPIE

Payment of Indemnities

Statement of considerations. On June 19, 1975, there was published in the FEDERAL REGISTER (40 FR 25829) proposed amendments to the regulations in Part 54, Title 9, Code of Federal Regulations.

The purpose of the proposal was to: (1) Provide for the destruction of animals which have been directly exposed to scrapie in lieu of surveillance; (2) eliminate salvage and use for human consumption of bloodline and exposed animals; and (3) increase indemnity which may be paid for animals destroyed because of scrapie from $25 to $40 per head for grade animals and from $75 to $90 per head for purebred animals.

A period of 30 days was allowed for submission of comments by interested persons. In response to publication of the proposed rulemaking, comments were received from four organizations and one individual as follows: Representatives of the National Governors' Conference, the National Association of Counties, the International City Management Association, and the National League of Cities all advised that they had no comments to offer, and one individual commended the Department for the action proposed.

After due consideration of all relevant material, including that submitted with such notice, the proposed amendments are hereby adopted without change except that a provision has been added in § 54.7(b) whereby affected, bloodline and exposed animals may be moved for destruction to a location other than the premises where appraised when movement to such location is approved in advance by State and Federal regulatory officials of the State or States involved. Accordingly, Part 54, Title 9, Code of Federal Regulations is amended in the following respects:

1. In § 54.1, paragraph (d) is amended; paragraph (e) is redesignated as paragraph (g); and new paragraphs (e) and (f) are added to read:

§ 54.1 Definitions.

* * * * *

(d) "Affected animal" means any sheep or goat for which a diagnosis of scrapie is confirmed.

(e) "Bloodline animal" means any sheep or goat which is: the sire or dam of an affected animal; the descendant of an affected animal; or the full or half brother or sister of an affected animal.

(f) "Exposed animal" means any sheep and/or goat that has been held, pastured or penned on a source flock or an infected flock premises in contact with an animal for which a diagnosis of scrapie is confirmed.

* * * * *

2. In § 54.3, paragraph (a) is amended to read:

§ 54.3 Appraisal of animals.

(a) Affected animals, bloodline animals, and exposed animals shall be appraised at their actual value at the time and place of appraisal by a representative of Veterinary Services and a representative of the State jointly, except that, if the owner and State authorities approve, such animals may be appraised by a representative of Veterinary Services alone. Such animals may be appraised in groups providing they are the same species and type and providing that where appraisal is by the head each animal in the group is the same value per head or where appraisal is by the pound each animal in the group is the same value per pound.

* * * * *

3. In § 54.7, the heading and paragraphs (a) and (b) are amended and a new paragraph (c) is added so that the section will read:

§ 54.7 Destruction and Disposition of Animals.

(a) Affected animals, bloodline animals, and exposed animals shall be destroyed on the premises where held, ing the written agreement of the owner to accept as compensation in full from the United States, 50 percent of the appraisal value not to exceed $40 per head for grade animals and $90 per head for purebred animals.

(b) Affected animals, bloodline animals, and exposed animals shall be destroyed on the premises where held, pastured or penned at the time of appraisal except that such animals may be moved for destruction to a location other than the premises where appraised when movement to such location is approved in advance by State and Federal regulatory officials of the State or States involved, and shall not be processed for human food. The animals designated for destruction shall be disposed of by burial or incineration.

(c) The destruction and disposition of animals destroyed in accordance with this Part shall be supervised by a Veterinary Services or State representative who shall prepare and transmit to the Deputy Administrator, Veterinary Services, a report identifying the animals and showing the disposition thereof.

4. In § 54.8, paragraphs (a) and (b) are amended to read:

§ 54.8 Payments to owners for animals destroyed.

(a) Owners of affected animals, bloodline animals, and/or exposed animals destroyed in accordance with this Part shall be paid an indemnity not to exceed 50 percent of the appraisal value of each animal so destroyed.

(b) The Federal indemnity shall be limited to $40 per head for grade animals and $90 per head for purebred animals.

* * * * *

(Sec. 3, 23 Stat. 32, as amended; sec. 2, 32 Stat. 792, as amended; sec. 11, 58 Stat. 734, as amended; (21 U.S.C. 111, 114, 114a, 134a-134h); 37 FR 28464, 28477, 38 FR 19141.)

Effective date. The foregoing amendments shall become effective September 3, 1975.

Because of the urgency involved in eradicating scrapie and preventing the dissemination of this disease among livestock of the country, it is essential that these provisions be placed in effect without delay.

It is believed the amendments will expedite the eradication of scrapie and will protect gains made in the State-Federal cooperative scrapie eradication program and will therefore be of benefit to affected persons.

Accordingly, under the administrative procedure provisions in 5 U.S.C. 553, good cause is found for making these amendments effective less than 30 days after publication in the FEDERAL REGISTER.

Done at Washington, D.C., this 27th day of August, 1975.

PIERRE A. CHALOUX,
Acting Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service.

[FR Doc.75-23305 Filed 9-2-75;8:45 am]

SUBCHAPTER D—EXPORTATION AND IMPORTATION OF ANIMALS (INCLUDING POULTRY) AND ANIMAL PRODUCTS

PART 91—INSPECTION AND HANDLING OF LIVESTOCK FOR EXPORTATION

Ports of Export; Chicago, Illinois, Added as an Airport and Portland, Oregon, Deleted as an Airport and Ocean Port

This amendment adds Chicago, Illinois, to and deletes Portland, Oregon, from the list of airport ports of export for certain animals and deletes Portland, Oregon, from the list of ocean port ports of export for such animals.

Statement of considerations. The purpose of this amendment is to add Chicago, Illinois, to and to delete Portland, Oregon, from the list of designated airports in § 91.3(a)(1)(i) and to delete Portland, Oregon, from the list of designated ocean ports in § 91.3(a)(2)(i) of Part 91, 9 CFR. Portland, Oregon, is deleted due to the fact that the airport and ocean port export inspection facilities at Portland, Oregon, were closed on July 1, 1975. The airport export inspection facilities at Chicago, Illinois, have been inspected by the Animal and Plant Health Inspection Service and were found to comply with the standards for approved export inspection facilities contained in § 91.3(c) of Part 91, 9 CFR.

Accordingly, in § 91.3, paragraphs (a)(1)(i) and (a)(2)(i) are amended to read:

§ 91.3 Ports of export.

(a) * * *

(1) *Airports.* (i) Chicago, Illinois; Harrisburg, Pennsylvania; Helena, Montana; Richmond, Virginia; Miami, Tampa, and St. Petersburg, Florida; New Iberia, Louisiana; Brownsville and Houston, Texas; San Francisco, California; Moses Lake, Washington; and Honolulu, Hawaii.

* * * * *

(2) *Ocean ports.* (i) Richmond, Virginia; Miami and Tampa, Florida; Brownsville and Houston, Texas; San Francisco, California; and Honolulu, Hawaii.

* * * * *

(Secs. 4, 5, 23 Stat. 32, as amended; sec. 1, 32 Stat. 791, as amended; sec. 10, 26 Stat. 417; secs. 12, 13, 14, 18, 34 Stat. 1263, as amended; 81 Stat. 584, 588, 592; secs. 3 and 11, 76 Stat. 130, 132; sec. 1109, 72 Stat. 799, as amended (21 U.S.C. 105, 112, 113, 120, 121, 134b, 134f, 612, 613, 614, 618); 49 U.S.C. 1509(d)); 37 FR 28464, 28477; 38 FR 19141.)

Effective date. The foregoing amendment shall become effective September 3, 1975.

The amendment relieves certain restrictions by permitting the exportation of livestock through an adiitional port of export, and should be made effective promptly to be of maximum benefit to affected persons. The amendment also deletes a port of export and thus imposes certain restrictions necessary to prevent the dissemination of diseases and must be made effective immediately to accomplish its purpose in the public interest. It does not appear that public participation in this rulemaking proceeding would make additional relevant information available to the Department.

Accordingly, under the administrative procedure provisions in 5 U.S.C. 553, it is found upon good cause that notice and other public procedure with respect to the amendment are impracticable, unnecessary, and contrary to the public interest, and good cause is found for making it effective less than 30 days after publication in the FEDERAL REGISTER.

Done at Washington, D.C., this 27th day of August 1975.

PIERRE A. CHALOUX,
Acting Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service.

[FR Doc.75-23306 Filed 9-2-75;8:45 am]

Title 12—Banks and Banking

CHAPTER II—FEDERAL RESERVE SYSTEM

SUBCHAPTER A—BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

[Reg. M]

PART 213—FOREIGN ACTIVITIES OF NATIONAL BANKS

PART 215—LOANS TO EXECUTIVE OFFICERS OF MEMBER BANKS

Additional Powers of Foreign Branches

On March 27, 1975, a proposal regarding amendments to § 213.3(b) was published in the Federal Register (40 FR 13524). Interested persons were given until May 9, 1975, to submit written comments, suggestions or objections. The Board has reviewed all comments received and has decided to adopt the following amendments.

The first amendment concerns the amount of credit which a foreign branch of a member bank may extend to an executive officer of the branch in order to finance the acquisition or construction of living quarters to be used as his resi-

dence abroad, provided each such credit extension is promptly reported to its home office. The original amendment proposed by the Board would have increased the loan limit to $100,000 and did not provide for any circumstances under which that limit could be exceeded. Most comments received from commercial banks in response to the Board's proposal pointed out that in many countries the $100,000 figure would be inadequate. Although the specific dollar limit has the advantage of uniformity, the Board was concerned that the purpose of the regulation might be frustrated by the wide variations in housing costs from one country to the next. Therefore, in view of the comments received, the Board has adopted an amendment which provides more flexibility to the foreign branches in extending credit to their executive officers. Under the amendment the proposed $100,000 limit is retained, but it may be exceeded, with the prior specific approval of the parent bank's board of directors, in order to compensate for the disparity of housing costs among countries. The procedures contained in the amendment are similar to those of section 22(g) of the Federal Reserve Act, 12 U.S.C. 375(a).

In connection with this amendment, the Board is revising Published Interpretation ¶5620, 12 CFR 215.103 in order to (1) reflect the new amendment to Regulation M and (2) correct the references to § 213.4(f) to read "213.3(b)."

The second amendment to Regulation M allows foreign branches of member banks to engage in insurance agency and brokerage activities where such activities are usual in connection with the transaction of the business of banking in the place where the foreign branch transacts its business. The Board has received several comments supporting the proposed amendment. No comments have been received opposing adoption of the amendment. The amendment has thus been adopted without any changes.

In consideration of the comments received and pursuant to section 25 of the Federal Reserve Act (76 Stat. 388; (12 U.S.C. 604a)), 12 CFR Parts 213 and 215 are amended as set forth below. As these amendments are intended to relieve a restriction or grant an exemption, they shall become effective immediately.

1. Effective August 25, 1975, Regulation M is amended by revising § 213.3(b)(6), by substituting a semicolon for the period at the end of paragraph (b)(7), and by adding a new paragraph (b)(8). As amended § 213.3(b) reads as follows:

§ 213.3 Foreign branches.

* * * * *

(b) *Further powers of foreign branches.* In addition to its other powers, a foreign branch may, subject to paragraph (c) of this section and § 213.6 and so far as usual in connection with the transaction of the business of banking in the places where it shall transact business:

* * * * *

(6) Extend credit to an executive officer of the branch in an amount not to exceed $100,000 or its equivalent in order to finance the acquisition or construction of living quarters to be used as his residence abroad, provided each such credit extension is promptly reported to its home office; *Provided, however,* That, with the specific prior approval of the parent bank's board of directors, such amount limitation may be exceeded when necessary to meet local housing costs.

(7) Pay to any officer or employee of the branch a greater rate of interest on deposits than that paid to other depositors on similar deposits with the branch;

(8) Act as insurance agent or broker.

2. Effective August 25, 1975, § 215.103 (a) and (c) are amended to read as follows:

§ 215.103 Loans to executive officers of foreign branches of national and State member banks.

(a) Section 22(g) of the Federal Reserve Act (12 U.S.C. 375a) provides, with certain exceptions, that "no executive officer of any member bank shall borrow from or otherwise become indebted to, any member bank of which he is an executive officer, and no member bank shall make any loan or extend credit in any other manner to any of its own executive officers * * *." Pursuant to the authority conferred by the ninth paragraph of section 25 of the Federal Reserve Act (12 U.S.C. 604a), which was added to that section by the Act of August 15, 1962 (Pub. L. 87-588), the Board of Governors in § 213.3(b) of this subchapter (Regulation M) has, subject to certain conditions, authorized foreign branches of national banks to make certain home loans to their executive officers. The question has arisen whether foreign branches of State member banks would violate section 22(g) by extending credit to their executive officers to the same extent and subject to the same conditions as foreign branches of national banks. A separate but related question is whether executive officers of foreign branches of national (and State member) banks may borrow from their respective branches as envisaged by § 213.3(b) of this subchapter.

* * * * *

(c) On the basis of the foregoing considerations, the Board of Governors is of the opinion that foreign branches of State member banks would not violate section 22(g) by extending credit to their executive officers subject to the same restrictions and conditions as apply to foreign branches of national banks under § 213.3(b) of this subchapter. * * *

Board of Governors of the Federal Reserve System, August 25, 1975.

[SEAL] THEODORE E. ALLISON, *Secretary of the Board.*

[FR Doc.75-23209 Filed 9-2-75;8:45 am]

Title 15—Commerce and Foreign Trade

CHAPTER III—DOMESTIC AND INTERNATIONAL BUSINESS ADMINISTRATION, DEPARTMENT OF COMMERCE

PART 371—GENERAL LICENSES

PART 377—SHORT SUPPLY CONTROLS

Continuation of Short Supply Controls on Petroleum and Petroleum Products Throughout the Third Quarter 1975

In accordance with its responsibilities under the Export Administration Act and as part of the overall effort to conserve and allocate petroleum, the Department of Commerce has controlled exports of petroleum and petroleum products since December 14, 1973. These controls were imposed to avoid an excessive drain of these scarce materials from the United States and to reduce the serious inflationary impact on the domestic economy. They were also intended to supplement the domestic controls issued under authority of the Emergency Petroleum Allocation Act (EPAA). In passing the EPAA in 1973 Congress had found that "shortages of crude oil, residual fuel oil, and refined petroleum products . . . have created or will create severe economic dislocations and hardships," and had directed that these materials produced or refined in the United States, to the extent practicable and necessary to accomplish the objectives of the EPAA, should "be totally allocated for use by ultimate users in the United States."

Since the EPAA will likely expire on August 31, the export control program has been reviewed in cooperation with the Federal Energy Administration and other interested agencies. Based on this review, the Department concluded that the domestic petroleum situation as of 31 August 1975 still meets the criteria of the Export Administration Act of 1969, as amended and extended in 1972 and as amended in 1974, for the imposition of export controls on crude oil and certain petroleum products. The Department has decided that the present restrictions on export of those commodities should continue unchanged through the remainder of the third quarter of 1975; i.e., September 30, 1975. Authority for continuing these controls is contained in the Mineral Leasing Act of 1920, as amended by the Alaskan Pipeline Act, and in the Export Administration Act of 1969, as amended.

In reaching these conclusions, it was noted that while the growth of overall demand for petroleum products slowed appreciably in 1974 and during the first half of 1975, as a result of price increases, energy conservation, and a reduced rate of growth in the economy, the domestic production of petroleum liquids has shown a steady decline from 11.3 MMBD in 1970 to 10.0 MMBD in May 1975. The gap betwen this level of domestic production and the estimated average demand of 16.4 MMBD for 1975 indicates the extent of the present shortage of petroleum in the United States.

Analysis of the expected crude oil costs after August 31 shows that, sub-

ject to marketing variations, the resulting product price levels in the United States could offer attractive incentives for export of petroleum products. The extremely low prices charged on the world tanker market at present, and the availability of extensive tanker capacity deadheading from the United States as a result of our high level of petroleum imports, combine to offer further incentives to spot export market transactions. In view of these and other factors, it was considered necessary to continue for the time being the present controls on the export of petroleum products in order to prevent the excessive drain of scarce supplies from the U.S. market. In addition, controls were considered necessary so that the scarcity of these materials, exacerbated by foreign demand based on the potential attractiveness of U.S. supplies, will not lead to further inflation of domestic prices.

We are continuing our comprehensive review, and will announce our decisions with regard to possible continuation of controls for the fourth quarter 1975 in advance of the end of the third quarter.

Effective date of action: August 31, 1975.

Revision of Restrictions on Bunkering Vessels in Cuban Trade

The Organ of Consultation of the Organization of American States, acting under the Rio Treaty, adopted a resolution on July 29, 1975, which allows each member state to determine for itself the nature of its economic and diplomatic relations with the Government of Cuba. In keeping with this action by the OAS, the United States on August 21 announced modifications of the aspects of our Cuban denial policy that affect other countries. The Export Administration Regulations are hereby revised to reflect the changes in United States policy on bunkering. General License SHIP STORES is modified to permit general license bunkering of third country ships engaged in Cuba trade. Bunkers will not be afforded, however, to vessels registered in, owned or controlled by, or under charter or lease to Cuba or a Cuban national.

§ 371.9 [Amended]

Accordingly, the Export Administration Regulations (15 CFR Part 371) are amended by revoking and reserving subparagraph 371.9(b)(2) and by changing the reference in 371.9(b)(4) from "371.9 (b) (1), (2), and (3)" to "371.9(b) (1) and (3)".

Effective date of action: August 29, 1975.

RAUER H. MEYER,
Director,
Office of Export Administration.

[FR Doc.75-23358 Filed 8-29-75;10:25 am]

Title 16—Commercial Practices

CHAPTER I—FEDERAL TRADE COMMISSION

[Docket C-2680]

PART 13—PROHIBITED TRADE PRACTICES, AND AFFIRMATIVE CORRECTIVE ACTIONS

The Greystone Corp.

Subpart—Advertising falsely or misleadingly: § 13.10 Advertising falsely or misleadingly; § 13.160 Promotional sales plans; § 13.205 Scientific or other relevant facts; § 13.260 Terms and conditions. Subpart—Corrective actions and/or requirements: § 13.533 Corrective actions and/or requirements; 13.533-20 Disclosures; 13.533-50 Maintain means of communication; 13.533-55 Refunds, rebates and/or credits. Subpart—Delaying or withholding corrections, adjustments or action owed: § 13.675 Delaying or withholding corrections, adjustments or action owed. Subpart—Misrepresenting oneself and goods—Goods: § 13.1740 Scientific or other relevant facts.—Prices: § 13.1823 Terms and conditions.—Promotional sales plans: § 13.1830 Promotional sales plans. Subpart—Neglecting, unfairly or deceptively, to make material disclosure: § 13.1895 Scientific or other relevant facts; § 13.1905 Terms and conditions. Subpart—Using deceptive techniques in advertising: § 13.2275 Using deceptive techniques in advertising.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45)

In the Matter of The Greystone Corporation, a corporation.

Consent order requiring a New York City seller and distributor of encyclopedia and other educational material, among other things to cease distributing any product through the use of a continuity program that provides for the delivery, on approval, any product at intervals with the balance being sent in one or more multi-unit shipments in violation of the Federal Trade Commission Act.

The Order to cease and desist, including further order requiring report of compliance therewith, is as follows: [1]

ORDER

It is ordered, That respondent The Greystone Corporation, a corporation, its successors and assigns, and its officers, and it agents, representatives, employees, directly or through any corporation, subsidiary, division, or other device, in connection with the advertising, offering for sale or sale, inducing or collecting payments for, and distribution of any encyclopedia or educational series of books, or of any merchandise, hereinafter such books and merchandise sometimes collectively referred to as products, through the use of a continuity program that provides contractually for the delivery, on an approval basis, of any of said products to any person at intervals, with the balance of the program sent in one or more multi-unit shipments, in commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

1. Representing, directly or by implication, that:

(a) Any person has the option to receive each product, separately and individually, and to accept or reject same, unless such representation is true.

(b) Any person will not receive any further products after the respondent has received and processed a properly identified notice of his cancellation of any such continuity program, unless such representation is true; or misrepresenting, in any manner, the consequences resulting from any person's cancellation of his participation in any such continuity program.

(c) Any person incurs no risk or obligation by joining any such continuity program unless such representation is true; or misrepresenting, in any manner, any condition, right, duty or obligation imposed on said person.

2. Disseminating, or causing the dissemination of, any advertisement for such continuity program by means of the United States mails or by any means in commerce, as "commerce" is defined in the Federal Trade Commission Act, which fails to disclose in a clear and conspicuous manner a description of the material conditions and terms of any such continuity program, and the material duties and obligations of any subscriber thereto, including:

(a) A description of each product, the billing charge to be made therefor, the anticipated total number of products included in any such continuity program, the number of products included in each shipment, except that as to the last two shipments, respondent may instead disclose the approximate number of volumes in the second to last shipment and the fact that the respondent will grant an allowance or credit against billing charges for any unwanted product that has been rejected or returned pursuant to the terms of the continuity program; and

(c) That in order for any communication, including any cancellation, to be processed by the respondent prior to the shipment of any product, such communication must be received by the respondent within the time period provided to the subscriber in accordance with paragraph 4, *infra.*

3. Failing to disclose, clearly and conspicuously, on any return coupon, order

[1] Copies of the Complaint, Decision and Order, filed with the original document.

form or any other document used for responding to any such continuity program offered, and, in magazine or newspaper advertising, in immediate and close conjunction with any return coupon, order form or any other document used for responding to any such continuity program offered, the following information:

(a) The anticipated total number of products included in any such continuity program;

(b) The number of products included in each shipment, except that as to the last two shipments, respondent may instead disclose the approximate number of volumes in the second to last shipment and the fact that the last shipment contains the balance of the products to be sent; and

(c) The number of and the approximate intervals between each such shipment.

4. Failing to notify the subscriber subsequent to enrollment, clearly and conspicuously, in conjunction with the delivery of products sent to any subscribers, of the time period or periods after which the respondent will initiate processing of any future shipment or shipments.

5. Failing to establish and implement adequate procedures so that the subscriber will be provided with any such notifications required by paragraph 4, *supra*, at least 15 days prior to the anticipated processing date of any subsequent shipment.

6. Failing to advise the subscriber clearly and conspicuously, in close conjunction with the notification required in paragraph 4, *supra*, that the subscriber must advise the respondent prior to the anticipated processing date if any change is desired in the status of the subscriber's account.

7. Preparing shipping labels for any shipment of any product in such continuity program for which the recipient will incur a monetary obligation, until at least 4 days after the anticipated processing date established pursuant to paragraph 4, *supra*, in connection with that shipment.

8. Failing to establish and implement adequate procedures to credit, for the full invoiced amount thereof, any properly identified return of any product sent to a subscriber to any such continuity program, and to guarantee to the postal service or the subscriber postage adequate to return such product to the respondent, when:

(a) The product is sent to a subscriber after the respondent has received and processed such notice of cancellation prior to the anticipated processing date established in conjunction with the shipment of such product as required by paragraph 4, *supra;* or

(b) Such notice of cancellation is received by the respondent within 4 days of the anticipated processing date established pursuant to paragraph 4, *supra*, but has been mailed by the subscriber and postmarked at least three days prior to the date disclosed as aforesaid.

9. Failing to establish and implement adequate procedures to prevent the sending of any product to any subscriber to any such continuity program, or mailing any bill or invoice therefor, after the respondent has received and processed any properly identified notice of cancellation from said subscriber prior to the date upon which the respondent may initiate the processing for the shipment of said product pursuant to paragraph 7, *supra*.

10. Failing to establish and implement adequate procedures to do the following, after receipt of any properly identified claim for adjustment in connection with any bill or invoice or any defense raised by any alleged debtor in connection with any such continuity program:

(a) Make any such adjustment within 14 days of receipt of such claim; or

(b) Acknowledge the receipt of the claim or defense within 14 days of receipt by the respondent and suspend all collection procedures with such alleged debtor until 25 days after complying with the procedures set forth in (c), below; and

(c) Make the requested adjustment within 60 days, or, within said period, inform the alleged debtor in writing of the respondent's understanding of the facts alleged in the claim or defense.

It is further ordered, That respondent shall forthwith distribute a copy of this order to each of its operating divisions.

It is further ordered, That respondent notify the Commission at least 30 days prior to any proposed change in the corporate respondent such as dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in the corporation which may affect compliance obligations arising out of the order.

It is further ordered, That the respondent herein shall within sixty (60) days after service upon it of this order, file with the Commission a report, in writing, setting forth in detail the manner and form in which it has complied with this order.

The Decision and Order was issued by the Commission July 14, 1975.

CHARLES A. TOBIN,
Secretary.

[FR Doc.75-23210 Filed 9-2-75;8:45 am]

Title 17—Commodity and Securities Exchange

CHAPTER II—SECURITIES AND EXCHANGE COMMISSION

[Release 34-11604]

SELF-REGULATORY ORGANIZATIONS

Proposed Rule Changes

The Securities and Exchange Commission, acting pursuant to the authority vested in it by the Securities Exchange Act of 1934 (the "Act"),[1] and particularly Sections 2, 3, 6, 13, 15A, 17, 19 and 23 thereof,[2] Section 13 (new Section 15B of the Act), Section 15 (new Section 17A of the Act) and Section 31(b) of the Securities Acts Amendments of 1975 (the "1975 Amendments"),[2] has adopted Rule 19b-4, together with related Forms 19b-4A[*] and 19b-4B, effective immediately. Rule 19b-4 provides procedures for self-regulatory organizations to file proposed rule changes and to give notice as to certain stated policies, practices or interpretations on the related forms. It also prescribes procedures to be followed by the Commission in considering proposed rule changes filed with the Commission. In connection with the adoption of Rule 19b-4, the Commission has provided certain delegated authority to the Director of the Division of Market Regulation and has rescinded Securities Exchange Act Rules 9b-1 and 17a-8, effective immediately, and 15Aj-2 and 15Aj-3, effective December 1, 1975.

Background. Effective June 4, 1975, Section 19(b) of the Act requires that, in connection with a proposed rule or proposed change in, addition to, or deletion from the rules of a self-regulatory organization (a proposed rule change), self-regulatory organizations shall file, in accordance with rules prescribed by the Commission, copies of the proposed rule change accompanied by a concise general statement of the basis and purpose thereof. Self-regulatory organizations are national securities exchanges registered pursuant to Section 6 of the Act, securities associations registered pursuant to Section 15A of the Act, clearing agencies registered pursuant to new Section 17A(b) of the Act upon its effectiveness on December 1, 1975, and the Municipal Securities Rulemaking Board to be created pursuant to new Section 15B of the Act, which for purposes of Sections 19(b), 19(c) and 23(b) of the Act, is defined as a self-regulatory organization in Section 3(a)(26) of the Act. Under Sections 3(a)(27) and 3(a)(28) of the Act, the rules of a self-regulatory organization mean the constitution, articles of incorporation, by-laws, and rules, or instruments corresponding to the foregoing and such of the stated policies, practices and interpretations of the self-regulatory organization as the Commission, by rule, determines to be necessary or appropriate in the public interest or for the protection of investors to be deemed to be rules.

Subject to limited exceptions, the Commission is required, upon the filing of a proposed rule change, to publish notice

[1] 15 U.S.C. 78a *et seq.*, as amended by Pub. L. No. 94-29 (June 4, 1975).

[2] 15 U.S.C. 78b, 78c, 78f, 78o-3, 78q, 78s and 78w, as amended by Pub. L. No. 94-29, 2, 3, 4, 14, 16 and 18 (June 4, 1975); amendments to certain of such sections, including relevant parts of Sections 6 and 15A, and new Sections 15B and 17A become effective on December 1, 1975, pursuant to Pub. L. No. 94-29, 31(a). All references in Form 19b-4A to particular provisions of the Act are to such provisions as amended by the 1975 Amendments.

[3] Pub. L. No. 94-29, 13, 15 and 31(b) (June 4, 1975).

[*] Form filed as a part of the original document.

thereof together with the terms of substance or a description of the subjects and issues involved. Interested persons will have an opportunity to submit written data, views and arguments concerning the proposed rule change. A proposed rule change may not take effect unless approved by the Commission or otherwise permitted by Section 19(b) of the Act. Section 19(b)(2) prescribes the procedure by which, and time periods within which, the Commission will take action to approve a proposed rule change or to institute proceedings to determine whether the proposed rule change should be disapproved and, if such proceedings are instituted, to approve or disapprove a proposed rule change. Section 19(b)(3)(A) provides that the Commission may, by rule, specify as without the provisions (and procedures) of Section 19(b)(2) proposed rule changes which are designated by a self-regulatory organization as (i) constituting a stated policy, practice or interpretation with respect to the meaning, administration or enforcement of an existing rule of the self-regulatory organization, (ii) establishing or changing a due, fee or other charge imposed by the self-regulatory organization or (iii) concerned solely with the administration of the self-regulatory organization or other matters, and such rule changes may take effect upon filing with the Commission. Section 19(b)(3)(B) authorizes the Commission to put rule changes into effect summarily if it appears to the Commission that such action is necessary for the protection of investors, the maintenance of fair and orderly markets, or the safeguarding of securities or funds.

New Section 19(b) of the Act became effective upon enactment. Accordingly, the former procedures for national securities exchanges (Rule 17a-8)[4] and registered securities associations (Section 15 A(j)) do not meet the requirements for proposed rule changes for which filings may have been made prior to such date but on which final action had not been taken.[5] Accordingly, all such pending proposals are required to be refiled pursuant to new Section 19(b) and Rule 19b-4 thereunder and notice thereof published.[6] Subject to the giving of such notice, the Commission may, for good cause shown, give expedited treatment to proposed rule changes which are currently pending.

Rule 19b-4. Rule 19b-4 provides procedures for self-regulatory organizations to file proposed rule changes and to give notices as to stated policies, practices and interpretations which the self-regulatory organization believes may be characterized as not constituting a rule. In addition, it specifies the procedures to be followed by the Commission in passing upon proposed rule changes and provides procedures for reviewing, pursuant to Section 31(b) of the 1975 Amendments, all rules of exchanges and associations registered with the Commission on June 4, 1975.

Under the Act, a proposed rule change of a self-regulatory organization means any proposed rule or any proposed change in, addition to, or deletion from the rules of a self-regulatory organization. A stated policy, practice or interpretation of a self-regulatory organization is deemed by Rule 19b-4 to be a rule of the self-regulatory organization if (i) action thereon by the members or by the board of directors, or similar governing body, of such self-regulatory organization is required under its constitution, articles of incorporation, by-laws, rules, or instruments corresponding thereto, (ii) a self-regulatory organization elects or is required, pursuant to its constitution, articles of incorporation, by-laws, rules, or instruments corresponding thereto, to treat it as a rule change thereunder, (iii) it represents a change in, addition to, or deletion from a stated policy, practice or interpretation which the self-regulatory organization previously treated as a proposed rule change or (iv) it requires a determination, or affects a prior determination, pursuant to Rules 8c-1(g) or 15c2-1(g). Filings with respect to proposed rule changes (including filings which are being made pursuant to Section 19(b)(3) in addition to or in lieu of filings pursuant to Section 19(b)(2)) by a self-regulatory organization are to be made on Form 19b-A.

Stated policies, practices and interpretations of a self-regulatory organization include any material aspect of the operation of the facilities of the self-regulatory organization or any statement made available generally to the membership of, or all participants in, or persons having or seeking access (including, in the case of national securities exchanges or registered securities associations, through a member)[7] to facilities of, a self-regulatory organization, or to a group or category of such persons, establishing or changing any standards or guidelines with respect to (i) the rights or obligations of such persons or, in the case of national securities exchanges or registered securities associations, persons associated with such persons or (ii) the application or interpretation of an existing rule.

Persons having or seeking access to facilities of a national securities exchange, registered securities association or registered clearing agency include issuers of securities. Notice as to a stated policy, practice or interpretation which the self-regulatory organization believes may be characterized as not constituting a rule is required to be mailed to the Commission on Form 19b-4B not later than the date on which it is first made generally available.

To implement Section 19(b)(3)(A) of the Act, Rule 19b-4 provides that a proposed rule change may take effect upon filing with the Commission if designated by the self-regulatory organization as (i) constituting a stated policy, practice or interpretation with respect to the meaning, administration, or enforcement of an existing rule, (ii) establishing or changing a due, fee, or other charge, or (iii) concerned solely with the administration of the self-regulatory organization.

In approving any proposed rule change, the Commission may endorse the justification therefor filed by the self-regulatory organization except that, where the proposed rule change would, in the judgment of the Commission, have significant policy implications under the Act, the Commission will issue its own statement as to the regulatory need for and appropriateness of the proposed rule change.[8] In connection with proceedings to determine whether a proposed rule change should be disapproved, the Commission will afford the self-regulatory organization and all interested persons an opportunity to submit additional written data, views and arguments concerning the proposed rule change and, in the discretion of the Commission, an opportunity to make oral presentations.

Notice of orders issued by the Commission pursuant to Section 19(b) of the Act will be given by their prompt publication together with a statement of the reasons therefor.

On or prior to April 1, 1976, each national securities exchange and each securities association registered with the Commission on June 4, 1975, will be required to file with the Commission the information required by items 3, 4, 5 and 6 of Form 19b-4A with respect to all rules

[4] For proposed rule changes involving an exchange's plan regulating transactions in options on that exchange, the procedures pursuant to Rule 9b-1 were not dissimilar to those to be prescribed by Rule 19b-4 and, as indicated, Rule 9b-1 is being rescinded.

[5] Under Rule 17a-8, a national securities exchange was required to file a report with respect to any proposed change in its constitution, articles of incorporation, by-laws, or rules or instruments corresponding thereto or its stated policies 21 days in advance of action thereon by its board of governors or members. Where, even though a report pursuant to Rule 17a-8 might have been filed more than 21 days prior to June 4, 1975, action had not been taken on such change prior to June 4, 1975, an exchange will be required to file such change in accordance with the procedures hereby established under new Section 19(b) unless, under such procedures, only notice on Form 19b-4B, described herein, would be required. Absent advice to the contrary that pending proposed changes are stated practices, policies or interpretations which the exchange believes may be characterized as not constituting rules under Rule 19b-4, the Commission will assume that such changes will not take effect until the new procedures are complied with.

[6] On June 11, 1975, and July 23, 1975, the Commission took action with respect to certain pending proposed rule changes pursuant to Section 19(b)(3)(B) of the Act on condition that such rule changes thereafter be considered pursuant to the customary procedures of Section 19(b)(2). *See* Securities Exchange Release Nos. 11461, 11554, 11555 and 11556.

[7] Clearing agencies, under Section 17A(b)(6), may not prohibit or limit access by any person to services offered by any participant therein.

[8] *See Report of the Senate Committee on Banking, Housing and Urban Affairs to Accompany S.249*, S. Rep. No. 75, 94th Cong., 1st Sess., at 30 (1975).

in effect on June 4, 1975, and on the date of filing.[9]

Self-regulatory organizations will be required, under Rule 19b–4, to retain at their principal place of business a file, available for public inspection and copying, of all filings pursuant to the rule and all related correspondence.

Form 19b–4A. Form 19b–4A requires that, with respect to a proposed rule change, a self-regulatory organization shall file the text of the proposed rule change, indicate the action taken to adopt the change, state the purpose thereof, describe the basis therefor under the Act, summarize comments received thereon and explain any burden on competition to be imposed thereby. In addition, Form 19b–4A provides for the self-regulatory organization to indicate whether it consents to the extension of the time periods prescribed by Section 19(b). If a proposed rule change is to take, or to be put into, effect pursuant to Section 19(b)(3), the self-regulatory organization is required to state the basis therefor.

The Commission will not approve a proposed rule change prior to the time all action required to be taken under the constitution, articles of incorporation, by-laws, rules, or instruments corresponding thereto (excluding action specified in any such instrument with respect to compliance with the procedures of the Act or the formal filing of amendments pursuant to state law) of the self-regulatory organization has been completed. Proposed rule changes may, however, be initially filed prior to the completion of all such action if the self-regulatory organization consents to an extension of the period of time specified in Section 19(b)(2) until at least thirty-five days after it has filed appropriate amendments setting forth the taking of all such action. The Commission encourages the early filing of proposed rule changes in order to provide an increased opportunity for public comment.

Notwithstanding that, under Section 31(a) of the 1975 Amendments, amendments to Sections 6 and 15A of the Act do not become effective until December 1, 1975, national securities exchanges and registered securities associations should indicate whether proposed rule changes, if approved prior to that date, will be consistent with such sections when so amended. In the case of proposed rule changes by a national securities exchange or registered securities association filed prior to December 1, 1975, relating to a facility of such exchange or association which will be required to be registered as a clearing agency on December 1, 1975, paragraph (b) of item 4 of Form 19b–4A should be completed, as appropriate.

Form 19b–4B. Form 19b–4B is to be used to give notice of a stated policy, practice or interpretation of a self-regulatory organization and must include the basis on which the self-regulatory organization believes such stated policy, practice or interpretation may be characterized as not constituting a rule.

All filings on Form 19b–4A and notices on Form 19b–4B by self-regulatory organizations are to be identified with the initials of the self-regulatory organization, the year and the number of the filing for that year. Thus the first filing, pursuant to the rule, in 1975 by the National Association of Securities Dealers, Inc., would be identified as SR–NASD–75–1.

Rescission of Rules 9b–1, 17a–8, 15Aj–2 and 15Aj–3. Under Section 9(b)(1) of the Act it is unlawful for any person to effect, by use of any facility of a national securities exchange, in contravention of Commission rules, any transaction in connection with any security whereby any party to such transaction acquires any put, call, straddle, or other option or privilege of buying the security from or selling the security to another without being bound to do so. In 1972, the Chicago Board Options Exchange (CBOE) applied for registration, on a pilot project basis, as a national securities exchange to establish an exchange market dealing in options. The application of the CBOE raised for the first time the possibility of a significant number of option transactions being effected on national securities exchanges. While the application was pending, the Commission published for comment proposed Rule 9b–1. Rule 9b–1 provided for the filing by exchanges of plans regulating transactions in options. The rule also provided generally for the Commission to give public notice and opportunity for submission of written data, views and arguments as to any such plan (or amendment thereto) and for the Commission to declare any such plan effective if it found the plan to be necessary or appropriate in the public interest; amendments to a plan became effective 30 days after publication (or such earlier date as the Commission allowed) unless disapproved by the Commission.

While the 1975 Amendments have not affected the Commission's authority under Section 9 of the Act, and the Commission, if appropriate, might in the future adopt rules to regulate exchange trading of options pursuant to Section 9, the procedures provided by Rule 9b–1 are duplicated in large part by new Section 19(b) of the Act and Rule 19b–4 thereunder. At the same time there would remain a number of small differences which could create technical problems for exchanges in complying with both rules. Accordingly, the Commission has determined to rescind Rule 9b–1, effective immediately. Rules of exchanges constituting part of their plans for the regulating of options which were in effect on June 4, 1975, will continue in effect. In the future, proposed rule changes of self-regulatory organizations (including the package of proposed rule changes necessary to permit institution of option trading or institution of a new type of option trading, such as trading in puts or straddles) will be considered, pursuant to the procedures of Rule 19b–4; the Commission will, of course, continue to review option trading closely in light of its broad authority under Section 9 of the Act.

Rule 17a–8 is superseded by Rule 19b–4 and is therefore rescinded, effective immediately. Rules 15Aj–2 and 15Aj–3 relate to quotation and clearing systems operated by registered securities associations. In view of the revisions[10] to the Act made by the 1975 Amendments, it no longer appears necessary to retain such rules and, accordingly, they are rescinded, effective December 1, 1975.

Delegation. The rules of the Commission relating to general organization are concurrently being amended to delegate authority to the Division of Market Regulation to publish proposed rule changes of self-regulatory organizations and to approve proposed rule changes.

The Commission for good cause finds that notice and public procedure and prior publication pursuant to 5 U.S.C. 553 (b) and (c) are unnecessary with respect to the foregoing action and that Rule 19b–4, and related Forms 19b–4A and 19b–4B (and the related delegation of authority) should be adopted, effective immediately, in order to provide as promptly as possible an orderly procedure for consideration of proposed rule changes of self-regulatory organizations. The Commission, however, encourages interested persons to submit comments with respect to Rule 19b–4 and the related forms. The Commission intends to review the operation of the rule with a view to improving and simplifying to the extent feasible the procedures implemented pursuant to Section 19(b) of the Act. The Commission further finds that the adoption of Rule 19b–4 and the related forms will not impose any burden on competition.

(secs. 2, 3, 6, 13, 17, 19, 23, 48 Stat. 881, 882, 885, 894, 897, 898, 901, as amended by secs. 2, 3, 4, 14, 16, 18, 89 Stat. 97, 97–104, 104–109, 137–141, 146–154, 155–156; sec. 1, 52 Stat. 1070, as amended by sec. 12, 89 Stat. 127–131; sec. 13, 89 Stat. 131–137; sec. 15, 89 Stat. 141–146; sec. 31(b), 89 Stat. 170; 76 Stat. 394 (15 U.S.C. 78b, 78c, 78f, 78q, 78s, and 78w, as amended by Pub. L. No. 94–29; 15 U.S.C. 78o–3, as amended by Pub. L. No. 94–29; 15 U.S.C. 78o–4, as added by Pub. L.

[9] Pursuant to Section 11A(c)(4)(A) of the Act, enacted by the 1975 Amendments, the Commission will also initially review any and all rules of national securities exchanges which limit or condition the ability of members to effect transactions in securities otherwise than on such exchanges. Pursuant to that section, the Commission is required to report to the Congress the results of its review by September 2, 1975, and to commence a proceeding in accordance with Section 19(c) to amend any such rule imposing a burden on competition which does not appear to the Commission necessary or appropriate in furtherance of the purposes of the Act. Any such proceeding is to be completed within 90 days after publication of notice of its commencement. *See* Securities Exchange Act Release No. 11521 (July 2, 1975), 40 Fed. Reg. 30332 (July 18, 1975).

[10] *See, e.g.,* Sections 11A and 17A of the Act enacted by Sections 7 and 15 of the 1975 Amendments.

No. 94-29; 15 U.S.C. 78q-1, as added by Pub. L. No. 94-29; 15 U.S.C. 78d-1, 78d-2))

By the Commission.

[SEAL] GEORGE A. FITZSIMMONS, *Secretary.*

AUGUST 19, 1975.

PART 200—ORGANIZATION, CONDUCT AND ETHICS; AND INFORMATION AND REQUESTS

DELEGATION OF AUTHORITY

Section 200.30-3(a) is amended by adding a new subparagraph (13) as follows:

§ 200.30-3 Delegation of Authority to Director of Division of Market Regulation.

(a) * * *

(13) Pursuant to Rule 19b-4 (§ 240.19b-4) of this chapter, to publish notices of proposed rule changes filed by self-regulatory organizations and to approve such proposed rule changes.

* * * * *

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

TEXT OF THE RULE

Rule 19b-4 (17 CFR § 240.19b-4), as hereby adopted, reads as follows:

§ 240.14b-4 Filings with respect to proposed rule changes by, and notices as to certain stated policies, practices and interpretations of, self-regulatory organizations.

(a) The term "proposed rule change" means any proposed rule or any proposed change in, addition to, or deletion from the rules of a self-regulatory organization. A stated policy, practice, or interpretation of a self-regulatory organization shall be deemed to be a rule of the self-regulatory organization if (1) action thereon by the members or by the board of directors, or similar governing body, of such self-regulatory organization is required under its constitution, articles of incorporation, by-laws, rules, or instruments corresponding thereto, (2) a self-regulatory organization elects or is required, pursuant to its constitution, articles of incorporation, by-laws, rules, or instruments corresponding thereto, to treat it as a rule change hereunder, (3) it represents a change in, addition to, or deletion from a stated policy, practice or interpretation which the self-regulatory organization previously treated as a proposed rule change or (4) it requires a determination, or affects a prior determination, pursuant to Rules 8c-1(g) or 15c2-1(g).

(b) The term "stated policies, practices and interpretations" includes any material aspect of the operation of the facilities of the self-regulatory organization or any statement made generally available to the membership of, or all participants in, or persons having or seeking access (including, in the case of national securities exchanges or registered securities associations, through a member) to facilities of, a self-regulatory organization, or to a group or category of such persons, establishing or changing any standards or guidelines with respect to (1) the rights or obligations of such persons or, in the case of national securities exchanges or registered securities associations, persons associated with such persons or (2) the application or interpretation of an existing rule.

(c) Filings with respect to proposed rule changes by a self-regulatory organization shall be made on Form 19b-4A. Notice on Form 19b-4B as to a stated policy, practice or interpretation which the self-regulatory organization believes may be characterized as not constituting a rule pursuant to paragraph (a) of this section shall be mailed first class, postage prepaid, to the Commission, not later than the date on which it is first made generally available.

(d) A proposed rule change may take effect upon filing with the Commission pursuant to Section 19(b)(3)(A) of the Act if designated by the self-regulatory organization as (1) constituting a stated policy, practice or interpretation with respect to the meaning, administration, or enforcement of an existing rule, (2) establishing or changing a due, fee, or other charge, or (3) concerned solely with the administration of the self-regulatory organization.

(e) After instituting proceedings to determine whether a proposed rule change should be disapproved, the Commission will afford the self-regulatory organization and interested persons an opportunity to submit additional written data, views and arguments and, in the discretion of the Commission, an opportunity to make oral presentations.

(f) Notice of orders issued pursuant to Section 19(b) of the Act will be given by prompt publication thereof, together with a statement of written reasons therefor.

(g) On or prior to April 1, 1976, each national securities exchange and securities association registered with the Commission on June 4, 1975, shall file with the Commission the information required by items 3, 4, 5 and 6 of Form 19b-4A with respect to each of its rules in effect on June 4, 1975, and on the date of filing.

(h) Self-regulatory organizations shall retain at their principal place of business a file, available to interested persons for public inspection and copying, of all filings made pursuant to this rule and all correspondence received by such self-regulatory organization with respect to any such filing.

PART 249—FORMS, SECURITIES EXCHANGE ACT OF 1934

ADOPTION OF FORMS

Part 249—Forms, Securities Exchange Act of 1934, is hereby amended (1) by adding to Subpart A—Forms for Registration or Exemption of, and Notification of Action Taken by, National Securities Exchanges, Sections 249.19a and 249.19b, and (2) by adding to Subpart I—Forms for Registration of and Reporting by National Securities Associations and Affiliated Securities Associations, §§ 249.819a and 249.819b as follows:

§ 249.19a Form 19b-4A, for filings with respect to proposed rule changes by all self-regulatory organizations.

This form shall be used by all self-regulatory organizations, as defined in Section 3(a)(26) of the Securities Exchange Act of 1934, to file proposed rule changes with the Commission pursuant to Section 19(b) of that Act and Rule 19b-4 thereunder.

§ 249.19b Form 19b-4B, for giving notice as to stated policies, practices and interpretations of self-regulatory organizations.

This form shall be used by all self-regulatory organizations, as defined in Section 3(a)(26) of the Securities Exchange Act of 1934, to give notice, pursuant to Section 19(b) of that Act and Rule 19b-4 thereunder, as to stated policies, practices and interpretations of self-regulatory organizations which such organizations believe may be characterized as not constituting rules.

§ 249.819a Form 19b-4A, for filings with respect to proposed rule changes by all self-regulatory organizations.

This form shall be used by all self-regulatory organizations, as defined in Section 3(a)(26) of the Securities Exchange Act of 1934, to file proposed rule changes with the Commission pursuant to Section 19(b) of that Act and Rule 19b-4 thereunder.

§ 249.819b Form 19b-4B, for giving notice as to stated policies, practices and interpretations of self-regulatory organizations.

This form shall be used by all self-regulatory organizations, as defined in Section 3(a)(26) of the Securities Exchange Act of 1934, to give notice, pursuant to Section 19(b) of that Act and Rule 19b-4 thereunder, as to stated policies, practices and interpretations of self-regulatory organizations which such organizations believe may be characterized as not constituting rules.

RESCISSION

Rules 9b-1 (17 CFR § 240.9b-1), and 17a-8 (17 CFR § 240.17a-8) are hereby rescinded, effective immediately. Rules 15Aj-2 (17 CFR § 240.15Aj-2) and 15Aj-3 (17 CFR § 240.15Aj-3) are hereby rescinded, effective December 1, 1975.

[FR Doc.75-23298 Filed 9-2-75;8:45 am]

[Release No. 34-11615; File No. S7-563]

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

Arrest and Indictment Records of Associated Persons Brokers-Dealers' Maintenance

Introduction. The Securities and Exchange Commission today announced adoption of amended Rule 17a-3(a)(12)

(A) (8) under the Securities Exchange Act of 1934 (§ 240.17a-3(a) (12) (i) (h)). Rule 17a-3(a) (12) (A) requires every member of a national securities exchange who transacts a business in securities directly with others than members of a national securities exchange, and every broker or dealer who transacts a business in securities through the medium of any such member, and every registered broker or dealer to obtain from each associated person[1] a questionnaire or application for employment containing, among other things, a record of any arrests, indictments, or convictions for any felony or misdemeanor, except minor traffic offenses, to which the associated person has been subject.[2] The Commission has amended Rule 17a-3(a) (12) (A) (8) to limit the reference to arrests or indictments to crimes which are related to the safe operation of the securities industry.

The impetus for this amendment originated with the Commission's concern as to whether requiring the maintenance of records of all arrests and indictments might be too broad in light of certain recent civil rights decisions, and as such might no longer comport with public policy. The amendment was proposed in Securities Exchange Act Release No. 11402, May 7, 1975.[3]

Comments. The Commission received four comment letters on proposed Rule 17a-3(a) (12) (A) (8) from the public during the comment period which expired June 18, 1975. In addition, the Commission received comments from the Criminal Division of the Department of Justice and from the Equal Employment Opportunity Commission. Finally the Commission solicited through a voluntary questionnaire information from the various states concerning their state law or policy. The rule as adopted differs only slightly from the rule as proposed. Several commentators stated that the proposed amendment should not be adopted. One, a state securities administrator, asserted that the proposed amendment would place the rights of an individual above those of the public "on a suppositional possibility that some individual could be damaged." Further, he indicated that on some occasions a routine investigation of an applicant's arrest record discloses additional information which constitutes grounds for refusing registration.

Another commentator, a major brokerage firm, asserted that the proposed amendment would eliminate from the employment application records of arrests or indictments for some offenses which might alert the broker-dealer to the possibility that in certain situations such person might respond in ways which would make it inappropriate for him to handle funds or securities for the firm.

In regard to the comments that the Commission not modify its current requirement, the Commission believes that the amended rule represents a sound compromise between the sometimes conflicting objectives of avoiding hardship to individuals and the securities industry's position of public trust. The Commission notes that the Criminal Division of the Department of Justice stated of the amendment, "such a step is appropriate and is in accord with the Department's policy concerning the protection of individual privacy." The rule as amended no longer requires the maintenance of arrest and indictment records for "victimless" offenses or certain other lesser crimes. At the same time, the rule continues to require the maintenance of arrest and indictment records for more serious crimes which may more directly reflect on an individual's trustworthiness in dealing with customers' funds and securities.

The Commission has adopted one modification to the rule as proposed. Language has been added which assures that persons disclosing arrest or indictment information will be given the opportunity to explain or discuss the circumstances surrounding the event and to indicate the disposition of the arrest or indictment.

The Commission notes that Rule 17a-3(a) (12) (A) (8) should not be interpreted to require or suggest that the fact of any arrest or conviction record is to be used as an absolute bar to employment. Rather, the Commission advises broker-dealers that they should look at the circumstances surrounding the arrest or conviction in light of applicable regulations under Title VII of the Civil Rights Act of 1964,[4] as well as relevant court cases.[5]

The Commission has determined that the adoption of amended Rule 17a-3(a) (12) (A) (8) will not impose a burden on competition.

In view of the foregoing, the Commission has adopted the amendment to Rule 17a-3(a) (12) (A) (8).

Statutory authority. The Securities and Exchange Commission, acting pursuant to the provisions of the Securities Exchange Act of 1934, particularly sections 17(a) and 23(a) thereof, and deeming it necessary for the exercise of the functions vested in it, and necessary and appropriate in the public interest and for the protection of investors, hereby amends Part 240 of Chapter II of Title 17 of the Code of Federal Regulations by amending § 240.17a-3, effective October 1, 1975.

Text of amended paragraph (a) (12) (A) (8) of Rule 17a-3. The text of amended paragraph (a) (12) (A) (8) ((a) (12) (i) (h)) of Rule 17a-3 (§ 240.17a-3) is as follows:

§ 240.17a-3 Records to be made by certain exchange members, brokers and dealers.

(a) * * *

(12) (i) * * *

(h) A record of any arrest or indictment for any felony or misdemeanor involving the purchase, sale, or delivery of any security, or arising out of the conduct of the business of a broken, dealer, fiduciary, investment company, investment adviser, underwriter, bank, trust company, insurance company or other financial institution, or involving any crime in which violence or threats of violence against any person, dishonesty, the wrongful taking of any property, or any manner of fraud was a factor, or involving conspiracy to commit any of the foregoing, and the disposition of any such arrest or indictment or further explanation thereof, and a record of any conviction for any felony or any misdemeanor, except minor traffic offenses, of which he has been the subject.

* * * * *

(15 U.S.C. 78q(a); 15 U.S.C. 78w(a).)

By the Commission.

[SEAL] GEORGE A. FITZSIMMONS, *Secretary.*

AUGUST 25, 1975.

[FR Doc.75-23297 Filed 9-2-75;8:45 am]

Title 24—Housing and Urban Development

CHAPTER VIII—LOW INCOME HOUSING, DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. R-75-349]

PART 888—SECTION 8 HOUSING ASSISTANCE PAYMENTS PROGRAM — FAIR MARKET RENTS AND CONTRACT RENT AUTOMATIC ANNUAL ADJUSTMENT FACTORS

Amendment of Schedule A—Fair Market Rents for New Construction and Substantial Rehabilitation; Interim Rule

The Department of Housing and Urban Development, on March 31, 1975, amended Title 24 of the Code of Federal Regulations by adding to Chapter VIII a new Part 888—Section 8 Housing Assistance Payments Program—Fair Market Rents and Contract Rent Automatic Annual Adjustment Factors.

Since March 31, 1975, additional comments and data have been received indicating continuing need to revise these rents in light of the most recent data available. This material submitted by interested members of the general public, as well as HUD Field Offices, has generally indicated a need to increase the

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[1] Rule 17a-3(a) (12) (B) (§ 240.17a-3(a) (12) (ii)) defines an associated person to be a "partner, officer, director, salesman, trader, manager, or any employee handling funds or securities or soliciting transactions or accounts for such member, broker or dealer."

[2] Form SECO-2, the Personnel Form for nonmember brokers and dealers, requests similar information. Effective October 1, 1975, the Commission has amended Form SECO-2 by the substitution of Form U-4, a uniform application for registration of associated persons. (Securities Exchange Act Release No. 11424, May 16, 1975, 40 FR 30634). Insofar as the requirements regarding arrest records, indictments, and convictions are concerned, Form U-4 will contain requirements similar to Rule 17a-3(a) (12) (A) (8).

[3] 40 FR 21498.

[4] 42 U.S.C. 2000e et seq. (Supp. II, 1972), and 42 U.S.C. 1981 (1970).

[5] See e.g., Griggs v. Duke Power Co., 401 U.S. 424 (1971); Gregory v. Litton Systems, Inc., 316 F. Supp. 401 (C.D. Cal. 1970), modified, 472 F. 2d 631 (9th Cir. 1972).

published rents in order to meet specific local housing market conditions.

The Department proposes to incorporate in Part 888, Subpart A, in the respective appropriate places at 40 FR 14509, 14516, 14522, 14551, and 14555 revised Schedules A for the following market areas: Camden, Atlantic City, Burlington, Gloucester, Trenton, and Vineland, New Jersey; New Castle, Pittsburgh, Erie, Sharon, Altoona and Johnstown, Pennsylvania; Columbus, Georgia; Denver, Colorado; and Cedar City, Logan, and Moab, Utah.

Revision of the Schedule A for the Columbus, Georgia market area consists of a change in the rent for a 1 bedroom elevator dwelling unit to correct an error made in the previous publication of the Fair Market Rents. The Schedules A for the Cedar City, Logan, and Moab, Utah market areas provide Fair Market Rents for market areas within the State of Utah for which Fair Market Rents have not previously been established.

Because these Schedules represent tables of Fair Market Rents which change periodically and are republished annually, data and public comments with respect thereto are timely and relevant whenever interested parties wish to submit them, and such information will be considered at any time. Therefore, the Assistant Secretary for Housing Production and Mortgage Credit-FHA Commissioner has determined it to be reasonable and in the public interest to allow for a 15 day comment period.

Interested parties are invited to submit written comments, suggestions and objections regarding the proposed amendment by October 3, 1975. All materials which persons wish to submit should be filed with the Rules Docket Clerk, Office of the General Counsel, Room 10245, Department of Housing and Urban Development, 451 7th Street, SW., Washington, D.C. 20410.

(Sec. 7(d) Department of Housing and Urban Development Act, 42 USC 3535(d))

Issued at Washington, D.C., August 27, 1975.

DAVID S. COOK,
Assistant Secretary-Commissioner.

U. S. DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT
Section 8 Housing Assistance Payments Program

Schedule A - Fair Market Rents for New Construction and Substantial Rehabilitation (Including Housing Finance and Development Agencies Program)

Effective Date (publication) These Fair Market Rents include projection for construction time through July 1, 1977.

NOTE: The Fair Market Rents for (1) dwelling units designed for the elderly or handicapped are those for the appropriate size unit, not to exceed 2-Bedroom, multiplied by 1.05 and rounded to the next higher whole dollar, (2) congregate housing dwelling units are the same as for non-congregate units, and (3) single-room occupancy dwelling units are those for 0 - Bedroom units of the same type.

AREA OFFICE CAMDEN, NEW JERSEY REGION II - NEW YORK

MARKET AREA	STRUCTURE TYPE	NUMBER OF BEDROOMS				
		0	1	2	3	4 or more
CAMDEN	DETACHED	-	-	391	442	463
	SEMI-DETACHED/ROW	-	313	356	395	424
	WALKUP	223	242	316	368	409
	ELEVATOR	258	292	357	-	-
ATLANTIC CITY	DETACHED	-	-	372	421	453
	SEMI-DETACHED/ROW	-	314	357	394	425
	WALKUP	228	247	297	364	404
	ELEVATOR	277	338	438	-	-
BURLINGTON	DETACHED	-	-	391	442	463
	SEMI-DETACHED/ROW	-	313	355	395	424
	WALKUP	228	247	309	360	400
	ELEVATOR	258	292	357	-	-
GLOUCESTER	DETACHED	-	-	391	442	463
	SEMI-DETACHED/ROW	-	313	356	395	424
	WALKUP	223	242	316	368	409
	ELEVATOR	258	292	357	-	-
TRENTON	DETACHED	-	-	403	454	479
	SEMI-DETACHED/ROW	-	323	367	405	436
	WALKUP	245	264	345	388	426
	ELEVATOR	287	343	460	-	-
VINELAND	DETACHED	-	-	355	406	435
	SEMI-DETACHED/ROW	-	297	341	376	407
	WALKUP	216	235	278	330	381
	ELEVATOR	244	278	340	-	-

U. S. DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT
Section 8 Housing Assistance Payments Program

Schedule A - Fair Market Rents for New Construction and Substantial Rehabilitation (Including Housing Finance and Development Agencies Program)

These Fair Market Rents include projection for construction time through July 31, 1977.

NOTE: The Fair Market Rents for (1) dwelling units designed for the elderly or handicapped are those for the appropriate size unit, not to exceed 2-Bedroom, multiplied by 1.05 and rounded to the next higher whole dollar, (2) congregate housing dwelling units are the same as for non-congregate units, and (3) single-room occupancy dwelling units are those for 0 - Bedroom units of the same type.

AREA OFFICE PITTSBURGH, PA. REGION III - PHILADELPHIA

MARKET AREA	STRUCTURE TYPE	NUMBER OF BEDROOMS				
		0	1	2	3	4 or more
NEW CASTLE	DETACHED	-	-	306	350	420
	SEMI-DETACHED/ROW	-	263	289	333	400
	WALKUP	198	245	289	333	386
	ELEVATOR	222	278	321	-	-
PITTSBURGH	DETACHED	-	-	365	426	490
	SEMI-DETACHED/ROW	-	313	348	406	467
	WALKUP	212	260	313	370	429
	ELEVATOR	236	296	342	-	-
ERIE	DETACHED	-	-	335	377	449
	SEMI-DETACHED/ROW	-	281	319	356	427
	WALKUP	206	255	312	349	404
	ELEVATOR	234	290	366	-	-
SHARON	DETACHED	-	-	306	350	420
	SEMI-DETACHED/ROW	-	263	289	333	400
	WALKUP	198	245	289	333	386
	ELEVATOR	222	278	321	-	-
ALTOONA	DETACHED	-	-	340	386	432
	SEMI-DETACHED/ROW	-	292	321	368	416
	WALKUP	196	242	298	334	370
	ELEVATOR	219	278	354	-	-
JOHNSTOWN	DETACHED	-	-	283	384	484
	SEMI-DETACHED/ROW	-	243	267	362	456
	WALKUP	183	209	252	295	339
	ELEVATOR	219	278	354	-	-

INSURING OFFICE DENVER, COLORADO REGION VIII - DENVER

MARKET AREA	STRUCTURE TYPE	NUMBER OF BEDROOMS				
		0	1	2	3	4 or more
DENVER	DETACHED	-	-	288	345	390
	SEMI-DETACHED/ROW	-	217	255	322	345
	WALKUP	172	208	247	318	340
	ELEVATOR	178	215	254	-	-

INSURING OFFICE SALT LAKE CITY REGION VIII - DENVER

MARKET AREA	STRUCTURE TYPE	NUMBER OF BEDROOMS				
		0	1	2	3	4 or more
CEDAR CITY	DETACHED	-	-	235	260	280
	SEMI-DETACHED/ROW	-	181	211	236	250
	WALKUP	135	176	206	231	245
	ELEVATOR	-	-	-	-	-
LOGAN	DETACHED	-	-	230	255	270
	SEMI-DETACHED/ROW	-	160	180	205	235
	WALKUP	125	155	175	200	230
	ELEVATOR	-	-	-	-	-
MOAB	DETACHED	-	-	235	260	280
	SEMI-DETACHED/ROW	-	181	211	236	250
	WALKUP	135	176	206	231	245
	ELEVATOR	-	-	-	-	-

U. S. DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT
Section 8 Housing Assistance Payments Program

Schedule A - Fair Market Rents for New Construction and Substantial Rehabilitation (Including Housing Finance and Development Agencies Program)

These Fair Market Rents include projection for construction time through Dec. 31, 1976.

NOTE: The Fair Market Rents for (1) dwelling units designed for the elderly or handicapped are those for the appropriate size unit, not to exceed 2-Bedroom, multiplied by 1.05 rounded to the next higher whole dollar, (2) congregate housing dwelling units are the same as for non-congregate units, and (3) single-room occupancy dwelling units are those for 0 - Bedroom units of the same type.

AREA OFFICE ATLANTA, GEORGIA REGION IV - ATLANTA

MARKET AREA	STRUCTURE TYPE	NUMBER OF BEDROOMS				
		0	1	2	3	4 or more
COLUMBUS	DETACHED	-	-	261	298	342
	SEMI-DETACHED/ROW	-	186	230	280	323
	WALKUP	168	186	224	267	304
	ELEVATOR	186	217	273	-	-

[FR Doc.75-23162 Filed 9-2-75;8:45 am]

Title 41—Public Contracts and Property Management

CHAPTER 14—DEPARTMENT OF THE INTERIOR

PART 14–3—PROCUREMENT BY NEGOTIATION

Determinations and Findings—Cost Accounting Standards

Pursuant to the authority of the Secretary of the Interior contained in 5 U.S.C. 301, Part 14–3 of Chapter 14 of Title 41 of the Code of Federal Regulations is hereby amended as stated herein.

It is the general policy of the Department of the Interior to allow time for interested parties to participate in the rulemaking process. However, the amendments herein are administrative procedures to implement existing regulations. Subpart 14–3.3 is amended to add new paragraphs (o) and (p) to § 14–3.305–51 pertaining to determinations and findings required in connection with purchase descriptions and specifications and to add new paragraphs (q) through (t) to § 14–3.305–51 pertaining to determinations and findings in connection with cost accounting standards. A new Subpart 14–3.12 is added concerning cost accounting standards. Because the amendments implement the requirements of 41 CFR Subparts 1–1.3 and 1–3.12 and are entirely administrative in nature, the public rulemaking process is waived in this instance and the amendments stated below are effective immediately.

Dated: August 20, 1975.

RICHARD R. HITE,
Deputy Assistant Secretary of the Interior.

1. Part 14–3 is amended by adding the following Subpart 14–3.12 to the Table of Contents.

Subpart 14–3.12—Cost Accounting Standards

AUTHORITY: Sec. 205(c), 63 Stat. 389; (40 U.S.C. 486(c)).

2. Subpart 14–3.3 is amended by adding paragraph (o) through (t) to § 14–3.305–51 which read as follows:

§ 14–3.305–51 Summary of required determinations and findings.

* * * * *

(o) The determination required by § 1–1.307–1(b) of this title that particular features or restrictions specified in purchase descriptions are essential to the Government's requirements will be signed by the user.

(p) The determinations required by § 1–1.307–3 of this title that particular features or restrictions specified in commercial, technical, and State and local specifications and standards are essential to the Government's requirements will be signed by the user.

(q) The determination required by § 1–3.1203(b) of this title that a Disclosure Statement is adequate will be signed by the contracting officer or his authorized representative.

(r) The determination required by § 1–3.1203(d) of this title authorizing postaward submission of Disclosure Statement(s) will be signed by the contracting officer.

(s) The determination by the head of the agency pursuant to § 1–3.1203(e) of this title that it is impractical to secure Disclosure Statement(s) will be signed by the Assistant Secretary—Management.

(t) The determination by the head of the agency pursuant to § 1–3.1211 of this title to waive all or any part of the provisions of the Cost Accounting Standards clause with respect to nondefense contracts shall be prepared in accordance with § 14–3.1211 of this chapter and will be signed by the Assistant Secretary—Management. A waiver with respect to national defense contracts will require approval of the CASB pursuant to § 1–3.1211 of this title.

3. Part 14–3 is amended by adding a new Subpart 14–3.12 and new §§ 14–3.1203, 14–3.1208, 14–3.1210 and 14–3.1211 which read as follows:

Subpart 14–3.12—Cost of Accounting Standards

§ 14–3.1203 Prime contractor Disclosure Statement(s).

Determinations and findings by the head of the agency under § 1–3.1203(e) of this title that it is impractical to secure Disclosure Statement(s) in accordance with the clause entitled "Cost Accounting Standards" as set forth in § 1–3.1204 of this title, will be signed by the Assistant Secretary—Management.

§ 14–3.1208 Contract administration for CASB matters by other Government agencies other than DOD.

The designation of cognizant contracting officer for CASB matters within Interior pursuant to § 1–3.1208(b) of this title will be made by the Assistant Director for Procurement, Office of Management Services.

§ 14–3.1210 Cost Accounting Standards Board Report.

Each bureau and office shall collect, consolidate and submit to the Assistant Director for Procurement, Office of Management Services, within 90 days after the close of each calendar year, the information required by Subparagraph (c)(8) of § 1–3.1210 of this title. Cognizant contracting officers for CASB matters (if any) in each bureau or office are required to collect and report all information required by paragraph (c) of § 1–3.1210 of this title. The Assistant Director for Procurement, Office of Management Services, shall consolidate the information collected and submit the annual report to CASB.

§ 14–3.1211 Waiver of cost accounting standards, rules and regulations.

Each request for approval of a proposed waiver of all or any part of the provisions of the clause entitled "Cost Accounting Standards" (as set forth in § 1–3.1204 of this title) with respect to nondefense contracts shall be prepared and signed by the contracting officer after he has determined that it is impractical to obtain the materials, supplies, or services from any other source. This determination, and the documentation required by § 1–3.1211 of this title, shall be submitted through the Assistant Director for Procurement, Office of Management Services, to the Assistant Secretary-Management for approval. A waiver with respect to national defense contracts will require approval of the CASB pursuant to § 1–3.1211 of this title.

[FR Doc.75-23216 Filed 9-2-75;8:45 am]

CHAPTER 114—DEPARTMENT OF THE INTERIOR

[IPMR Release No. 75–8]

PART 114–42—PROPERTY REHABILITATION SERVICES AND FACILITIES

Precious Metals and Critical Materials

AUGUST 20, 1975.

Pursuant to the authority of the Secretary of the Interior contained in 5 U.S.C. 301 and Sec. 205(c), 63 Stat. 390; 40 U.S.C. 486(c), Subpart 114–42.3 of Chapter 114, Title 41 of the Code of Federal Regulations, is amended as set forth below.

This amendment relates only to matters of internal Department practice. It is, therefore, determined that the public rulemaking procedure is unnecessary and this amendment shall become effective September 3, 1975.

RICHARD R. HITE,
Deputy Assistant Secretary of the Interior.

Subpart 114–42.3 is revised in its entirety to read as follows:

AUTHORITY: 5 U.S.C. 301 and Sec. 205(c), 63 Stat. 390; 40 U.S.C. 486(c).

§ 114–42.301 General.

The head of each bureau and office is responsible for establishing and pursuing a program for recovery of precious metals and critical materials in accordance with the provision of FPMR 101–42.3.

§ 114–42.301–1 Guidelines for conducting intra-agency surveys.

(a) An annual survey shall be conducted at each installation, facility, or activity that generates used hypo solution, scrap film, or other precious metal-bearing scrap, and which has no precious metal recovery program, to determine the economic feasibility of implementing recovery procedures. The results of the survey should be recorded in the format illustrated in FPMR 101–42.4901, and a copy forwarded to the Director, Office of Management Services (PM).

(b) Each bureau and office having an existing or potential precious metal recovery program shall designate an individual to be responsible for coordinating the surveys, implementing recovery procedures, monitoring recovery programs, and submitting the consolidated annual report prescribed in § 114–42.301–2. A notice of such designation shall be submitted to the Director, Office of Management Services (PM).

§ 114–42.301–2 Reporting to GSA.

Within 25 calendar days after the close of each fiscal year, and using the format illustrated in FPMR 101–42.4902, each bureau and office shall submit a consolidated annual report to the Office of Management Services (PM) for Departmental consolidation and submission to the General Services Administration.

§ 114–42.302 Recovery of silver from used hypo solution and scrap film.

The head of each bureau and office is responsible for establishing, maintaining, and pursuing a program for silver recovery from used hypo solution and scrap film in accordance with the procedures set forth in FPMR 101–42.302.

§ 114–42.303 Recovery and utilization of precious metals through the Defense Precious Metals Recovery Program.

§ 114–42.303–1 Recovery of precious metals through the Defense Property Disposal Precious Metals Recovery Office (DPDPMRO).

Each bureau and office generating precious metal-bearing scrap and having no disposal facility should establish procedures for reporting accumulations of such scrap to DPDPMRO, and for sending GSA a copy of each such report in accordance with FPMR 101–42.303–1.

§ 114–42.303–2 Utilization of DOD-recovered precious metals as Government-furnished material (GFM) in Federal procurements.

Prior to the procurement of any precious metal, consideration should be given to the acquisition of such material through the procedures set forth in FPMR 101–42.303–2.

[FR Doc.75-23217 Filed 9-2-75;8:45 am]

Title 45—Public Welfare

CHAPTER I—OFFICE OF EDUCATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PART 169—STRENGTHENING DEVELOPING INSTITUTIONS PROGRAM

Correction

In FR Doc. 75–14333, appearing at page 23857 in the issue for Tuesday, June 3, 1975, on page 23861, third column, § 169.28, Paragraph (a), third line, the reference to "§ 100.26(b)", should be to "§ 100a.26(b)".

Title 49—Transportation

CHAPTER X—INTERSTATE COMMERCE COMMISSION

[Docket No. 35819]

ICC DESIGNATIONS TO BE SHOWN ON TARIFFS AND SCHEDULES, AND ASSIGNMENT OF ALPHA CODE CARRIER AND AGENT DESIGNATIONS

Correction

In FR Doc. 75–21994 appearing at page 36346 in the issue of Wednesday, August 20, 1975, make the following changes:

1. In the second column of page 36357 the first two sentences of § 1306.18(d)(2) should be deleted. In their place insert the following sentence to read:

§ 1306.18 ICC numbering systems.

* * * * *

(d) * * *

(2) Any reference in one tariff or schedule to another tariff or schedule by its old MP–ICC or ME–ICC number, after such referred to publication has been reissued or converted using the standard ICC designation system, must be corrected by publication(s) filed within 60 days of the effective date of the changed designation. * * *

* * * * *

2. In the third column of page 36359 the third line of § 1307.44(c) should be corrected by changing "no" to "not", so that the corrected line reads "bers (not standard ICC designations), and".

3. In the second column of page 36362 a heading was dropped from § 1308.13(d)(1). Immediately above the paragraph set out in small print insert the heading:

NOTICE OF CHANGE OF ICC NUMBER

SUBCHAPTER A—GENERAL RULES AND REGULATIONS

[SO No. 1126; Amdt. No. 5]

PART 1033—CAR SERVICE

Baltimore and Ohio Railroad Co.

At a Session of the Interstate Commerce Commission, Railroad Service Board, held in Washington, D.C., on the 26th day of August, 1975.

Upon further consideration of Service Order No. 1126 (38 FR 6999, 22790; 39 FR 8327, 31237 and 40 FR 8561), and good cause appearing therefor:

It is ordered, That: § 1033.1126 The Baltimore and Ohio Railroad Company authorized to operate over tracks of Penn Central Transportation Company, Robert W. Blanchette, Richard C. Bond, and John H. McArthur, Trustees Service Order No. 1126 be, and it is hereby, amended by substituting the following paragraph (e) for paragraph (e) thereof:

(e) *Expiration date.* The provisions of this order shall expire at 11:59 p.m., November 30, 1975, unless otherwise modified, changed, or suspended by order of this Commission.

Effective date. This amendment shall become effective at 11:59 p.m., August 31, 1975.

(Secs. 1, 12, 15, and 17(2), 24 Stat. 379, 383, 384, as amended; 49 U.S.C. 1, 12, 15, and 17(2). Interprets or applies Secs. 1 (10–17), 15(4), and 17(2), 40 Stat. 101, as amended, 54 Stat. 911; 49 U.S.C. 1(10–17), 15(4), and 17(2).)

It is further ordered, That a copy of this amendment shall be served upon the Association of American Railroads, Car Service Division, as agent of all railroads subscribing to the car service and car hire agreement under the terms of that agreement, and upon the American Short Line Railroad Association; and that notice of this amendment be given to the general public by depositing a copy in the Office of the Secretary of the Commission at Washington, D.C., and by filing it with the Director, Office of the Federal Register.

By the Commission, Railroad Service Board.

[SEAL] ROBERT L. OSWALD, *Secretary.*

[FR Doc.75-23341 Filed 9-2-75;8:45 am]

[SO No. 1131; Amdt. No. 7]

PART 1033—CAR SERVICE

Chicago, Rock Island and Pacific Railroad Co.

At a Session of the Interstate Commerce Commission, Railroad Service Board, held in Washington, D.C., on the 26th day of August, 1975.

Upon further consideration of Service Order No. 1131 (38 FR 9232, 17845, 33399; 39 FR 8327, 19218, 41853, 40 FR 8823) and good cause appearing therefor:

It is ordered, That: § 1033.1131 Chicago, Rock Island and Pacific Railroad Company authorized to operate over tracks of Chicago, Milwaukee, St. Paul and Pacific Railroad Company Service Order No. 1131 be, and it is hereby, amended by substituting the following paragraph (e) for paragraph (e) thereof:

(e) *Expiration date.* The provisions of this order shall expire at 11:59 p.m., February 29, 1976, unless otherwise modified, changed or suspended by order of this Commission.

Effective date. This amendment shall become effective at 11:59 p.m., August 31, 1975.

(Secs. 1, 12, 15, and 17(2), 24 Stat. 379, 383, 384, as amended; 49 U.S.C. 1, 12, 15, and 17(2). Interprets or applies Secs. 1 (10–17), 15(4), and 17(2), 40 Stat. 101, as amended, 54 Stat. 911; 49 U.S.C. 1(10–17), 15(4), and 17(2).)

It is further ordered, That a copy of this amendment shall be served upon the Association of American Railroads, Car Service Division, as agent of all railroads subscribing to the car service and car hire agreement under the terms of that agreement, and upon the American Short Line Railroad Association; and that notice of this amendment be given to the general public by depositing a copy in the Office of the Secretary of the Commission at Washington, D.C., and by filing it with the Director, Office of the Federal Register.

By the Commission, Railroad Service Board.

[SEAL] ROBERT L. OSWALD, *Secretary.*

[FR Doc.75-23342 Filed 9-2-75;8:45 am]

[S.O. No. 1218]

PART 1033—CAR SERVICE

The Kansas City Southern Railway Co.

At a Session of the Interstate Commerce Commission, Railroad Service Board, held in Washington, D.C., on the 27th day of August, 1975.

It appearing, That The Kansas City Southern Railway Company (KCS) is unable to operate over a portion of its lines in Lake Charles, Louisiana, because of its inability to operate over its bridge across the Calcasieu River; that operation of KCS trains over parallel tracks of the Southern Pacific Transportation Company (SP) will enable the KCS to continue service to all shippers located along its lines in Lake Charles; that the SP has consented to use of its tracks by the KCS; that operation by the KCS over the aforementioned tracks of the SP is necessary in the interest of the public and the commerce of the people; that notice and public procedure herein are impracticable and contrary to the public interest; and that good cause exists for making this order effective upon less than thirty days' notice.

It is ordered, That:

§ 1033.1218 **Service Order 1218. The Kansas City Southern Railway Company authorized to operate over certain tracks of Southern Pacific Transportation Company.**

(a) The Kansas City Southern Railway Company (KCS) be, and it is hereby, authorized to operate over tracks of the Southern Pacific Transportation Company (SP) between SP mileposts 218.0 and 222.8 at Lake Charles, Calcasieu Parish, Louisiana, a distance of approximately 4.8 miles.

(b) *Application.* The provisions of this order shall apply to intrastate, interstate, and foreign traffic.

(c) *Rates applicable.* Inasmuch as this operation by the KCS over tracks of the SP is deemed to be due to carrier's disability, the rates applicable to traffic moved by the KCS over these tracks of the SP shall be the rates which were applicable on the shipments at the time of shipment as originally routed.

(d) *Effective date.* This order shall become effective at 12:01 a.m., August 27, 1975.

(e) *Expiration date.* The provisions of this order shall expire at 11:59 p.m., November 30, 1975, unless otherwise modified, changed or suspended by order of this Commission.

(Secs. 1, 12, 15, and 17(2), 24 Stat. 379, 383, 384, as amended; 49 U.S.C. 1, 12, 15, and 17(2). Interprets or applies Secs. 1(10–17), 15(4), and 17(2), 40 Stat. 101, as amended, 54 Stat. 911; 49 U.S.C. 1(10–17), 15(4), and 17(2).)

It is further ordered, That copies of this order shall be served upon the Association of American Railroads, Car Service Division, as agent of the railroads subscribing to the car service and car hire agreement under the terms of that agreement, and upon the American Short Line Railroad Association; and that notice of this order shall be given to the general public by depositing a copy in the Office of the Secretary of the Commission at Washington, D.C., and by filing it with the Director, Office of the Federal Register.

By the Commission, Railroad Service Board.

[SEAL] ROBERT L. OSWALD, *Secretary.*

[FR Doc.75-23343 Filed 9-2-75;8:45 am]

Title 50—Wildlife

CHAPTER I—FISH AND WILDLIFE SERVICE, DEPARTMENT OF THE INTERIOR

PART 32—HUNTING

Certain Wildlife Refuges, Montana

The following special regulations are issued and are effective September 3, 1975.

§ 32.12 **Special regulations; migratory game birds, upland game birds, big game; for individual wildlife refuge areas.**

MONTANA

National Bison Range, Ninepipe and Pablo Refuges, Northwestern Montana, Wetlands, and Swan River Refuge, all in northwestern Montana.

(1) Hunting is prohibited on the National Bison Range and Ninepipe and Pablo Refuges.

(2) Northwestern Montana Wetlands as posted are open to public hunting in accordance with State and Federal hunting regulations. Flathead Waterfowl Production Area is closed to big game hunting.

(3) Swan River Refuge is open to public hunting as posted.

SPECIAL CONDITIONS

(a) Hunting blinds must be constructed of native material available at the hunting site. Construction of blind does not establish priority to the blind or the hunting area.

(b) Use of dogs is permitted during the waterfowl and pheasant hunting seasons only.

(c) Vehicle travel is permitted only on designated roads and parking areas.

The provisions of this special regulation supplement the regulations which govern hunting on wildlife refuge areas generally which are set forth in Title 50, Code of Federal Regulations, Part 32.

MARVIN R. KASCHKE, *Refuge Manager.*

AUGUST 26, 1975.

[FR Doc.75-23301 Filed 9-2-75;8:45 am]

PART 32—HUNTING

Sherburne National Wildlife Refuge, Minnesota

The following special regulation is issued and is effective September 3, 1975.

§ 32.22 **Special regulations; upland game, for individual wildlife refuge areas.**

MINNESOTA

SHERBURNE NATIONAL WILDLIFE REFUGE

The public hunting of ruffed grouse, gray and fox squirrels, rabbits and hares, and pheasants on the Sherburne National Wildlife Refuge is permitted only on the area designated by signs as open to hunting. This open area, comprising approximately 18,360 acres, is delineated on a map available at refuge headquarters, Route 2, Zimmerman, Minnesota 55398, and from the Regional Director, U.S. Fish and Wildlife Service, Federal Building, Fort Snelling, Twin Cities, Minnesota 55111.

Hunting shall be in accordance with all applicable State regulations covering the hunting of upland game subject to the following special conditions:

(1) All motorized conveyances are prohibited from traveling off of established roads and parking areas open to such travel.

(2) Parking of vehicles is restricted to designated parking areas.

(3) Practice and target shooting, overnight camping and open fires are prohibited.

(4) Construction of any permanent artificial scaffold, platform, blind or other construction is prohibited.

(5) Boats, without motors, may be used on the St. Francis River only from designated river access sites.

(6) Snowmobile operations are prohibited on the refuge except within the rights-of-way of County Roads 4, 5, 9, 11, and 48.

The provisions of these special regulations supplement the regulations which govern hunting on wildlife refuge areas generally, which are set forth in Title 50, Code of Federal Regulations, Part 32 and are effective through February 28, 1976.

JOHN E. WILBRECHT, *Refuge Manager, Sherburne National Wildlife Refuge.*

AUGUST 22, 1975.

[FR Doc.75-23212 Filed 9-2-75;8:45 am]

PART 32—HUNTING

Sherburne National Wildlife Refuge, Minnesota

The following special regulation is issued and is effective September 3, 1975.

§ 32.32 Special regulations; big game; for individual wildlife refuge areas.

MINNESOTA

SHERBURNE NATIONAL WILDLIFE REFUGE

Public hunting of deer on the Sherburne National Wildlife Refuge is permitted only on the areas designated by signs as open to hunting. The open area, comprising 18,360 acres, is delineated on a map available at the refuge headquarters, Route 2, Zimmerman, Minnesota 55398, and from the Regional Director, U.S. Fish and Wildlife Service, Federal Building, Fort Snelling, Twin Cities, Minnesota 55111.

Hunting shall be in accordance with all applicable State regulations covering the hunting of deer subject to the following special conditions:

(1) All motorized conveyances are prohibited from traveling off of established roads and parking areas open to such travel.

(2) Parking of vehicles is restricted to designated parking areas.

(3) Practice and target shooting, overnight camping and open fires are prohibited.

(4) Construction of any permanent artificial scaffold, platform, blind or other construction is prohibited.

(5) Boats, without motors, may be used on the St. Francis River only from designated river access sites.

(6) Snowmobile operation is prohibited on the refuge except within the rights-of-way of County Roads 4, 5, 9, 11 and 48.

The provisions of these special regulations supplement the regulations which govern hunting on wildlife refuge areas generally, which are set forth in Title 50, Code of Federal Regulations, Part 32 and are effective through December 14, 1975.

AUGUST 22, 1975.

JOHN E. WILBRECHT,
Refuge Manager, Sherburne National Wildlife Refuge.

[FR Doc.75-23213 Filed 9-2-75;8:45 am]

PART 32—HUNTING

J. Clark Salyer National Wildlife Refuge

The following special regulation is issued and is effective September 3, 1975.

§ 32.32 Special regulations; big game; for individual wildlife refuge areas.

NORTH DAKOTA

J. CLARK SALYER NATIONAL WILDLIFE REFUGE

Public hunting of deer on portions of the J. Clark Salyer National Wildlife Refuge, North Dakota, is permitted from 12:00 noon to sunset November 14, 1975, and from sunrise to sunset November 15, 1975 through November 23, 1975, only on the area south of State Highway #14 designated by signs as open to hunting. This open area is delineated on a map available at the refuge headquarters, Upham, North Dakota 58789, and from the Area Office, U.S. Fish and Wildlife Service, P.O. Box 1897, Bismarck, North Dakota 58501. Hunting shall be in accordance with all applicable State regulations covering the hunting of deer subject to the following conditions.

(1) A special access permit is required, with a limited number of permits being issued from refuge headquarters.

(2) All hunters must exhibit their special access permit, hunting license, deer tag, game and vehicular contents to Federal and State officers upon request.

The provisions of this special regulation supplement the regulations which govern hunting on wildlife refuge areas generally which are set forth in Title 50, Code of Federal Regulations, Part 32, and are effective through November 23, 1975.

DAROLD T. WALLS,
Acting Refuge Manager, J. Clark Salyer N.W. Refuge.

AUGUST 25, 1975.

[FR Doc.75-23214 Filed 9-2-75;8:45 am]

PART 32—HUNTING

Tewaukon National Wildlife Refuge

The following special regulation is issued and is effective on September 3, 1975.

§ 32.32 Special regulations; upland game; for individual wildlife refuge areas.

NORTH DAKOTA

TEWAUKON NATIONAL WILDLIFE REFUGE

Hunting of pheasants on the Tewaukon National Wildlife Refuge, North Dakota, is suspended for the 1975 season due to a low population on the refuge.

HERBERT G. TROESTER,
Refuge Manager, Tewaukon National Wildlife Refuge.

AUGUST 25, 1975.

[FR Doc.75-23215 Filed 9-2-75;8:45 am]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

[75N-0001]

Administrative Practices and Procedures—Revocation of Regulations

The Commissioner of Food and Drugs is revoking the revised regulations pertaining to administrative practices and procedures, published in the FEDERAL REGISTER of May 27, 1975 (40 FR 22950) and is issuing proposed regulations pertaining to administrative practices and procedures elsewhere in this issue of the FEDERAL REGISTER.

Dated: September 2, 1975.

SAM D. FINE,
Associate Commissioner of Compliance.

[FR Doc.75-23540 Filed 9-2-75;3:00 pm]

proposed rules

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[50 CFR Part 17]

ENDANGERED AND THREATENED WILDLIFE

Proposal To Reclassify the American Alligator; Correction

In FEDERAL REGISTER Document 75-17348, appearing at page 28711 of the issue for Tuesday, July 8, 1975, the following changes are made:

1. On page 28713, the ninth line of the second column, the words "of an endangered animal" should be deleted.

2. On page 28715, in § 17.7, the tenth line of paragraph (c)(1) is changed to read "tics of the wildlife are minute, or can be".

3. On page 28717, in § 17.13, the table should be designated paragraph (h); also, the second entry under the "Special rules" column is changed to read § 17.35 (a), and the third entry under the same column is changed to read § 17.54(a).

4. On page 28720, in § 17.54, the ninth line of paragraph (e), the words "or foreign" should be deleted.

Dated: August 27, 1975.

LYNN A. GREENWALT,
Director,
Fish and Wildlife Service.

[FR Doc.75-23283 Filed 9-2-75;8:45 am]

[50 CFR Part 17]

THREATENED OR ENDANGERED FAUNA OR FLORA

Proposed Regulation Determining Critical Habitat for the Mississippi Sandhill Crane

Pursuant to authority in section 4(f), (16 U.S.C. 1533(f)), of the Endangered Species Act of 1973, (16 U.S.C. 1531-1543), the Director, United States Fish and Wildlife Service, proposes to amend 50 CFR Part 17 by adding a new Subpart F for Critical Habitats and a new § 17.80 thereunder which would designate critical habitat for the Mississippi sandhill crane (*Grus canadensis pulla*), an endangered species. The Mississippi sandhill crane was listed as an endangered species on June 4, 1973 (38 FR 14678).

The area being proposed for designation as critical habitat comprises approximately 100,000 acres, most of which is habitat currently utilized by the cranes for one purpose or another or is suitable for use should measures being taken to protect the crane result in an increase in its numbers. The proposed critical habitat is a five-sided area of land, water and airspace in Jackson County, Mississippi, bordered generally on the east by the West Pascagoula River, on the west by the Jackson-Harrison County line, on the south by U.S. Route 90 and on the north by a line running north of Vancleave, Mississippi.

This proposed rulemaking for determination of critical habitat is made necessary by section 7, 16 U.S.C. § 1536, of the Endangered Species Act. When a Federal agency or department authorizes, funds, or carriers out action which could result in the modification or destruction of habitat which is frequented by an endangered or threatened species, the Secertary of the Interior must determine if that habitat is critical for that species. If such habitat is determined to be critical, the Federal agency or department whose project would otherwise affect the habitat must take whatever action may be necessary to insure that its program will not result in the destruction or modification of that habitat. Such destruction or modification would be a violation of section 7 of the Act, subject to being enjoined through litigation brought in the District courts.

In implementing its responsibilities under section 7 of the Endangered Species Act, the United States Fish and Wildlife Service, in conjunction with the National Marine Fisheries Service, published a notice in the FEDERAL REGISTER on April 22, 1975 (40 FR 17764-17765), presenting information and discussing concepts relevant to the determination of critical habitats. On May 16, 1975, the Fish and Wildlife Service published a notice in the FEDERAL REGISTER announcing its intent to determine critical habitat for 108 currently listed endangered species, (40 FR 21499-21501). The notice stated that the Service was particularly interested in receiving data quickly on the Mississippi sandhill crane and nine other species, stating that the Service would determine critical habitat for these key species as rapidly as possible.

Following those announcements it became evident that an emergency situation existed with respect to the Mississippi sandhill crane. Therefore, on June 30, 1975, the Director's emergency determination of critical habitat for the Mississippi sandhill crane, under authority of section 4(f) of the Endangered Species Act, (16 U.S.C. 1533(f)), was published in the FEDERAL REGISTER (40 FR 27501-27502). That determination was made due to the imminent threat of habitat destruction from construction authorized and funded by the Federal Highway Administration of a new segment of Interstate Highway 10 and related development, as more fully set out therein. This notice of proposed rulemaking is being initiated at this time because under the Endangered Species Act the emergency determination can remain in effect for only 120 days following its publication in the FEDERAL REGISTER.

The rule proposed in this notice will be followed by a more complete rulemaking on the entire subject of critical habitat. That rulemaking will codify, among other things, the criteria for determining critical habitat, and general rules for Federal agencies. At the time that this future rulemaking is adopted, the specific determination proposed here for the Mississippi sandhill crane will become part of that rulemaking.

BASIS FOR DETERMINATION

The area being proposed for designation as critical habitat is the last remaining area containing the only known population of the Mississippi sandhill crane. This bird is non-migratory and confines its movements largely within the boundaries proposed for designation as critical, though there may be some wandering outside of the area. The population probably survived here because the land occupied was long considered unmanageable for agriculture, timber, or residential purposes, and consequently received little development or disturbance. The area in recent years has been increasingly subjected to various land uses including silviculture, residential development and highways, thus resulting in further jeopardy to the sandhill crane and its habitat.

Nesting occurs in seven known places which together comprise approximately ten percent of the total area delineated. The nesting grounds are mostly in the vicinity of the right-of-way of Interstate Highway 10, portions of which are nearing completion and other segments on which construction may begin in the near future. They consist mostly of swamps, wet savanna, and open pine. It is the wet, open character of the land, plus the relative lack of disturbance, that makes the area suitable for the crane. In addition to the nesting grounds, there is a large winter roosting site in Pascagoula Marsh in the eastern part of the delineated area. Also, during the winter, the cranes utilize farmland in the northern part of the area for feeding. At other times of the year, the birds may feed and roost in the vicinity of the breeding grounds. There is, of course, regular movement between the various nesting, roosting, and feeding sites. All the suitable habitat within the area proposed for designation is currently used by or has

potential for future use by the Mississippi sandhill crane.

PUBLIC COMMENTS SOLICITED

The Director intends that the finally adopted determination be as responsive as possible to the conservation of the critical habitat of the Mississippi sandhill crane and also that such determination adequately provides for the legitimate interests, consistent with the purposes of the Endangered Species Act, of persons who are engaged in or contemplating actions in the area of critical habitat for this species. The Director, therefore, desires to obtain the comments and suggestions of the public, other concerned Federal and State agencies, and private interests on this proposed determination.

Interested persons may participate in this rulemaking by submitting written comments, preferably in triplicate, to the Director, (FWS/LE), United States Fish and Wildlife Service, Post Office Box 19183, Washington, D.C. 20036. All comments received no later than October 6, 1975, will be considered. The Service will attempt to acknowledge receipt of comments, but substantive responses to individual comments may not be provided. Comments received will be available for public inspection during normal business hours at the Service's Office in Suite 600, 1612 K Street, N.W., Washington, D.C.

In consideration of the foregoing, the Director, United States Fish and Wildlife Service, proposes to amend 50 CFR Part 17 by adding a new Subpart F, as shown below.

Dated: August 27, 1975.

LYNN A. GREENWALT,
Director,
Fish and Wildlife Service.

1. Amend the table of contents in Part 17 by adding a new Subpart F as follows:

Subpart F—Critical Habitat

§ 17.80 Mississippi sandhill crane.

2. Amend Part 17 by adding new Subpart F reading as follows:

Subpart F—Critical Habitat

§ 17.80 Mississippi Sandhill Crane.

(a) The following area is critical habitat for the Mississippi sandhill crane (*Grus canadensis pulla*): a five-sided area of land, water, and airspace in Jackson County, Mississippi, between the West Pascagoula River and the Jackson-Harrison County line, and bounded by the following coordinates—30°33′ N. 88°-37′ W., 30°25′ N. 88°37′ W., 30°22′ N. 88°-44′ W., 30°29′ N. 88°51′ W., 30°33′ N. 88°-51′ W.

(b) Pursuant to section 7 of the Act, all Federal agencies must take such action as is necessary to insure that actions authorized, funded, or carried out by them do not result in the destruction or modification of this critical habitat area.

[FR Doc.75-23284 Filed 9-2-75;8:45 am]

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[7 CFR Part 51]

UNITED STATES STANDARDS FOR GRADES OF FLORIDA ORANGES, TANGELOS, GRAPEFRUIT, AND TANGERINES[1]

Notice of Proposed Rulemaking

Notice is hereby given that the United States Department of Agriculture is considering: the amendment of United States Standards for Grades of Florida Oranges and Tangelos (7 CFR, 51.1140–51.1180) pursuant to the Agricultural Marketing Act of 1946 (60 Stat. 1087, as amended; 7 U.S.C. 1621–1627); the amendment of United States Standards for Grades of Florida Grapefruit (7 CFR, 51.750–51.784) pursuant to the Agricultural Marketing Act of 1946 (60 Stat. 1087, as amended; 7 U.S.C. 1621–1627); and the amendment of United States Standards for Grades of Florida Tangerines (7 CFR, 51.1810–51.1835) pursuant to the Agricultural Marketing Act of 1946 (60 Stat. 1087, as amended; (7 U.S.C. 1621–1627)).

All persons who desire to submit written data, views or arguments for consideration in connection with these proposals should file the same in duplicate, not later than September 30, 1975, with the Hearing Clerk, U.S. Department of Agriculture, Room 112, Administration Building, Washington, D.C. 20250, where they will be available for public inspection during official hours of business (paragraph (b) of § 1.27, as amended at 29 FR 7311).

Statement of considerations leading to the proposed amendment of these grade standards. The Florida Fresh Citrus Shippers Association and the Florida Citrus Commission, Department of Citrus of the State of Florida have requested that the U.S. Grade Standards for Florida Oranges and Tangelos, Grapefruit and Tangerines be amended to provide for a tolerance for fruit affected by worms. The existing standards for these commodities provide no such tolerance.

It has been recognized that a zero tolerance for fruit affected by certain defects is too rigid and unrealistic. Producers find that citrus fruit totally free of natural defects such as worms is impractical to achieve under normal growing and harvesting conditions. Under inspection procedures, lots of citrus fruit offered for inspection and certification are sampled for examination. Adequate and representative samples of the entire lot are essential for accurate certification. However, it is recognized that no sampling plan short of 100 percent examination could assure that all fruits in the lot are free of certain damage. Therefore, this proposal would provide a one-half of one percent tolerance for fruit affected by worms. The tolerance would be expressed in numbers of fruits permitted in existing tolerance tables, based on statistical sampling.

As proposed to be amended § 51.1152 *Tolerances*, and Tables I and II, in the U.S. Standards for Grades of Florida Oranges and Tangelos shall remain the same except for the addition of acceptance numbers for wormy fruit. The foregoing amendment without setting forth in entirety Tables I and II shall read as follows:

TOLERANCES

§ 51.1152 Tolerances.

In order to allow for variations incident to proper grading and handling in each of the foregoing grades, based on sample inspection, the number of defective or offsize specimens in the individual sample, and the number of defective or offsize specimens in the lot, shall be within the limitations specified in Tables I and II.

[1] Packing of the product in conformity with the requirements of these standards shall not excuse failure to comply with the provisions of the Federal Food, Drug, and Cosmetic Act or with applicable State laws and regulations.

TABLE I(A).—*Shipping point*[1] *for 1 through 20 samples*

Factor	Grades	AL[2]	Number of 50-count samples[3]																			
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
			Acceptance numbers[4] (maximum permitted)																			
Wormy fruit	All		1	0	1	[5]1	1	2	[5]2	2	3	3	3	[5]3	3	4	4	[5]4	4	5	5	5	5
Very serious damage including decay and wormy fruit.	U.S. Fancy, U.S. No. 1, U.S. No. 2.		6	4	6	9	11	14	16	18	20	22	24	26	28	30	33	35	37	39	41	43	45
Total defects including decay, wormy fruit, and very serious damage.	All		8	7	12	17	22	27	32	36	41	45	50	54	59	63	68	72	76	81	85	90	94

TABLE I(B).—*Shipping point*[1] *for 21 through 40 samples*

Factor	Grades	AL[2]	Number of 50-count samples[3]																		
			21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40
			Acceptance numbers[4] (maximum permitted)																		
Wormy fruit	All	1	[5]5	6	6	6	6	[6]6	6	7	7	7	7	[7]7	7	8	8	8	[8]8	8	9	9
Very serious damage including decay and wormy fruit.	U.S. Fancy, U.S. No. 1, U.S. No. 2.	6	47	49	51	53	54	56	58	60	62	64	66	68	70	72	74	76	78	80	81	83
Total defects including decay, wormy fruit, and very serious damage.	All	8	98	103	107	111	116	120	124	129	133	137	141	146	150	154	159	163	167	171	176	180

TABLE II.—*En route or at destination*

Factor	Grades	AL[1]	Number of 50-count samples[3]																		
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
			Acceptance numbers[3] (maximum permitted)																		
Wormy fruit	All	1	0	1	[1]1	1	2	[2]2	2	3	3	3	[3]3	3	4	4	[4]4	4	5	5	5	5
Very serious damage other than decay and wormy fruit.	U.S. Fancy, U.S. No. 1, U.S. No. 2.	6	4	6	9	11	14	16	18	20	22	24	26	28	30	33	35	37	39	41	43	45
Total defects including very serious damage other than decay and wormy fruit.	All	8	7	12	17	22	27	32	36	41	45	50	54	59	63	68	72	76	81	85	90	94

2. As proposed to be amended § 51.761 Tolerances, and Tables I and II, in the U.S. Standards for Grades of Florida Grapefruit shall remain the same-except for the addition of acceptance numbers for wormy fruit. The foregoing amendment without setting forth in entirety Tables I and II shall read as follows:

TOLERANCES

§ 51.761 Tolerances.

In order to allow for variations incident to proper grading and handling in each of the foregoing grades, based on sample inspection, the number of defective or offsize specimens in the individual sample, and the number of defective or offsize specimens in the lot, shall be within the limitations specified in Tables I and II.

TABLE I(A).—*Shipping point*[1] *for 1 through 20 samples*

Factor	Grades	AL[1]	Number of 33-count samples[3]																			
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
			Acceptance numbers[4] (maximum permitted)																			
Wormy fruit	All	1	0	6	0	1	[1]1	1	2	2	2	[2]2	2	2	3	3	3	[3]3	3	4	4	4
Very serious damage including decay and wormy fruit.	U.S. Fancy, U.S. No. 1, U.S. No. 2.	4	3	5	7	8	10	11	13	14	16	17	18	20	21	23	24	25	27	28	30	31
Total defects including decay, wormy fruit, and very serious damage.	All	5	5	9	12	16	19	22	25	28	31	34	37	40	44	46	49	52	55	58	61	64

TABLE I(B).—*Shipping point*[1] *for 21 through 40 samples*

Factor	Grades	AL[2]	Number of 33-count samples[3]																			
			21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40
			Acceptance numbers[4] (maximum permitted)																			
Wormy fruit	All	1	4	4	[4]4	4	4	5	5	5	5	5	[5]5	5	5	6	6	6	6	6	[6]6	6
Very serious damage including decay and wormy fruit.	U.S. Fancy, U.S. No. 1, U.S. No. 2.	4	32	34	35	36	38	39	40	42	43	44	45	47	48	49	51	52	53	54	56	57
Total defects including decay, wormy fruit, and very serious damage.	All	5	67	70	73	76	79	82	84	87	90	93	96	99	102	105	107	110	113	116	119	122

TABLE II.—*En route or at destination*

Factor	Grades	AL[1]	Number of 33-count samples[3]																			
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
			Acceptance numbers[3] (Maximum permitted)																			
Wormy fruit	All	1	0	6	0	1	[1]1	1	2	2	2	[2]2	2	2	3	3	3	[3]3	3	4	4	4
Very serious damage other than decay and wormy fruit.	U.S. Fancy, U.S. No. 1, U.S. No. 2.	4	3	5	7	8	10	11	13	14	16	17	18	20	21	23	24	25	27	28	30	31
Total defects including very serious damage other than decay and wormy fruit.	All	5	5	9	12	16	19	22	25	28	31	34	37	40	44	46	49	52	55	58	61	64

3. As proposed to be amended § 51.1818 Tolerances, and Tables I and II, in the U.S. Standards for Grades of Florida Tangerines shall remain the same except for the addition of acceptance numbers for wormy fruit. The foregoing amendment without setting forth in entirety Tables I and II shall read as follows:

TOLERANCES

§ 51.1818 Tolerances.

In order to allow for variations incident to proper grading and handling in each of the foregoing grades, based on sample inspection, the number of defective or offsize specimens in the individual sample, and the number of defective or offsize specimens in the lot, shall be within the limitations specified in Tables I and II.

TABLE I(A).—*Shipping point [1] for 1 through 20 samples*

Factor	Grades	AL [2]	Number of 50-count samples [3]																			
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
			Acceptance numbers [4] (maximum permitted)																			
Wormy fruit	All	1	0	1	[5]1	1	2	[5]2	2	3	3	3	[5]3	3	4	4	[5]4	4	5	5	5	5
Very serious damage including decay and wormy fruit.	U.S. Fancy, U.S. No. 1, U.S. No. 2.	6	4	6	9	11	14	16	18	20	22	24	26	28	30	33	35	37	39	41	43	45
Total defects including decay, wormy fruit, and very serious damage.	All	8	7	12	17	22	27	32	36	41	45	50	54	59	63	68	72	76	81	85	90	94

TABLE I(B).—*Shipping point [1] for 21 through 40 samples*

Factor	Grades	AL [2]	Number of 50-count samples [3]																			
			21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40
			Acceptance numbers [4] (maximum permitted)																			
Wormy fruit	All	1	[5]5	6	6	6	6	[5]6	6	7	7	7	7	[5]7	7	8	8	8	[5]8	8	9	9
Very serious damage including decay and wormy fruit.	U.S. Fancy, U.S. No. 1, U.S. No. 2.	6	47	49	51	53	54	56	58	60	62	64	66	68	70	72	74	76	78	80	81	83
Total defects including decay, wormy fruit, and very serious damage.	All	8	98	103	107	111	116	120	124	129	133	137	141	146	150	154	159	163	167	171	176	180

TABLE II.—*En route or at destination*

Factor	Grades	AL [1]	Number of 50-count samples [2]																			
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
			Acceptance numbers [3] (maximum permitted)																			
Wormy fruit	All	1	0	1	[4]1	1	2	[4]2	2	3	3	3	[4]3	3	4	4	[4]4	4	5	5	5	5
Very serious damage other than decay and wormy fruit.	U.S. Fancy, U.S. No. 1, U.S. No. 2.	6	4	6	9	11	14	16	18	20	22	24	26	28	30	33	35	37	39	41	43	45
Total defects including very serious damage other than decay and wormy fruit.	All	8	7	12	17	22	27	32	36	41	45	50	54	59	63	68	72	76	81	85	90	94

(Secs. 203, 205, 60 Stat. 1087, as amended, 1090 as amended; 7 U.S.C. 1622, 1624)

Dated: August 26, 1975.

WILLIAM H. WALKER III,
Acting Administrator.

[FR Doc.75-23048 Filed 9-2-75;8:45 am]

[7 CFR Part 201]

FEDERAL SEED ACT REGULATIONS

Proposed Miscellaneous Amendments

The Agricultural Marketing Service is considering amendments of the regulations under the Federal Seed Act that would add the names of several agricultural and vegetable seeds to the list of kinds subject to the Act along with regulations for testing them. Also, the proposed amendments would change the botanical names for kinds of plants, regulations for testing seed, and standards for certified seed.

Under section 402 of the Federal Seed Act, as amended (7 U.S.C. 1592) and the administrative procedure provisions of 5 U.S.C. 553, notice is hereby given of intention to amend the Part 201 regulations (7 CFR Part 201) under the Act, to accomplish the above and to make minor editorial changes. A public hearing with respect to the proposed amendments will be held on October 7, 1975 at 9 a.m., in Room 2096, South Building, U.S. Department of Agriculture, 14th and Independence Avenue, SW., Washington, D.C. Interested persons or groups who wish to appear at the hearing to present oral or written data, views, or arguments relative to the proposed amendments, may do so either in person or through a representative. Interested persons or groups who may not wish to appear at the hearing but desire to submit written data, views, or arguments with respect to the proposed amendments, may do so by filing them, in duplicate, with the Hearing Clerk, U.S. Department of Agriculture, Room 112, Administration Building, Washington, D.C. 20250, not later than October 6, 1975. Data, views, or arguments which have been submitted in writing to the Hearing Clerk do not need to be presented orally at the public hearing.

All written comments filed with the Hearing Clerk, and a transcript or summary of the public hearing, will be available for public inspection at the Office of the Hearing Clerk during official hours of business.

Upon request and prior to the hearing, briefings on the proposal will be held with interested members of the seed industry and other interested persons to further explain the proposed changes and the reasons for proposing them. Requests for briefings should be directed to the Seed Branch, Grain Division, Agricultural Marketing Service, U.S. Department of Agriculture, 6525 Belcrest Road, Hyattsville, Maryland 20782.

The final decision in this matter will be based on the written comments filed with the Hearing Clerk, the transcript or

a summary of the public hearing, and other information available in the Department. If the proposals are adopted, it is planned that they will be made effective not later than January 1, 1976.

The substantive changes are summarized as follows:

The Part 201 regulations under the Act were amended in 1970 (35 FR 6107) with respect to the kinds of seeds subject to the Act. Since that date, several new kinds of agricultural seed and one new kind of vegetable seed have been introduced in interstate commerce or are being imported for seeding purposes in the United States. It is proposed that the names of these new kinds be added to the lists of the kinds of seeds subject to the Act.

The Part 201 regulations under the Act were amended in 1970 (35 FR 6107) with respect to the botanical names of seeds subject to the Act. Since that date, numerous changes have been made in the list of stabilized names of plants as adopted by the International Association of Plant Taxonomy and the International Seed Testing Association. It is proposed that the botanical names in the Part 201 regulations be updated to better conform with the names as adopted by the associations.

The Part 201 regulations were amended in 1973 (38 FR 12729) with respect to the methods and procedures for testing seeds. Since that date, the Association of Official Seed Analysts has adopted changes in its rules for testing seeds. It is proposed that the Part 201 regulations with respect to the methods and procedures for testing seed be updated to more closely conform with the rules for testing seed as adopted by the Association.

On November 1, 1973, the regulations (7 CFR Part 201) under the Federal Seed Act (7 U.S.C. 1551 et seq.) were amended (38 FR 25661) to establish seed certifying agency standards and procedures. Since November 1973, AOSCA has adopted certain technical changes in its land, isolation, field, and seed standards; and in its provisions for pollen control for hybrids. It is proposed that the Part 201 regulations for certified seed be amended to include the changes adopted by AOSCA.

In consideration of the foregoing, it is proposed to amend 7 CFR Part 201, as follows:

§ 201.2 [Amended]

1. Section 201.2 (h) and (i) would be amended as follows:

a. Add in proper alphabetical order in the list of "Agricultural Seeds," § 201.2 (h), the following:

Agrotricum—X Agrotriticum Ciferri and Giacom.
Brome, meadow—Bromus biebersteinii Roem. and Schult.
Clover, arrowleaf—Trifolium vesiculosum Savi.
Milkvetch—Astragalus cicer L.
Timothy, turf—Phleum nodosum (L.) Huds.
Saltbush, fourwing—Atriplex canescens (Pursh.) Nutt.
Wheat X Agrotricum—Triticum X Agrotriticum.

b. Add in proper alphabetical order in the list of "Vegetable Seeds," § 201.2(i), the following:

Gherkin, West India—Cucumis anguria L.

c. Change the names under "Agricultural Seeds", § 201.2(h), as follows:

Following "Barrelclover-Medicago" delete "tribuloides Desr." and insert "truncatula Gaertn."
Following "Bean, adzuki" delete "Phaseolus angularis Willd." and insert "Vigna angularis (Willd.) Ohwi and Ohashi."
Following "Bean, mung" delete "Phaseolus aureus Roxb." and insert "Vigna radiata (L.) Wilczek."
Following "Bentgrass, creeping-Agrostis" delete "palustris Huds." and insert "stolonifera var. palustris (Huds.) Farw."
Following "Bermudagrass—Cynodon dactylon (L.) Pers." add "var. dactylon."
Following "Bluestem, big-Andropogon" delete "furcatus Muhl." insert "gerardi Vitm."
Following "Bluestem, little" delete "Andropogon scoparius Michx." and insert "Schizachyrium scoparium (Michx.) Nash (Andropogon scoparius Michx.)"
Following "Bluestem, yellow" delete "Andropogon ischaemum L." and insert "Bothriochloa ischaemum (L.) Keng."
Following "Broomcorn—Sorghum" delete "vulgare var. technicum (Koern.) Jav." and insert "bicolor (L.) Moench."
Following "Buffelgrass" delete "Pennisetum ciliare (L.) Link." and insert "Cenchrus ciliaris L. (Pennisetum ciliare (L.) Link.)."
Following "Burclover, California—Medicago" delete "hispida Gaertn." and insert "polymorpha L."
Following "Clover, large hop—Trifolium" delete "procumbens L." and insert "campestre Schreb."
Following "Corn, pop—Zea mays" delete "var. everta (Sturt.) Bailey" and insert "L."
Following "Crotalaria, slenderleaf—Crotalaria" delete "intermedia Kotschy" and insert "brevidens Benth."
Following "Crotalaria, striped—Crotalaria" delete "striata DC. (C. mucronata Desv.")" and insert "pallida Ait."
Following "Fescue, hair—Festuca" delete "capillata Lam." and insert "tenuifolia Sibth."
Following "Fescue, hard—Festuca" delete "ovina var. duriscula (L.) Koch." and insert "longifolia Thuill."
Following "Fescue, meadow—Festuca" delete "elatior L." and insert "pratensus Huds."
Following "Fescue, red—Festuca rubra L." add "subsp. rubra."
Following "Fescue, sheep—Festuca ovina L." add "var. ovina."
Following "Hardinggrass—Phalaris" delete "tuberosa var. stenoptera (Hack.) Hitche." and insert "stenoptera Hack."
Following "Kudzu—Pueraria" delete "thunbergiana (Sieb. and Zucc.) Benth." and insert "lobata (Willd.) Ohwi."
Following "Lespedeza, Siberian—Lespedeza" delete "hedysaroides (Pallas) Ricker" and insert "juncea (L. f.) Pers."
Following "Millet, browntop" delete "Panicum ramosum L." and insert "Brachiaria ramosa (L.) Stapf."
Following "Millet, pearl—Pennisetum" delete "glaucum (L.) R. Br." and insert "americanum (L.) K. Schum."
Following "Mustard, white" delete "Brassica hirta Moench" and insert "Sinapsis alba L."
Following "Redtop—Agrostis" delete "alba L." and insert "gigantea Roth."
Following "Rescuegrass—Bromus" delete "catharticus Vahl." and insert "unioloides Kunth."
Following "Sorghum" delete "Sorghum vulgare Pers." and insert "Sorghum bicolor (L.) Moench."
Following "Sorghum-sudangrass" delete "hybrid Sorghum vulgare X S. sudanense" and insert "Sorghum bicolor X S. sudanense."
Following "Triticale" delete "Tritico-secale Whittmack." and insert "X Triticosecale (Secale X Triticum)."
Following "Velvetbean" delete "Stizolobium deeringianum Bort." and insert "Mucuna deeringiana (Bort.) Merr."
Following "Vetch, common—Vicia sativa L." add "subsp. sativa."
Following "Vetch, narrowleaf—Vicia" delete "angustifolia (L.) Reich" and insert "sativa subsp. nigra (L.) Ehrh."
Following "Vetch woollypod—Vicia" delete "dasycarpa Ten." and insert "villosa subsp. varia (Host) Corb."
Following "Wheatgrass, slender—Agropyron" delete "pauciflorum (Schwein.) Hitchc., (A. trachycaulum Steud.)" and insert "trachycaulum (Link) Malte. ex H. F. Lewis."

d. Change the names under "Vegetable Seeds", § 201.2(i), as follows:

Following "Asparagusbean—Vigna" delete "sesquipedalis (L.) Fruwirth." and insert "unguiculata (L.) Walp. subsp. sesquipedalis (L.) Verdc."
Following "Bean, lima—Phaseolus lunatus" delete "var. macrocarpus Van Eseltine" and insert "(L.)"
Following "Beet—Beta vulgaris L." add "var. vulgaris."
Following "Citron—Citrullus" delete "vulgaris Schrad." and insert "lanatus (Thunb.) Matsum. and Nakai var. citroides (Bailey) Mansf."
Following "Cornsalad—Valerianella locusta" delete "var. olitoria Pall." and insert "(L.) Laterrade."
Following "Cress, water" delete "Rorippa nasturtium-aquaticum (L.) Britt, and Rendle." and insert "Nasturtium officinale R. Br."
Following "Eggplant—Solanum melongena" delete "var. esculentum Nees." and insert "(L.)."
Following "Leek—Allium" delete "porrum L." and insert "ampeloprasum L."
Following "Okra" delete "Hibiscus esculentus L." and insert "Abelmoschus esculentus (L.) Moench."
Following "Parsley—Petroselinum" delete "hortense Hoffm." and insert "crispum (Mill.) A. W. Hill."
Following "Spinach, New Zealand—Tetragonia" delete "expansa Thunb." and insert "tetragonioides (Pall.) Ktze."
Following "Watermelon—Citrullus" delete "vulgaris Schrad." and insert "lanatus (Thunb.) Matsum. and Nakai."

§ 201.43 [Amended]

2. Section 201.43(c) is amended by deleting "sorghum," from the list of kinds of seed.

3. Section 201.43(d) is amended by adding to the list of seeds in proper alphabetical order the name "sorghum,".

§ 201.46 [Amended]

4. Section 201.46 would be amended as follows:

a. Add the following at the end of subparagraph (c): "If the approximate percentage of the components of a mixture are not known they may be estimated. The weight of the noxious-weed seed working sample shall be determined by mutiplying the weight of the purity working sample by 10 or by calculating the weighted average in the same manner described above for the purity working sample."

b. Delete subparagraph (d).

5. Section 201.46, Table 1, would be amended as follows:

a. Add in proper alphabetical order under "Agricultural Seed" in the respective columns the following:

Agrotricum—*X Agrotriticum*	65	500	39
Brome, meadow—*Bromus biebersteinii*	13	130	19
Clover, arrowleaf—*Trifolium vesiculosum*	3	30	90
Milkvetch—*Astragalus cicer*	10	100	293
Timothy, turf—*Phleum nodosum*	1	10	2565
Saltbush, fourwing—*Atriplex canescens*	15	150	165
Wheat X Agrotricum—*Triticum X Agrotriticum*	65	500	38

b. Add in proper alphabetical order under "Vegetable Seed" in the respective columns the following:

Gherkin, West India—*Cucumis anguria*	10	100	153

c. Under "Agricultural Seed" following "Barrelclover" in column 1 delete "tribuloides" and insert "truncatula." Also delete "50" and "300" from columns 2 and 3 respectively and insert "10," "100" and "250" in columns two, three, and four respectively.

d. Under "Agricultural Seed" opposite "Wheatgrass, Siberian—Agropyron sibiricum" delete "10" and insert "5" in column 2.

e. Under "Agricultural Seed" make the following changes in column 1:

Following "Bean, adzuki" delete "Phaseolus angularis" and insert "Vigna angularis."
Following "Bean, mung" delete "Phaseolus aureus" and insert "Vigna radiata."
Following "Bentgrass, creeping" delete "Agrostis palustris" and insert "Agrostis stolonifera var. palustris."
Following "Bluestem, little" delete "Andropogon scoparius" and insert "Schizachyrium scoparium."
Following "Bluestem, yellow" delete "Andropogon ischaemum" and insert "Bothriochloa ischaemum."
Following "Broomcorn" delete "Sorghum vulgare var. technicum" and insert "Sorghum bicolor."
Following "Buffelgrass" delete "Pennisetum ciliare" and insert "Cenchrus ciliaris."
Following "Burclover, California—Medicago" delete "hispida" and insert "polymorpha" in both instances.
Following "Clover, large hop—Trifolium" delete "procumbens (T. campestre)" and insert "campestre."
Following "Corn, pop—Zea mays" delete "var. everta."
Following "Crotalaria, striped—Crotalaria" delete "mucronata" and insert "pallida."
Following "Crotalaria, Slenderleaf—Crotalaria" delete "intermedia" and insert "brevidens."
Following "Fescue, hair—Festuca" delete "capillata" and insert "tenuifolia."
Following "Fescue, hard—Festuca" delete "ovina var. duriscula" and insert "longifolia."
Following "Fescue, meadow—Festuca" delete "elatior" and insert "pratensis."
Following "Fescue, red—Festuca rubra" insert "subsp. rubra."
Following "Fescue, sheep—Festuca ovina" insert "var. ovina."
Following "Hardinggrass—Phalaris" delete "var. stenoptera" and insert "stenoptera."
Following "Kudzu—Pueraria" delete "thunbergiana" and insert "lobata."
Following "Lespedeza, Siberian—Lespedeza" delete "hedysaroides" and insert "juncea."
Following "Millet, browntop" delete "Panicum ramosum" and insert "Brachiaria ramosa."
Following "Millet, pearl—Pennisetum" delete "glaucum" and insert "americanum."
Following "Mustard, white" delete "Brassica hirta" and insert "Sinapsis alba."
Following "Redtop—Agrostis" delete "alba" and insert "gigantea."
Following "Rescuegrass — Bromus" delete "catharticus" and insert "unioloides."
Following "Sorghum" delete "Sorghum vulgare" and insert "Sorghum bicolor."
Following "Sorghum-sudangrass" delete "hybrid, S. vulgare X S. sudanense" and insert "S. bicolor X S. sudanense."
Following "Triticale" insert "X Triticosecale."
Following "Velvetbean" delete "Stizolobium deeringianum" and insert "Mucuna deeringiana."
Following "Vetch, common—Vicia sativa" add "subsp. sativa."
Following "Vetch narrowleaf" delete "Vicia angustifolia" and insert "Vicia sativa subsp. nigra."
Following "Vetch, woollypod—Vicia" delete "dasycarpa" and insert "brevidens."

f. Under "Vegetable Seed" make the following changes in column 1:

Following "Asparagusbean—Vigna" delete "sesquipedalis" and insert "unguiculata subsp. sesquipedalis."
Following "Beans, lima—Phaseolus lunatus" delete "var. macrocarpus."
Following "Beet—Beta vulgaris" add "var. vulgaris."
Following "Citron—Citrullus" delete "vulgaris" and insert "lanatus var. citroides."
Following "Cornsalad—Valerianella locusta" delete "var. olitoria."
Following "Cress, water" delete "Rorippa nasturtium-aquaticum" and insert "Nasturtium officinale."
Following "Eggplant—Solanum melongena" delete "var. esculentum."
Following "Leek—Allium" "delete porrum" and insert "ampeloprasum."
Following "Okra" delete "Hibiscus esculentus" and insert "Abelmoschus esculentus (Hibiscus esculentus)."
Following "Parsley—Petroselinum" delete "hortense (P. crispum)" and insert "crispum."
Following "Spinach, New Zealand—Tetragonia" delete "expansa" and insert "tetragoniodes."
Following "Watermelon—Citrullus" delete "vulgaris" and insert "lanatus."

§ 201.48 [Amended]

6. Section 201.48(g) is amended by by changing the last sentence to read as follows:

"Attached empty florets of the following kinds shall not be removed from fertile florets when the analysis is made by the special method described under § 201.51a: Smooth brome (Bromus inermis), chewings fescue (Festuca rubra var. commutata), red fescue (Festuca rubra subsp. rubra), orchardgrass (Dactylis glomerata), fairway crested wheatgrass (Agropyron cristatum), standard crested wheatgrass (Agropyron desertorum), intermediate wheatgrass (Agropyron intermedium), and pubescent wheatgrass (Agropyron trichophorum).

7. Section 201.51a introductory text and the table to paragraph (b) would be amended to read as follows:

§ 201.51a Special procedures for purity analysis.

When the multiple units of the pure seed fraction (multiple florets or entire spikelets containing at least one caryopsis, to which is attached any type of inherent inert matter) of the kinds of grasses indicated in this section constitute 5 percent or more of the sample, the test shall be made by the following procedures:

* * * * *

(b) * * *

Factors applicable to multiple units

Kind of seed	Percent of single florets in sample									
	50 or less	50.01 to 55	55.01 to 60	60.01 to 65	65.01 to 70	70.01 to 75	75.01 to 80	80.01 to 85	85.01 to 90	90.01 to 95
Brome, smooth	0.72	0.74	0.75	0.76	0.78	0.79	0.81	0.82	0.83	0.85
Fescue, chewings	.91	.91	.91	.91	.91	.91	.91	.91	.91	.91
Fescue, red	.80	.81	.82	.83	.84	.86	.87	.88	.89	.90
Orchardgrass	.80	.81	.81	.82	.82	.82	.83	.83	.83	.84
Wheatgrass, crested [1]	.70	.72	.73	.74	.75	.76	.77	.78	.79	.79
Wheatgrass, intermediate	.72	.74	.75	.76	.77	.78	.79	.80	.81	.82
Wheatgrass, pubescent	.66	.67	.67	.67	.68	.68	.69	.69	.69	.70

[1] Includes both fairway crested wheatgrass and standard crested wheatgrass.

§ 201.58 [Amended]

8. Section 201.58(b) would be amended as follows:

a. Add new paragraph (b)(12) to read as follows:

(12) Garden beans (Phaseolus vulgaris); Use of calcium nitrate: If hypocotyl collar rot is observed on seedlings, the sample involved may be retested using a 0.3 to 0.6 percent solution of calcium nitrate to moisten the germination medium.

b. Add new paragraph (b)(13) to read as follows:

(13) Fourwing Saltbush (Atriplex canescens); preparation of seed for test: De-wing seeds and soak for 2 hours in 3 liters of water after which rinse with approximately 3 liters of distilled water. Remove excess water, air dry for 7 days at room temperature, then test for germination as indicated in Table 2.

9. Section 201.58(c)—Table 2; germination requirements for indicated kinds, would be amended as follows:

a. Add in proper alphabetical order under "Agricultural Seed" in the indicated columns the following new kinds:

Col. 1 "Agrotricum—Agrotriticum"	Col. 2 "B,T,S" Col. 3 "20;15" Col. 4 "4" Col. 5 "7" Col. 7 "Prechill at 5° or 10° C. for 5 days."
Col. 1. "Brome, meadow — Bromus beibersteinii"	Col. 2 "B,T,TB" Col. 3 "20–30" Col. 4 "6" Col. 5 "14" Col. 6 "light optional"
Col. 1 "Clover, arrowleaf—Trifolium vesiculosum"	Col. 2 "B,T" Col. 3 "20" Col. 4 "4" Col. 5 "14" Col. 6 "See par. (b) (11)"
Col. 1 "Milkvetch—Astragalus cicer"	Col. 2 "B,T" Col. 3 "20" Col. 4 "6" Col. 5 "14"
Col. 1 "Timothy, turf-Phelum nodosum"	Col. 2 "P,TB" Col. 3 "15–25;20–30" Col. 4 "5" Col. 5 "10" Col. 6 "Light" Col. 7 "KNO_3 & Prechill at 5° or 10° C. for 5 days."
Col. 1 "Saltbush, fourwing-Atriplex canescens"	Col. 2 "B" Col. 3 "20" Col. 4 "5" Col. 5 "14" Col. 6 "See par. (b) (13)" Col. 7 "prechill 5° C. for 7 days."
Col. 1 "Wheat X Agrotricum-Triticum X Agrotriticum"	Col. 2 "B, T, S" Col. 3 "20;15" Col. 4 "4" Col. 5 "7" or 10° C. for 5 days."

b. Make the following changes under "Agricultural Seed" for the kinds indicated in the appropriate column:

Fescue, Hair	Col. 6 delete "light"
Hardinggrass	Col. 6 delete "KNO_3"
Ricegrass, Indian	Col. 2 delete "S"; add "P" Col. 3 delete "5–15" and "15–25" Col. 5 delete "28"; add "42" Col. 7 delete "Dark; prechill in soil at 5° C. for 4 weeks." Add "prechill at 5° C. for 4 weeks and test for 21 additional days."
Add "Alternate Method"	Col. 2 "S" Col. 3 "5–15;15;15–25" Col. 4 "7" Col. 5 "28" Col. 7 "Dark; prechill in soil at 5° C. for 4 weeks."
Wheatgrass, western	Col. 2 delete "P" Col. 3 delete "15–25"; add "15–30" Col. 6 delete "light and KNO_3 optional" Col. 7 delete "and prechill at 5° or 10° C. for 7 days"

c. Add in proper alphabetical order under "Vegetable Seed" in the indicated columns, the following new kind:

Col. 1 "Gherkin, West India—Cucumis anguira"	Col. 2 "B,T,S" Col. 3 "20–30" Col. 4 "3" Col. 5 "7" Col. 7 "Test at 30° C."

d. Under "Vegetable Seeds" opposite "Beans, garden—Phaseolus vulgaris" delete "5" from column 4 and insert "none" and insert in column 6 "see par. (b) (12)."

e. Under "Agricultural Seed" make the following changes in column 1:

Following "Bean, adzuki" delete "Phaseolus angularis" and insert "Vigna angularis."

Following "Bean, mung" delete "Phaseolus aureus" and insert "Vigna radiata."

Following "Bentgrass, creeping" delete "Agrostis palustris" and insert "Agrostis stolonifera var. palustris."

Following "Bluestem, little" delete "Andropogon scoparius" and insert "Schizachyrium scoparium."

Following "Bluestem, yellow" delete "Andropogon ischaemum" and insert "Bothriochloa ischaemum."

Following "Broomcorn" delete "Sorghum vulgare var. technicum" and insert "Sorghum bicolor."

Following "Buffelgrass" delete "Pennisetum ciliare" and insert "Cenchrus ciliaris."

Following "Burclover, California—Medicago" delete "hispida" and insert "polymorpha" in both instances.

Following "Clover, large hop—Trifolium" delete "procumbens (T. campestre)" and insert "campestre."

Following "Corn, pop—Zea mays" delete "var. everta."

Following "Crotalaria, striped—Crotalaria" delete "mucronata" and insert "pallida."

Following "Fescue, hair—Festuca" delete "capillata" and insert "tenuifolia."

Following "Fescue, hard—Festuca" delete "ovina var. duriscula" and insert "longifolia."

Following "Fescue, meadow—Festuca" delete "elatior" and insert "pratensis."

Following "Fescue, red—Festuca rubra" insert "subsp. rubra."

Following "Fescue, sheep—Festuca ovina" insert "var. ovina."

Following "Hardinggrass—Phalaris" delete "tuberosa var. stenoptera" and insert "stenoptera."

Following "Kudzu—Pueraria" delete "thunbergiana" and insert "lobata."

Following "Lespedeza, Siberian—Lespedeza" delete "hedysaroides" and insert "juncea."

Following "Millet, browntop" delete "Panicum ramosum" and insert "Brachiaria ramosa."

Following "Millet, pearl—Pennisetum" delete "glaucum" and insert "americanum."

Following "Mustard, white" delete "Brassica hirta" and insert "Sinapsis alba."

Following "Redtop—Agrostis" delete "alba" and insert "gigantea."

Following "Rescuegrass—Bromus" delete "catharticus" and insert "unioloides."

Following "Sorghum: Grain and Sweet—Sorghum" delete "vulgare" and insert "bicolor."

Following "Sorghum-sudangrass" delete "hybrid, S. vulgare X. S. sudanense" and insert "S. bicolor X S. sudanense."

Following "Velvetbean" delete "Stizolobium deeringianum" and insert "Mucuma deeringianum."

Following "Vetch, common—Vicia sativa" add "subsp. sativa."

Following "Vetch narrowleaf" delete "Vicia augustifolia" and insert "Vicia sativa subsp. nigra."

f. Under "Vegetable Seed" make the following changes in column 1:

Following "Asparagusbean—Vigna" delete "sesquipedalis" and insert "unguiculata subsp. sesquipedalis."

Following "Beans, lima—Phaseolus lunatus" delete "var. macrocarpus."

Following "Beet—Beta vulgaris" add "var. vulgaris."

Following "Citron—citrullus" delete "vulgaris" and insert "lanatus var. citroides."

Following "Cornsalad—Valerianella locusta" delete "var. olitoria."

Following "Cress, water" delete "Rorippa nasturtium-aquaticum" and insert "Nasturtium officinale."

Following "Eggplant—Solanum melongena" delete "var. esculentum."

Following "Leek—Allium" delete "porrum" and insert "ampeloprasum."

Following "Okra" delete "Hibiscus esculentus" and insert "Abelmoschus esculentus (Hibiscus esculentus)."

Following "Parsley—Petroselinum" delete "hortense (P. crispum)" and insert "crispum."

Following "Spinach, New Zealand—Tetragonia" delete "expansa" and insert "tetragonioides."

Following "Watermelon—Citrullus" delete "vulgaris" and insert "lanatus."

§ 201.76 [Amended]

10. Section 201.76, Table 5, would be amended as follows:

a. Add in proper alphabetical order the following new standards:

TABLE 5

Crop kind	Foundation				Registered				Certified			
	Land	Isolation	Field	Seed	Land	Isolation	Field	Seed	Land	Isolation	Field	Seed
Alfalfa, hybrid	[1] [4] [47]	[47] 1,320	[47] 1,000	0.1					[1] [3] [1]	[3] [47] 165	[47] 100	1.0
Corn, backcross line	0	[42] 1,600	[42] 1,000	[42] 0.1								
Fava bean	[3] 1	[42] 0	2,000	6.05	[3] 1	[42] 0	1,000	0.10	[4] 1	[42] 0	500	0.20
Flat pea	[1] 4	[3, 47] 600	1,600	0.1	[1] [3]	[3, 47] 300	400	0.25	[1, 3] 1	[3, 47] 165	100	1.0

b. Make the following changes in standards in the columns indicated:

In all three classes under isolation, delete superscript "4" and insert superscript "47" for alfalfa, birdsfoot trefoil, clover, crownvetch, sainfoin, and vetch.

In all three classes under isolation, add superscript "42" for sunflower and hybrid sunflower.

For field pea, delete "[1]," "1000," "C.1"; "[1]," "500," "0.2"; "[1]," "200," and "0.5" from the three columns and insert "[1],"

"2000," "0.05"; ""1," "1000," "0.1"; ""1," "500," and "0.2," respectively.

c. Change footnotes at end of Table 5 to read as follows:

15. Refers to off-type ears. Ears with off-colored or different textured kernels are limited to 0.5 percent, or a total of 25 off-colored or different textured kernels per 1,000 ears.

28. Whiteheart fruits may not exceed 1 per 100, 40, and 20 for Foundation, Registered, and Certified classes, respectively. Citron or hard rind is not permitted in Foundation or Registered classes and may not exceed 1 per 1,000 fruits in the Certified class.

33. Unless the preceding crop was another kind or unless the preceding soybean crop was planted with a class of certified seed of the same variety, or unless the preceding soybean crop and the variety being planted are of contrasting pubescence or hilum color, in which case, no time need elapse.

d. Add the following footnotes at the end of Table 5 as follows:

42. Does not apply to Helianthus similes, H. ludens, or H. agrestis.

44. The ratio of male sterile (A) strains and pollen (B or C) strains shall not exceed 2:1.

46. Parent lines (A and B) in a crossing block, or seed and pollen lines in a hybrid seed production field, shall be separated by at least 6 feet and shall be managed and harvested in a manner to prevent mixing.

47. Distance between fields of certified classes of the same variety may be reduced to 10 feet regardless of the class or size of the fields.

12. Section 201.77 would be amended by adding a new paragraph (e) as follows:

§ 201.77 Length of stand requirements.

(e) Hybrid alfalfa. When at least 75 percent of the plants are in bloom and there is no more than 15 percent seed set, 200 plants shall be examined to determine the pollen production index (PPI). Each plant is rated as 1, 2, 3 or 4 with "1" representing no pollen, "2" representing a trace of pollen, "3" representing substantially less than normal pollen, and "4" representing normal pollen. The rating is weighted as 0, 0.1, 0.6 or 1.0, respectively. The total number of plants of each rating is multiplied by the weighted rating and the values are totaled. The total is divided by the number of plants rated and multiplied by 100 to determine the PPI. The maximum PPI allowed is 14 for the Foundation class, and 6 for 95 percent hybrid seed, and 42 for 75 percent hybrid seed of the Certified class.

Dated: August 22, 1975.

WILLIAM H. WALKER, III,
Acting Administrator,
Agricultural Marketing Service.

[FR Doc.75-23302 Filed 9-2-75;8:45 am]

[7 CFR Part 910]

HANDLING OF LEMONS GROWN IN THE STATES OF CALIFORNIA AND ARIZONA

Proposed Rule Making With Respect to Approval of Expenses and Fixing of Rate of Assessment for the 1975–76 Fiscal Year

This notice invites written comment relative to the proposed expenses of $324,000 and rate of assessment of $0.027 per carton of lemons to support the activities of the Lemon Administrative Committee for the 1975–76 fiscal year under Marketing Order No. 910.

Consideration is being given to the following proposals submitted by the Lemon Administrative Committee, established pursuant to the marketing agreement, as amended, and Order No. 910, as amended (7 CFR Part 910), regulating the handling of lemons grown in the State of Arizona and that part of the State of California south of a line drawn due east and west through the post office in Turlock, California, effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), as the agency to administer the terms and provisions thereof:

(1) That expenses that are reasonable and likely to be incurred by the Lemon Administrative Committee during the period August 1, 1975, through July 31, 1976, will amount to $324,000.

(2) That the rate of assessment for said period, payable by each handler in accordance with § 910.41, be fixed at $0.027 per carton of lemons.

All persons who desire to submit written data, views, or arguments in connection with the aforesaid proposals should file the same, in quadruplicate, with the Hearing Clerk, United States Department of Agriculture, Room 112, Administration Building, Washington, D.C. 20250, not later than September 18, 1975. All written submissions made pursuant to this notice will be made available for public inspection at the office of the Hearing Clerk during regular business hours (7 CFR 1.27 (b)).

Dated: August 28, 1975.

CHARLES R. BRADER,
Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc.75-23303 Filed 9-2-75;8:45 am]

[7 CFR Part 948]

IRISH POTATOES GROWN IN COLORADO—AREA NO. 2

Proposed Handling Regulation; Vegetables: Import Regulations

This proposal, designed to promote orderly marketing of Colorado Area No. 2 potatoes, would require inspection of fresh shipments to keep undesirable, low quality potatoes from being shipped to consumers.

Consideration is being given to issuing a handling regulation, hereinafter set forth, which was recommended by the Colorado Area No. 2 Committee, established pursuant to Marketing Agreement No. 97 and Order No. 948, both as amended (7 CFR Part 948). This program regulates the handling of Irish potatoes grown in the State of Colorado and is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601 et seq.).

This notice is based on the recommendations and information submitted by the Area No. 2 Committee and other available information. The recommendations of the committee reflect its appraisal of the composition of the 1975 crop in the production area and the marketing prospects for this season.

The proposed requirements this year would be U.S. No. 2, with a 2-inch minimum size for round varieties and a 1⅞-inch minimum size for long varieties. Size B could be shipped if U.S. No. 1, or better grade. Maturity requirements would be "moderately skinned" for all varieties, except that for the Russet Burbank and Red McClure varieties, any grade better than U.S. No. 2 must be no more than "slightly skinned." These maturity requirements would terminate on October 31.

The grade, size, and maturity requirements provided herein are necessary to prevent potatoes of low quality or undesirable sizes from being distributed in fresh market channels. They will also provide consumers with good quality potatoes consistent with the overall quality of the crop and standardize the quality of the potatoes shipped from the production area in order to provide the consumer with a more acceptable product.

Exceptions would be provided to certain of these requirements to recognize special situations in which such requirements would be unappropriate or unreasonable.

Shipments would be permitted to certain special purpose outlets without regard to the grade, size, maturity and inspection requirements, provided that safeguards are met to prevent such potatoes from reaching unauthorized outlets. Seed would be exempted because requirements for this outlet differ greatly from those for fresh market. Shipments for use as livestock feed would likewise be exempt. Since no purpose would be served by regulating potatoes used for charity purposes, such shipments would be exempt. Exemption of potatoes for most processing uses is mandatory under the legislative authority for this part and therefore shipments to processing outlets are unregulated.

All persons who desire to submit written data, views, or arguments in connection with this proposal may file the same, in duplicate, with the Hearing Clerk, Room 112-A, U.S. Department of Agriculture, Washington, D.C. 20250, not later than September 22, 1975. All written submissions made pursuant to this notice will be made available for public inspection at the office of the Hearing Clerk during regular business hours (7 CFR 1.27(b)).

The proposed regulation is as follows:

§ 948.374 Handling regulation.

From the effective date of this handling regulation, through June 30, 1976, no person shall handle any lot of potatoes grown in Area No. 2 unless such potatoes meet the requirements of paragraphs (a), (b), and (c) of this section, or unless such potatoes are handled in accordance with paragraphs (d), (e), or (f) of this section. The maturity requirements specified in paragraph (b) shall terminate October 31, 1975, at 11:59 p.m. M.S.T.

(a) *Minimum grade and size requirements.*

(1) *Round varieties.* U.S. No. 2, or better grade, 2 inches minimum diameter.

(2) *Long varieties.* U.S. No. 2, or better grade, 1⅞ inches minimum diameter.

(3) *All varieties.* Size B, if U.S. No. 1, or better grade.

(b) *Maturity (skinning) requirements.*

(1) *Russet Burbank and Red McClure varieties.* For U.S. No. 2 grade not more than "moderately skinned" and for other grades not more than "slightly skinned."

(2) *All other varieties.* Not more than "moderately skinned."

(c) *Inspection.* (1) No handler shall handle any potatoes for which inspection is required unless an appropriate inspection certificate has been issued with respect thereto and the certificate is valid at the time of shipment. For purposes of operation under this part it is hereby determined pursuant to paragraph (d) of § 948.40, that each inspection certificate shall be valid for a period not to exceed 5 days following the date of inspection as shown on the inspection certificate.

(2) No handler may transport or cause the transportation by motor vehicle of any shipment of potatoes for which an inspection certificate is required unless each shipment is accompanied by a copy of the inspection certificate applicable thereto and the copy is made available for examination at any time upon request.

(d) *Special purpose shipments.* (1) The grade, size, maturity and inspection requirements of paragraphs (a), (b) and (c) of this section and the assessment requirements of this part shall not be applicable to shipments of potatoes for:

(i) Livestock feed;

(ii) Relief or charity; or

(iii) Canning, freezing, and "other processing" as hereinafter defined.

(2) The grade, size, maturity and inspection requirements of paragraphs (a), (b) and (c) of this section shall not be applicable to shipments of seed pursuant to § 948.6 but such shipments shall be subject to assessments.

(e) *Safeguards.* Each handler of potatoes which do not meet the grade, size, and maturity requirements of paragraphs (a) and (b) of this section and which are handled pursuant to paragraph (d) for any of the special purposes set forth therein shall,

(1) Prior to handling, apply for and obtain a Certificate of Privilege from the committee.

(2) Furnish the committee such reports and documents as requested, including certification by the buyer or receiver as to the use of such potatoes, and

(3) Bill each shipment directly to the applicable processor or receiver.

(f) *Minimum quantity.* For purposes of regulation under this part, each person may handle up to but not to exceed 1,000 pounds of potatoes without regard to the requirements of paragraphs (a), (b) and (c) of this section, but this exception shall not apply to any shipment which exceeds 1,000 pounds of potatoes.

(g) *Definitions.* The terms "U.S. No. 1," "U.S. No. 2," "slightly skinned," and "moderately skinned" shall have the same meaning as when used in the U.S. Standards for Potatoes (§§ 51.1540–51.1566 of this title, effective September 1, 1971, as amended), including the tolerances set forth therein. The term "other processing" has the same meaning as the term appearing in the act and includes, but is not restricted to, potatoes for dehydration, chips, shoestrings, starch, and flour. It includes only that preparation of potatoes for market which involves the application of heat or cold to such an extent that the natural form or stability of the commodity undergoes a substantial change. The act of peeling, cooling, slicing, dicing, or applying material to prevent oxidation does not constitute "other processing." Other terms used in this section shall have the same meaning as when used in Marketing Agreement No. 97, as amended, and this part.

(h) *Applicability to imports.* Pursuant to section 8e of the act and § 980.1, Import regulations (7 CFR 980.1), Irish potatoes of the red skinned round type, except certified seed potatoes, imported into the United States during the period September 29, 1975, through June 30, 1976, shall meet the grade, size, and quality requirements specified in paragraph (a) of this section, and during the effective date of this handling regulation through October 31, 1975, shall be not more than "moderately skinned."

Dated: August 28, 1975.

CHARLES R. BRADER,
Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc.75-23304 Filed 9-2-75;8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 121]

[Docket No. 75N-0235]

PRIOR-SANCTIONED POLYVINYL CHLORIDE RESIN

Termination of Notice of Proposed Rulemaking

The Commissioner is withdrawing a proposal published in the FEDERAL REGISTER of May 17, 1973 (38 FR 12931) to establish a regulation under § 121.2009 (21 CFR 121.2009) to identify the criteria for the safe use of prior-sanctioned polyvinyl chloride resin as a component of food packaging material in contact with nonalcoholic food.

Since publication of the proposal, additional information has been received concerning the use of polyvinyl chloride in food packaging materials which indicates that this proposal was too narrow in its scope. Published elsewhere in this issue of the FEDERAL REGISTER are proposed regulations concerning the use of vinyl chloride polymers in contact with all types of food.

Accordingly, the Commissioner hereby withdraws the proposal published on May 17, 1973, and terminates the rule making proceeding begun by that proposal.

This action is taken pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (secs .409, 701(a), 52 Stat. 1055, 72 Stat. 1785–1788 (21 U.S.C. 348, 371(a)) and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Effective date. This order shall be effective September 3, 1975.

Dated: August 27, 1975.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

[FR Doc.75-23240 Filed 8-29-75;8:45 am]

[21 CFR Part 121]

[Docket No. 75N-0190]

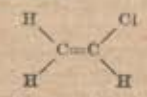
VINYL CHLORIDE POLYMERS IN CONTACT WITH FOOD

Notice of Proposed Rulemaking

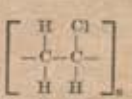
The Food and Drug Administration (FDA) is proposing regulations to restrict the uses of vinyl chloride polymers in contact with food. The proposal permits the continued use of vinyl chloride polymers in food packaging and other food-contact articles where the potential for migration of vinyl chloride is diminished to the extent that it may not reasonably be expected to become a component of food. The proposal includes an interim food additive regulation for the use of water pipe made from vinyl chloride polymers. The interim regulation would be in effect pending development of additional data to determine if vinyl chloride may reasonably be expected to be in potable water that is drawn from the tape. The proposed regulation would prohibit all other uses of vinyl chloride polymers in food-contact articles, including semirigid and rigid articles such as bottles and sheets, because in those uses vinyl chloride may reasonably be expected to become a component of food. Interested persons have until November 3, 1975 to submit comments.

USE OF VINYL CHLORIDE

Vinyl chloride is a chemical with the following structure:



It has a boiling point of −14° C (6.8° F) and consequently it is ordinarily a gas. This property led to its use as a propellant for aerosol products such as cosmetics, drugs, and pesticides. Vinyl chloride is polymerized to form polyvinyl chloride in which the basic monomeric unit is repeated:



In this formula, *n* represents the number of monomeric units that may be present, a sum which normally exceeds 800 units.

Vinyl chloride homopolymers and copolymers are used in the production of articles or components of articles in-

tended to contact food, including food-packaging materials, coatings, parts for food processing equipment, flexible tubing, and water pipes.

Polyvinyl chloride has several properties that make it useful for packaging, such as clarity, resistance to water and many chemicals, capability of acting as a barrier to gas and water, capability of being sealed by heat, and capability of being molded into deep shapes. Approximately 300 million pounds of polyvinyl chloride are used each year in the packaging of food, making it (after polyethylene) the second most commonly used plastic for packaging food. The production of water pipe is one of the single largest uses of polyvinyl chloride, accounting annually for over 400 million pounds of resin. In addition, the polymers of vinyl chloride have also been found useful as packaging materials for other products within FDA's jurisdiction, including drug products, blood, and cosmetics. Vinyl chloride polymers are also used as components of certain medical devices.

Early investigatory work reviewed by Dr. A. J. Lehman, then Chief of the Division of Pharmacology, Food and Drug Administration, indicated that polyvinyl chloride was insoluble in various solvent systems used to simulate food. Consequently, there was little concern about the safety of food-contact articles made from polyvinyl chloride. In 1950, Dr. Lehman reported to the Association of Food and Drug Officials:

> We consider as the most important single physical characteristic of a film its solubility or the leaching out of any of its constituents in the common media with which the plastic may come in contact. If nothing can be extracted when tested with representative food-type solvents (lard-oil, vinegar, sodium bicarbonate, meat juice, water, etc.) under conditions somewhat more rigorous than might be experienced under practical usage, we usually have no objections to use of the film in situations where direct contact with food may result. Toxicological problems relate more to the plasticizers employed to give the film certain desirable characteristics than to the film itself. Plasticizers are legion, but to develop one which is nontoxic and yet efficient is not easy of accomplishment.

Reports of this work were published by Dr. Lehman in "Chemicals in Food: A report to the Association of Food and Drug Officials on Current Developments," *Quarterly Bulletin of the Association of Food and Drug Officials of the United States*, 15(3):82, 1951, and "Food Packaging," *Ibid.*, 20(4):159, 1956.

MIGRATION OF VINYL CHLORIDE TO FOOD

In early 1973, representatives of Schenley Distillers, Inc., Cincinnati, Ohio, reported to FDA their having found vinyl chloride in distilled alcoholic beverages, such as vodka and gin, packaged in polyvinyl chloride bottles. The findings of their migration studies were subsequently confirmed by FDA and led to a proposal concerning the use of polyvinyl chloride. This proposed regulation, published in the FEDERAL REGISTER of May 17, 1973 (38 FR 12931), would have precluded use of polyvinyl chloride resin in articles for use in contact with alcoholic foods and was based on: (1) The finding that residual vinyl chloride in polyvinyl chloride bottles was being extracted by bottled distilled spirits and wines, and (2) the fact that no available animal feeding studies established a safe level of consumption when vinyl chloride was extracted from containers into food. At that time there were no data that indicated that polyvinyl chloride articles in contact with nonalcoholic foods would result in migration of residual vinyl chloride into the food and, accordingly, there was no reason to consider restriction of such uses.

The existence of residual vinyl chloride in articles made from vinyl chloride polymers is related to the manufacturing process and the physical structure of the polymers. The gas vinyl chloride becomes the packaging material consisting of polyvinyl chloride or one of the copolymers of vinyl chloride through a series of distinct steps. The first step is the polymerization of the vinyl chloride to form a polymer, e.g., polyvinyl chloride resin. This resin is then blended with a number of other substances that may include plasticizers, stabilizers, lubricants, and processing aids to form a compounded material ordinarily referred to as a "compound," e.g., a polyvinyl chloride flexible film "compound" or a polyvinyl chloride bottle "compound." This "compound" is then used by the fabricator to produce the finished article that is used in contact with food.

The individual molecules of polyvinyl chloride may be visualized as short strands of thread. The individual molecules are attracted to each other by physical forces that tend to hold them together so strongly that the polyvinyl chloride, by itself, is rigid. The polymeric material contains an exceedingly large number of polyvinyl chloride molecules, which are intermingled and provide a number of open spaces (interstices) among the individual molecules.

The origin of the possibility that vinyl chloride may migrate to food is its incomplete polymerization into polyvinyl chloride. Estimates indicate that somewhat less than 90 percent of the vinyl chloride is converted to polyvinyl chloride. Most of the remaining 10 percent vinyl chloride is either vented to the atmosphere, or recovered by techniques, such as vacuum stripping, and reused. However, some vinyl chloride remains in the polyvinyl chloride resin following its polymerization and isolation: At one time as much as 2000 parts per million (ppm) residual vinyl chloride remained, but with new processing methods, as little as 1 to 2 ppm remain. It is theorized that the vinyl chloride becomes physically trapped among the interstices of the polymer "threads."

This model permits an explanation of the varying degrees to which vinyl chloride is removed from the different forms of the polymer. A large amount of the vinyl chloride that fails to polymerize never becomes trapped in the resin; it either finds its way out of the resin maze, due to its volatility, or can be removed by vacuum stripping. Most, if not all, of the remaining vinyl chloride may be removed in the preparation of polyvinyl chloride "compound" for such flexible plastic materials as gaskets, films, and tubing. In preparing these "compounds" the polyvinyl chloride resin is mixed and heated with as much as 50 to 60 parts of plasticizer per hundred parts of resin. The addition of the plasticizer "opens" the spaces between the polymer "threads," and the heat tends to drive out the remaining vinyl chloride molecules. Further opportunity for removal of vinyl chloride is provided during the fabrication of the "compound" into articles because heat is usually used in the process. By contrast, it is much more difficult for the vinyl chloride molecules to escape from rigid and semirigid polyvinyl chloride articles because they contain little or no plasticizer and are generally thicker than plasticized articles. Many rigid articles have been analyzed and found to contain residual vinyl chloride. However, FDA has not been able to detect vinyl chloride in any of the plasticized, flexible polyvinyl chloride products it has analyzed.

Even in the case of rigid unplasticized polyvinyl chloride, there is a loss of vinyl chloride during fabrication into articles. Once fabricated, the polyvinyl chloride articles continue to lose vinyl chloride by diffusion. Data have been developed showing a gradual loss of residual vinyl chloride from polyvinyl chloride articles during their storage prior to use. This diffusion phenomenon continues to occur when the polyvinyl chloride is used in contact with food. If vinyl chloride is present, a certain amount may be expected to migrate to the food. In the case of semirigid and rigid articles that contain high levels of residual vinyl chloride, this amount has been shown to be substantial. However, in the case of coatings, films, and other plasticized food-packaging materials in which the amount of residual vinyl chloride is extremely small, there appears to be little likelihood that vinyl chloride would reasonably be expected to be present in the food.

The migration of vinyl chloride may be viewed as a simple diffusion phenomenon: The vinyl chloride is leaving the location of highest concentration, the plastic article, and moving to a location of lower concentration, whether it be the surrounding air or the food contained in the article. This hypothesis appears to be supported by the work of scientists at Ethyl Corp. ("VCM extraction from PVC bottles," *Modern Packaging*, pp. 45–48, April 1975). Their data indicate that the vinyl chloride levels in the plastic article and its food content eventually reach a point of equilibrium. However, there continues to be a loss of residual vinyl chloride to the surrounding atmosphere so that the level in the plastic article becomes lower relative to the level in the food inside it. When this occurs, there is a migration of vinyl chloride from the food into the plastic article: This is represented by a decrease in the concentration of vinyl chloride that can be detected in the food. The ob-

vious end point indicated by this hypothesis is that there would be no vinyl chloride in the food or in the plastic article at that distant point in time when it has all migrated to the surrounding atmosphere.

A modification and extension of this hypothesis has been proposed by Professor Seymour Gilbert, Ph.D., Department of Food Science, Rutgers University, New Brunswick, N.J. Dr. Gilbert's work indicates that there are active sites in rigid polyvinyl chloride that tend to adsorb and hold on to vinyl chloride molecules. At high vinyl chloride concentrations these active sites are covered by a very small part of the total vinyl chloride and the remainder tends to migrate from the polyvinyl chloride in accordance with the usual diffusion theory. He postulates that at vinyl chloride concentrations of less than 1 ppm in the polyvinyl chloride, not all the active sites are covered and thus there are few unadsorbed vinyl chloride molecules left to migrate. His theory is supported by the results of equilibrium studies in which powdered polyvinyl chloride resins containing no vinyl chloride were added to food-simulating solvents containing known concentrations of vinyl chloride. Vinyl chloride was found to be taken up by the resin and its concentrations in the food-simulating solvents were reduced to a much greater extent than would be explained by simple diffusion or partitioning.

Schenley Distillers reported levels of vinyl chloride as high as 20 ppm in vodka and 25 ppm in gin. Confirmatory work on samples of the same material by FDA showed levels of 11 ppm vinyl chloride in vodka and 12 ppm in gin. Since that time FDA has received many additional reports of findings of vinyl chloride in various types of food packaged in polyvinyl chloride bottles. Generally, these reports have not included suitable information to evaluate accuracy, such as: an adequate description of the methodology, including chromatograms; data from recovery studies verifying the claimed sensitivities; data showing confirmation by mass spectroscopy; and identification of the plastic material. It should be noted that analysis for vinyl chloride requires careful analytical techniques to assure credible findings. The analysis becomes progressively more difficult as the concentration of vinyl chloride decreases.

The problems involved with the analysis for vinyl chloride are emphasized by the difficulties that firms have encountered in obtaining consistent results during "round-robin" studies in which a number of laboratories have analyzed the same material. FDA has developed a method for the determination of vinyl chloride in polyvinyl chloride and in food-simulating solvents. (Copies are available from the Division of Food and Color Additives, Food and Drug Administration, 200 C St., SW., Washington, D.C. 20204.) This method is considered to be capable of measuring levels of vinyl chloride in food-simulating solvents as low as 20 parts per billion (ppb) (in 50 percent ethanol) and in polyvinyl chloride as low as 0.35 ppm.

On December 20, 1973, representatives of FDA and the Society of the Plastics Industry, Inc. (SPI) met to discuss chemical information concerning vinyl chloride that SPI had submitted with its comments of October 15, 1973, on the original proposal of May 17, 1973. In response to questions raised at this and subsequent meetings, members of the SPI have obtained information about polyvinyl chloride, including analyses of various types of foods for the presence of vinyl chloride, refinement of the methodology for detection, and review of the toxicological aspects. Memoranda of these meetings and the information supplied are on public display at the office of the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20852.

Data supplied by SPI indicated that vinyl chloride could migrate to nonalcoholic foods from polyvinyl chloride bottles. Analyses of two samples of vegetable oils packed in polyvinyl chloride bottles revealed the presence of vinyl chloride at levels of 1.6 and 6.5 ppm. Reported results of analyses of additional samples of foods, drugs, and cosmetics disclosed varying levels of vinyl chloride, e.g., vinegar (5 ppb), mineral oil (74 ppb and approximately 2 ppm from two other samples), a vitamin supplement (approximately 1 ppm), and a mouthwash (174 ppb). No vinyl chloride was reported from a series of water samples using an analytical method reportedly sensitive to 50 ppb. These latter samples had been collected from operating potable water systems of various polyvinyl chloride formulations at six different building sites.

In early 1974, the British Ministry of Agriculture, Fisheries, and Food reported finding vinyl chloride in concentrations ranging from 10 to 80 ppb in fruit squashes and from 10 to 40 ppb in cooking oils. The Canadian Health Protection Branch of the Ministry of Health and Welfare reported finding vinyl chloride ranging from 0.9 to 8.4 ppm in seven samples of apple cider vinegar. It also reported vinyl chloride in samples of various wines (less than 0.025 to 0.98 ppm), gin (0.22 to 0.7 ppm), and malt vinegar (1.5 ppm).

Data from experimental work using food-simulating solvents, i.e., distilled water, 3 percent acetic acid, ethanol, and *n*-heptane, support these earlier data showing migration of vinyl chloride to types of foods other than alcoholic beverages: The data show that the use of alcohol and *n*-heptane as solvents representing alcoholic and fatty foods, respectively, results in the highest levels of vinyl chloride extractives as compared to the amounts extracted by distilled water (representing aqueous foods) and 3 percent acetic acid (representing acidic foods). All of these data are on public display in the office of the Hearing Clerk, Food and Drug Administration.

The available data indicate that certain applications of vinyl chloride do not present a realistic possibility of vinyl chloride migration. The Commissioner is unaware of any findings of vinyl chloride migration from film, cap liners, coatings, gaskets or flexible tubing. Results of analyses of extractives from such articles have shown no detectable vinyl chloride. Analyses of these plastic articles themselves have shown no detectable vinyl chloride using analytical methods reported to be capable of detecting a level as low as 1 ppm residual vinyl chloride. No residual vinyl chloride was found in FDA analysis of polyvinyl chloride blood bags and flexible tubing using a method capable of detecting 0.35 ppm residual vinyl chloride.

The lack of findings of extractable vinyl chloride from film is not surprising, for theoretical calculations indicate that if film contained residual vinyl chloride, 100 percent migration of the residual vinyl chloride from a 1 mil (0.001 inch) film would result in 2 ppb vinyl chloride in food. These calculations assume that 10 grams of food contact each square inch of film, the film weighs 20 milligrams per square inch per mil thickness, and the film contains 1 ppm residual vinyl chloride. However, these assumptions are exaggerated, e.g., the vinyl chloride will migrate into the air as well as the food, and much lower levels of migration into food would be expected to occur under actual conditions of use, to the point where they would be extremely small. The data substantiate this conclusion because the levels of extractable vinyl chloride have never been shown to approach 100 percent in those cases where actual values have been presented for article thickness, residual vinyl chloride level, and levels of extraction of vinyl chloride.

The greatest likelihood for migration of vinyl chloride appears to be from polyvinyl chloride bottles and other rigid or semirigid polyvinyl chloride articles that are intended for one-time use. A wide variety of products have been packaged in such containers, including vegetable oils, vinegar, honey, and liquid vitamin supplements. Large quantities of processed meats are packaged in rigid and semirigid containers composed of vinyl chloride polymers. Jelly, honey, and other condiments are frequently packaged in individual serving containers composed of vinyl chloride polymers. These various articles range in thickness from approximately 7 mils to 30 mils. Semirigid articles with a thickness of 7 to 12 mils were reported in a submission from the American Meat Institute to contain 0 to 180 ppm residual vinyl chloride and to yield 4 to 20 ppb vinyl chloride when extracted by *n*-heptane. Rigid articles with a thickness of 10 to 21 mils were reported by the American Meat Institute to contain 6 to 127 ppm residual vinyl chloride and to yield 2 to 237 ppb vinyl chloride when extracted by *n*-heptane.

Water pipe is a use of polyvinyl chloride that presents little likelihood that vinyl chloride will become a component of potable water. The pipe's rigid, relatively thick wall would be expected to have a potential for high levels of residual vinyl chloride; data show that the level of residual vinyl chloride attainable in water pipe may vary from less than

10 ppm to more than 100 ppm. However, the potential for extraction of vinyl chloride from potable water pipe is greatly reduced because of the low solubility of vinyl chloride in water, the short time of contact, the large volume of water in contact with the pipe, and the comparatively low temperatures of exposure. The primary use of polyvinyl chloride potable water pipe is from water mains to buildings where a large volume of water flow occurs, and the temperature of exposure is lowered because the pipe is buried. Moreover, the small amount of vinyl chloride that might migrate into water from water pipe would be expected to dissipate during the aeration and agitation that occur at the tap.

TOXICITY OF VINYL CHLORIDE

FDA is unaware of any suitable toxicity data from animal feeding studies that demonstrate a safe level of ingestion of vinyl chloride. Results of a 90-day feeding study with rats were submitted to FDA in October 1974. However, that study was not conclusive and, furthermore, could not resolve the prime issue of safety, namely carcinogenicity, since it was a short-term feeding study. Lifetime studies are necessary to evaluate properly the potential for long-range effects, such as carcinogenicity.

Considerable data exist concerning the toxic effects of vinyl chloride from atmospheric exposures, especially by inhalation and occupational contact. As the Commissioner pointed out in his April 22, 1974, proposal (39 FR 14215) to prohibit the use of vinyl chloride as an ingredient in drug and cosmetic aerosol products:

> There is ample evidence that vinyl chloride inhalation can result in acute toxicity manifested by an array of symptoms, including unconsciousness as a result of high concentration by inhalation. Cardiac effects, bone changes, and degenerative changes in the brain, liver, and kidneys have also been reported in animals.

The results from studies by Torkelson, et al., on the chronic effects of vinyl chloride on laboratory animals (T. R. Torkelson, F. Oyen, and V. K. Rowe, "The Toxicity of Vinyl Chloride as Determined by Repeated Exposure of Laboratory Animals," *American Industrial Hygiene Association Journal*, 22(5), 354–361, 1961) indicated slight effects in rats exposed to atmospheres containing 100 and 200 ppm vinyl chloride. An exposure of 50 ppm was considered to be a "no-effect" level. Published scientific reports implicate vinyl chloride as a causative agent for "acroosteolysis" of the hands and feet as well as systemic effects among industrial workers engaged in the manufacture of vinyl chloride. Dr. P. L. Viola, in studies, exposed rats to an atmosphere containing 3 percent (30,000 ppm) vinyl chloride vapors for 4 hours per day for 5 days per week for 1 year (P. L. Viola, A. Bigotti, and A. Caputo, "Oncogenic Response of Rat Skin, Lungs, and Bones to Vinyl Chloride," *Cancer Research*, 31: 516–522, May 1971). He reported that rats subjected to such exposure developed tumors of the skin, lungs, and bones. Copies of these reports are on file with the Hearing Clerk, Food and Drug Administration.

Reporting at the February 15, 1974, fact-finding hearing, which was called by a notice that the Occupational Safety and Health Administration published in the FEDERAL REGISTER of January 30, 1974 (39 FR 3874), Dr. Cesare Maltoni discussed preliminary results from his investigations directed at clarifying the type and degree of carcinogenic effects of vinyl chloride, as previously reported by Dr. Viola. Dr. Maltoni's investigations involved various types and levels of exposure to vinyl chloride, including: (1) An attempt to reproduce the conditions of Dr. Viola's experiment using a level of 30,000 ppm; (2) experiments using atmospheric exposure to vinyl chloride vapors at levels ranging from 50 to 10,000 ppm; (3) an experiment investigating the effects upon ingestion (intubation) of vinyl chloride; and (4) experiments investigating endoperitoneal and subcutaneous routes of administration. (C. Maltoni & G. Lefemine: "Carcinogenicity Bio-assays of Vinyl Chloride," *Environmental Research*, 7:387–405, 1974 and "Le potenzialitá dei saggi sperimentali nella predizione dei rischi oncogeni ambientali. Un esempio il cloruro di vinile," *Accademia Nazionale Dei Lincei*, 56:1–11, 1974). In addition to rats, Dr. Maltoni reported that experiments were also being conducted using mice and hamsters.

At the February meeting, Dr. Maltoni discussed his preliminary findings of the development of angiosarcoma of the liver, along with other types of tumors, at levels of atmospheric exposure as low as 250 ppm. At the New York Academy of Sciences meeting, May 10–11, 1974 ("Carcinogenicity Bioassays of Vinyl Chloride: Current Results." *Annals of the New York Academy of Sciences*, 246:195–218, January 31, 1975), he subsequently reported the development of angiosarcoma of the liver and other types of tumors at levels of atmospheric exposure as low as 50 ppm. Further, he announced that additional experiments were being started; the experiments are using larger numbers of animals and lower dose levels of inhalation exposure. Inhalation exposure studies using similar low levels of vinyl chloride are also in progress at Industrial Biotest Research Laboratories (IBRL) under the sponsorship of the Manufacturing Chemists Association. In discussing these two studies in regulations, published in the FEDERAL REGISTER of October 4, 1974 (39 FR 35890), establishing standards for industrial exposure to vinyl chloride, the Occupational Safety and Health Administration stated:

> These investigators have induced angiosarcoma of the liver in rats and mice at exposure concentrations of 50 ppm and in hamsters at higher concentrations of exposure. Additional tumors involving other organs, including the kidneys, lungs, and skin of exposed animals, were also observed in frequencies much in excess of control animals.

As noted above, the Food and Drug Administration issued a proposal on April 22, 1974, concerning the use of vinyl chloride as a propellant in aerosol drugs and cosmetics. At the same time, manufacturers were requested to recall any outstanding stocks of such products from the market. A final regulation was published in the FEDERAL REGISTER of August 26, 1974 (39 FR 30830), prohibiting the use of vinyl chloride as a propellant in cosmetic aerosols and requiring an approved new drug application for the marketing of aerosol drugs containing vinyl chloride as a propellant.

In separate actions, the Environmental Protection Agency, banned the use of vinyl chloride as a propellant in certain pesticide aerosols by notice published in the FEDERAL REGISTER of April 26, 1974 (39 FR 14753), and the Consumer Product Safety Commission banned the use of other self-pressurized household products containing vinyl chloride, by a notice published in the FEDERAL REGISTER of August 21, 1974 (39 FR 30112).

Dr. Cesare Maltoni has issued a preliminary report concerning the progress of his studies investigating the effects of vinyl chloride when ingested (Cesare Maltoni, Adriano Ciliberti, Luciano Gianni, Pasquale Chieco, "Insorgenza Di Angiosarcomi in Ratti, in Sequito A Somministrazione Per Via Orale Di Cloruro Di Vinile," *Gli Ospedali della Vita*, Anno II, Numero 1, Gennaio-Febbraio 1975). Dr. Maltoni's study involves the administration to rats by intubation of vinyl chloride in an olive oil solution at dosage levels of 50 milligrams per kilogram of body weight, 16.5 milligrams per kilogram of body weight and 3.3 milligrams per kilogram of body weight. The study was initiated with 40 male and 40 female rats at each dosage level, plus a control group of the same number. After 52 weeks, the examination of those rats that had died revealed one rat in the highest dose group to have angiosarcoma of the thymus, and a rat in the 16.5 milligrams dose level was found to have angiosarcoma of the liver. No tumors were reported in the 3.3 milligrams dosage group or in the controls. The experiment is continuing with an anticipated completion date in early 1976. In addition, Dr. Maltoni has initiated an experiment using lower dosage levels.

After evaluating all the data, the Commissioner concludes that it is likely that when the Maltoni study has been completed, it will show that vinyl chloride is carcinogenic when ingested. He notes that these results are consistent with the finding that inhalation of vinyl chloride has been shown to produce cancer. The Commissioner acknowledges that the finding of angiosarcoma in one rat in each of the two highest dosage levels may be regarded by some persons as inconclusive evidence that vinyl chloride is carcinogenic when ingested. However, Dr. Maltoni reports that, to his knowledge, no spontaneous angiosarcomas of rats have been reported in the literature. Additionally, Dr. Maltoni reports that angiosarcoma of the thymus and of the liver have never occurred spontaneously in their colony of Sprague-Dawley rats. The Commissioner concludes that the preliminary data from the incomplete ingestion studies, when combined with the

other data already available concerning the hazards of vinyl chloride, are sufficient to warrant the actions proposed in this proposal.

PROPOSED ACTION

Under section 201(s) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(s)), a substance is excluded from the definition of "food additive" if its use was sanctioned by FDA prior to September 6, 1958. A number of uses of vinyl chloride polymers were so approved and consequently are "prior sanctioned."

Subsequent to the enactment of the Food Additives Amendment of 1958, FDA issued letters stating that polyvinyl chloride resin was generally recognized as safe in specific compositions, including rigid and semirigid articles intended to contact foods. These letters were based on the premise that the uses and data cited in the Lehman articles for film and coatings could be interpreted to extend to other food-contact articles containing polyvinyl chloride.

In addition, since 1958, a variety of uses of vinyl chloride polymers in food-contact articles have been approved by the issuance of food additive regulations in 21 CFR Part 121, Subparts D and F: § 121.1179 *Coatings on fresh citrus fruit;* § 121.2507 *Cellophane;* § 121.2514 *Resinous and polymeric coatings;* § 121.2520 *Adhesives;* § 121.2521 *Vinyl chloride-propylene copolymers;* § 121.2524 *Polyethylene phthalate polymers;* § 121.2526 *Components of paper and paperboard in contact with aqueous and fatty foods;* § 121.2543 *Packaging materials for use during the irradiation of prepackaged foods;* § 121.2545 *Textryls;* § 121.2550 *Closures with sealing gaskets for food containers;* § 121.2569 *Resinous and polymeric coatings for polyolefin films;* § 121.2571 *Components of paper and paperboard in contact with dry food;* § 121.2591 *Semirigid and rigid acrylic and modified acrylic plastics;* § 121.2608 *Vinyl chloride-lauryl vinyl ether copolymers;* § 121.2609 *Vinyl chloride-ethylene copolymers;* § 121.2623 *Vinyl chloride-hexene-1 copolymers;* § 121.2631 *Microporous polymeric filters.*

The safety of a substance used in food-contact articles may be reevaluated at any time. Use of a prior-sanctioned substance may be prohibited or limitations may be established for its safe use under section 402(a) of the act (21 U.S.C. 342(a)) when the Commissioner determines that such use may be injurious to health. For a substance used pursuant to a food additive regulation, under section 409 of the act (21 U.S.C. 348) approval must be revoked when a fair evaluation of the data before the Commissioner fails to establish that the substance is safe under its conditions of use. In the case of a substance that is neither prior-sanctioned nor the subject of a food additive regulation, use may continue only as long as the substance is generally recognized as safe.

The Commissioner has reviewed the uses of vinyl chloride polymers in light of (1) the available data concerning the safety of vinyl chloride and (2) the likelihood of the migration of vinyl chloride to food. Although testing for the carcinogenicity of vinyl chloride upon ingestion is not complete, the Commissioner concludes, as discussed above, that sufficient data have been accumulated to establish the likelihood that it will be shown to be carcinogenic and therefore to require appropriate action to restrict the use of vinyl chloride polymers. The Commissioner concludes that the use of vinyl chloride polymers should be prohibited where there is a reasonable expectation of any migration of vinyl chloride into food.

This conclusion is consistent with the requirements of the act for all uses of vinyl chloride polymers, whether prior-sanctioned, approved food additives, or based on the assumption that they are generally recognized as safe.

The Commissioner interprets section 402(a) of the act, which prohibits use of food-contact articles that may render food injurious to health, as requiring a showing of both possible migration and possible harm. The Commissioner concludes that the criterion of migration in section 201(s) of the act is appropriately used in applying section 402(a) of the act. Consequently, a poisonous or deleterious component of a prior-sanctioned food-contact article comes within the terms of section 402(a) of the act if it may reasonably be expected to become a component of food. Since the carcinogenic potential of vinyl chloride upon ingestion is already sufficiently well documented to warrant a determination that it may, if present, render food injurious to health, the only prior-sanctioned uses of vinyl chloride polymers that may continue to be authorized are those where there is no reasonable expectation of migration.

Because of the likelihood that vinyl chloride is a carcinogen when ingested, for uses approved by food additive regulations a fair evaluation of the data before the Commissioner fails to establish their safety wherever there is reasonable expectation that vinyl chloride will migrate from the polymers into food. Therefore, the only uses that may continue to be approved are those where there is no reasonable expectation of such migration.

For uses of vinyl chloride polymers that have been generally recognized as safe, when there is a reasonable expectation that vinyl chloride will migrate into food, the evidence of potential carcinogenicity upon ingestion requires the conclusion that general recognition of their safety does not exist. Thus, as in the uses that are prior-sanctioned or approved by food additive regulation, the only permissible uses are those where there is no reasonable expectation of such migration.

In considering whether particular food-contact articles raise a reasonable expectation of migration of vinyl chloride into food, the Commissioner has reached several tentative conclusions upon which this proposal is based.

The Commissioner concludes that there is no reasonable expectation of migration of vinyl chloride from thin plasticized film because of the method of manufacture and the thickness of most film used for wrapping food (approximately 1 mil). As discussed above, plasticizing the film results in an article essentially free of vinyl chloride, and there is no reasonable expectation that any remaining vinyl chloride actually migrates into food.

The Commissioner also concludes that there is no reasonable expectation of migration of vinyl chloride from jar and bottle cap liners and gaskets. Polyvinyl chloride cap liners and gaskets, which have almost completely replaced the rubber and cork materials formerly used, are of two major types. Some are applied in liquid form as a ring around the part of the cap in contact with the container, and others consist of a circular disc cut from film and inserted so as to cover completely the inside surface of the cap. A majority of those types are plastisols which are applied as liquid and are made from paste resins containing finely ground (1 micron or less) polyvinyl chloride and plasticizer. These plastisols contain about 100 parts polyvinyl chloride and 60 parts plasticizer. Other gaskets are made by combining these plastisols with other polyvinyl chloride resins. In addition to removal of residual vinyl chloride in the plasticizing process, additional vinyl chloride is thought to be removed when the plastisol is heated to approximately 350° F for 5 to 8 minutes during application. The small potential for residual vinyl chloride that exists after such processing, together with the fact that a gasket has only limited contact with food, leads to the conclusion that there is no reasonable expectation of migration of vinyl chloride into food. Similarly, no migration may be expected from cap inserts cut from thin plasticized film, for the reasons previously discussed. Moreover, in the case of all cap liners there will be only slight contact with food. Considering these factors, the Commissioner concludes that there is no reasonable expectation of migration of vinyl chloride from cap liners.

Can coatings containing polyvinyl chloride are primarily used on the inside of beer and soft drink cans and, to a much lesser extent, inside food cans. Most of the polyvinyl chloride used for can coatings is produced by the solution polymerization process which produces polyvinyl chloride with the lowest residual vinyl chloride content. After conversion of the resin into can coatings, no residual vinyl chloride has been reported, presumably because the thinness of the applied film and the baking it has received, at above 300° F, have caused the removal of the residual vinyl chloride. In such a case, it can be concluded that there is no reasonable expectation of migration of vinyl chloride into food.

Polyvinyl chloride flexible tubing, ranging in internal diameter from 2 to 3 thousandths of an inch to 3 to 4 inches, is highly plasticized. As previously discussed, it is thought that plasticization reduces residual vinyl chloride content to the point where there is no reasonable expectation that any will migrate into

food. In addition, flexible tubing is generally used in applications where food contacts the tubing only briefly and the temperature of the food is often low. These circumstances further reduce the possibility of any migration of vinyl chloride.

Textryls incorporating vinyl chloride polymers in accordance with § 121.2545 (21 CFR 121.2545) are nonwoven sheets prepared from natural or synthetic fibers and bonded with fibryls. The fibryls consist of vinyl chloride-vinyl acetate copolymer resin that is prepared by solution polymerization, a process that has been shown to result in less than 1 ppm vinyl chloride in the resin. The fibryls are formed by precipitating a solvent solution of the copolymer in water and then washing the precipitate until all solvent is removed. The fibryl is commingled with fibers prepared from polyethylene terephthalate resins to facilitate sheet formation and subsequently heat cured to fuse the fibryl and effect bonding. These procedures for manufacturing textryls should result in a reduction of level of the residual vinyl chloride to the point that the Commissioner concludes that their use would not reasonably be expected to result in vinyl chloride becoming a component of food.

Microporous polymeric filters used in accordance with § 121.2631 (21 CFR 121.2631) are based on polyvinyl chloride resins produced by solution polymerization, which, as noted above, results in low levels of residual vinyl chloride. The filters are prepared by adding silicon dioxide to a solvent solution of the resins, resulting in "opening" of the resins and further loss of residual vinyl chloride. The filter is formed by extrusion and calendering followed by a hot water wash to remove solvent. Each of these steps, together with the preuse treatment required by § 121.2631, would result in a reduction of any remaining vinyl chloride to the point that the Commissioner concludes that the use of microporous polymeric filters would not reasonably be expected to result in vinyl chloride becoming a component of food.

Adhesives containing vinyl chloride polymers in accordance with § 121.2520 (21 CFR 121.2520) have no contact with food except incidentally at the edges of food-packaging materials. Because of this slight contact, the Commissioner concludes that the continued use of adhesives containing vinyl chloride polymers would not reasonably be expected to result in vinyl chloride becoming a component of food.

However, the data indicate that rigid and semirigid polyvinyl chloride articles intended to contact food (including bottles, blister packs, boxes and pipe, except as noted below for water pipe) may transmit vinyl chloride to the food they contact. Therefore, the Commissioner finds that these uses can no longer be permitted for contact with food.

The use of vinyl chloride polymers as coatings for fresh citrus fruits, which is permitted by § 121.1179 (21 CFR 121.1179), presents the possibility of ingestion of vinyl chloride because the polymers are applied directly to the fruit. Therefore, the Commissioner concludes that the available data do not demonstrate that this use is safe.

Because copolymers of vinyl chloride might also be expected to contain residual vinyl chloride capable of migrating to food, this proposal applies to vinyl chloride copolymers, as well as to the homopolymer, polyvinyl chloride.

In accordance with these conclusions, the proposed regulations take the following approach:

1. Prior-sanctioned uses of vinyl chloride homopolymers and copolymers as coatings, gaskets, cap liners, flexible tubing, and plasticized films would be identified in regulations permitting their continued use. This proposal identifies all such prior sanctions known to the Commissioner. Persons aware of other prior-sanctioned uses should submit proof of the sanctions during the period for comment on this proposal.

2. Prior-sanctioned uses of vinyl chloride homopolymers and copolymers in semirigid and rigid applications would no longer be permitted except in water pipe as discussed below. This proposal would amend § 121.106 (21 CFR 121.106) of the regulations to so provide. Once these proposed regulations become final, vinyl chloride polymers could be used in semirigid and rigid applications only after approval of a food additive petition, submitted pursuant to § 121.51 (21 CFR 121.51) of the regulations. In addition to the other required information for a food additive petition, data would be necessary to demonstrate that there is no reasonable expectation that vinyl chloride will become a component of food.

3. Uses of vinyl chloride homopolymers and copolymers as coatings, gaskets, cap liners, flexible tubing, and plasticized films that are not prior-sanctioned and that are not subject to food additive regulations are not expressly affected by this proposal. Such uses could be continued if they are otherwise generally recognized as safe. A petition to affirm such uses as generally recognized as safe may be submitted pursuant to § 121.40 (21 CFR 121.40).

4. Food additive regulations permitting the use of vinyl chloride polymers would be amended to permit the continued use of these polymers as coatings (other than those applied directly to food), gaskets, cap liners, flexible tubing, and plasticized films and to prohibit other uses except in water pipe as discussed below.

5. Food additive regulations specifically providing for the use of adjuvants in the production of food-contact articles containing vinyl chloride polymers would be amended to be consistent with the proposed restrictions on the use of vinyl chloride polymers.

At the time final regulations are issued, it may be necessary to define the classes of permitted polyvinyl chloride food-contact articles with greater particularity. Thus, based on available data and on information concerning theoretical prospects of migration of vinyl chloride, specifications for permitted articles might be established in terms of thickness, degree of plasticization, method of polymerization used, vinyl chloride content of the "compound" used, heat applied during processing, and similar criteria. Comments should include all available data and information that help to identify particular applications and specifications that assure no reasonable expectation of migration. The Commissioner advises that at the time the final regulations are issued, based on such data and information, it may be appropriate to restrict or eliminate uses that are here proposed to be continued.

Determining whether any food packaging component, such as vinyl chloride, is reasonably expected to become a component of food necessarily involves fine judgment, for which precise standards cannot be articulated. If there is no detectable vinyl chloride in a food-contact article, and there are no detectable extractives of vinyl chloride from the article into food-simulating solvents, and there is a sound theoretical basis for predicting no migration below the detectable level, e.g., the article is plasticized or contact with food is slight, the Commissioner concludes that there is no reasonable expectation of migration. Where vinyl chloride is detected at a very low level in the food-contact article, it may nevertheless be possible to conclude that there is no reasonable expectation of migration into food based on theoretical considerations peculiar to the particular product and use. The Commissioner advises that the detection of vinyl chloride extractives in food-simulating solvents under testing conditions appropriate for food-contact articles indicates that the residual vinyl chloride in the article may reasonably be expected to migrate into food. The Commissioner concludes that testing conducted with food-simulating solvents is an appropriate method for ascertaining the likelihood of migration from a food-contact article to food. Because of analytical difficulties, food often cannot be reliably tested for evidence of migration. For this reason, food-simulating solvents have long been used both by industry and FDA to test food-contact articles.

The Commissioner is aware that the technology for reducing the amount of vinyl chloride in vinyl chloride polymers, or eliminating it altogether, is improving rapidly and that major advances not known to FDA may have been made within recent months. Thus, additional classes of food-contact articles may exist for which it can be concluded that there is no reasonable expectation that vinyl chloride would migrate into food. Comments on this proposal suggesting that such articles do exist should include data, analytical methodology used, and a theoretical analysis of the expectation of migration.

In the case of polyvinyl chloride potable water pipe, the Commissioner concludes that the data available at this time indicate that vinyl chloride may not reasonably be expected to be present in water drawn from a polyvinyl chloride water pipe system. Although data from the testing of polyvinyl chloride water pipe containing static water have shown

migration of vinyl chloride, no vinyl chloride has been detected in samples of water drawn from operating polyvinyl chloride potable water pipe. It is likely that static testing does not reasonably assess the likelihood of the presence of vinyl chloride in water. It is proposed that an interim period of time be provided for the continued use of polyvinyl chloride water pipe, pending development of data from tests appropriate for the determination of the potential for the presence of vinyl chloride in water drawn from a polyvinyl chloride potable water pipe system.

Under the proposal, polyvinyl chloride water pipe would be subject to the provisions of § 121.4000 (21 CFR 121.4000), concerning food additives approved on an interim basis. Within 60 days following the effective date of a final regulation, an interested person would be required to satisfy FDA that studies have been undertaken to determine whether vinyl chloride may reasonably be expected to be present in water drawn from a system containing polyvinyl chloride pipe. If no such commitment were made, or adequate and appropriate studies were not undertaken, the regulation permitting continued use of polyvinyl chloride water pipe would be revoked.

This announcement provides 60 days for public comment, after which time the comments will be reviewed and final regulations issued. The Commissioner proposes that the regulations become effective 30 days after their promulgation as final regulations. No recall of affected articles is now anticipated to be necessary. The Commissioner concludes that the hazard to the public health is not so immediate as to warrant issuance of these regulations without opportunity for public comment or to require recall and destruction of foods already packaged. The continued use of installed equipment having food-contact surfaces composed of vinyl chloride polymers would be permitted; any residual vinyl chloride is likely to have dissipated to the atmosphere during the period of service.

These proposed regulations deal only with vinyl chloride contamination of food. The Commissioner plans to issue additional announcements in the near future concerning cosmetics, drugs, and medical devices. Also, the proposed regulations would not immediately affect the status of vinyl chloride polymers used in food-contact articles in the household, food service establishments, and food dispensing equipment. Such articles are the subject of a notice published in the FEDERAL REGISTER of April 12, 1974 (39 FR 13285), and they will be evaluated in accordance with the terms of that notice.

The Commissioner has carefully considered the environmental effects of the proposed regulations and, because the proposed action would not significantly affect the quality of the human environment, has concluded that an environmental impact statement is not required. The Commissioner has also carefully considered the inflation impact of the proposed regulations, and has found that the proposed action would not cause a major inflation impact as defined in OMB Circular A-107. Therefore, no inflation impact statement is required. At the time additional announcements concerning cosmetics, drugs, and medical devices are issued, these conclusions will be reevaluated. Data and information concerning environmental and inflation impact may be submitted as a comment on this proposal. Copies of the FDA environmental and inflation impact assessments are on file with the Hearing Clerk, Food and Drug Administration.

A petition to ban the use of polyvinyl chloride in food packaging was received by the Commissioner on July 7, 1975 from Public Citizen's Health Research Group, 2000 P St., NW., Washington, DC 20036, as this proposal on the use of vinyl chloride polymers was being prepared. Each of the petitioner's comments has been considered in the drafting of this document. A letter will be sent to the petitioner responding to the petition.

Copies of the reports and data referred to above are on file at the office of the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852.

Published elsewhere in this issue of the FEDERAL REGISTER is a notice withdrawing a proposal to add § 121.2009 (21 CFR 121.2009) and terminating the rule making proceeding on the use of polyvinyl chloride resin in articles for use in contact with alcoholic foods, which was begun on May 17, 1973 (38 FR 12931).

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 402, 409, 701, 52 Stat. 1042, 1046-1047 as amended, 1049, 1055 (21 U.S.C. 321(s), 342, 348, 371)) and under authority delegated to him (21 CFR 2.120), the Commissioner proposes to amend Part 121, as follows:

1. In § 121.106 by adding new paragraph (e)(4) as follows:

§ 121.106 Substances prohibited from use in human food.

* * * * *

(e) * * *

(4) *Vinyl chloride.* (i) Vinyl chloride has the molecular formula C_2H_3Cl. It is a synthetic chemical not found in natural products and has been used in the production of polymeric substances that may contact food.

(ii) Food containing any added or detectable level of vinyl chloride is deemed to be adulterated in violation of the act.

(iii) The use in food-contact articles of vinyl chloride homopolymers and copolymers is prohibited, except that such use is not prohibited:

(*a*) In coatings, gaskets, cap liners, flexible tubing, and plasticized films if such use is otherwise in accordance with the requirements of the act and this chapter; or

(*b*) If specifically permitted in this part.

§ 121.1179 [Amended]

1a. In § 121.1179 *Coatings on fresh citrus fruit* by deleting and reserving paragraph (b)(3), and deleting the reference to paragraph (b)(3) from paragraph (b)(4).

2. By adding the following new section to Subpart E, to read as follows:

§ 121.2009 Vinyl chloride, polymer resins.

Polyvinyl chloride resins consist of basic resins produced by the polymerization of vinyl chloride. Polyvinyl chloride basic resins have a maximum volatility of not over 3 percent when heated for 1 hour at 105° C, as determined by ASTM Method D 3030-72,[1] and an inherent viscosity of not less than 0.35 as determined by ASTM Methods D 1243-66.[1] Vinyl chloride copolymer resins are the polymers produced by the copolymerization of vinyl chloride with other monomeric substances. Vinyl chloride homopolymers and copolymers may be safely used as follows:

(a) *Coatings.* (1) Polyvinyl chloride for use as a can enamel.

(2) Vinyl chloride-vinyl acetate copolymer for use as a can enamel.

(3) Vinyl chloride-butadiene-acrylonitrile copolymer for use as a component of conveyer belts intended for use with fresh fruits, vegetables, and fish, and as a component of coatings of paper and paperboard in contact with meat and lard.

(4) Vinyl chloride-vinylidene chloride copolymer for use as a liner, i.e., coating, for steel pipe.

(b) *Plasticized films.* (1) Polyvinyl chloride for use in plasticized film in contact with food.

(2) Vinyl chloride-butadiene-acrylonitrile copolymer for use in plasticized film in contact with oleomargarine.

(3) Vinyl chloride-vinylidene chloride copolymer for use in plasticized film in contact with food.

(4) Vinyl chloride-vinyl acetate copolymer for use in plasticized film in contact with food.

3. In § 121.2507, by amending paragraph (c) by revising the entry in the list of substances for "polyvinyl chloride" to read as follows:

§ 121.2507 Cellophane.

* * * * *

(c) * * *

	Limitations * * *
Polyvinyl chloride...	As the basic polymer for use only in coatings.

* * * * *

4. In § 121.2511, by amending paragraph (b) by revising the listing entries for "dicyclohexyl phthalate" and "diphenyl phthalate" to read as follows:

§ 121.2511 Plasticizers in polymeric substances.

* * * * *

(b) * * *

[1] Copies may be obtained from: American Society for Testing and Materials, 1916 Race St., Philadelphia, PA 19103.

	Limitations
* * * * *	
Dicyclohexyl phthalate.	For use only: 1. As provided in §§ 121.2507, 121.2520, 121.2526, and 121.2571. 2. Alone or in combination with other phthalates, in plastic film prepared from polyvinyl acetate, polyvinyl chloride, and/or vinyl chloride copolymers complying with § 121.2521 or in plastic sheet prepared from polyvinyl acetate. Such plastic film or sheet shall be used in contact with food at temperatures not to exceed room temperature and shall contain no more than 10 percent by weight of total phthalates, calculated as phthalic acid.
* * * * *	
Diphenyl phthalate. For use only:	1. As provided in § 121.2520. 2. Alone or in combination with other phthalates, in plastic film prepared from polyvinyl acetate, polyvinyl chloride, and/or vinyl chloride copolymers complying with § 121.2521 or in plastic sheet prepared from polyvinyl acetate. Such plastic film or sheet shall be used in contact with food at temperatures not to exceed room temperature and shall contain no more than 10 percent by weight of total phthalates, calculated as phthalic acid.
* * * * *	

5. In § 121.2521, by redesignating the present paragraph (f) as paragraph (g) and adding a new paragraph (f) as follows:

§ 121.2521 Vinyl chloride-propylene copolymers.

* * * * *

(f) Vinyl chloride-propylene copolymers may be used only in coatings, gaskets, cap liners, flexible tubing, and plasticized films, and in water pipe as permitted by § 121.4009.

* * * * * *

6. In § 121.2541, by adding a new paragraph (e) to read as follows:

§ 121.2541 Emulsifiers and/or surface-active agents.

* * * * *

(e) The use of the emulsifiers and/or surface-active agents in any polymeric substance or article subject to any regulation in this Subpart F must comply with any specifications and limitations prescribed by such regulation for the finished form of the substance or article.

7. In § 121.2566, (1) by amending paragraph (b) by deleting the listings for "hydrogenated 4,4 - isopropylidenediphenol-phosphite ester resins produced by the condensation of 1 mole of triphenyl phosphite and 1.5 moles of hydrogenated 4,4' - isopropylidenediphenol" and "poly[(1,3-dibutyldistannthianediyl-idene)-1,3-dithio] having the formula $[C_4H_{18}Sn_2S_3]_n$ (where n averages 1.5–2)", and by revising the listing for "4,4'-isopropylidenediphenol alkyl (C_{12}–C_{15}) phosphites" and, (2) by adding a new paragraph (c) to read as follows:

§ 121.2566 Antioxidants and/or stabilizers for polymers.

* * * * *

(b) List of substances:

	Limitations
* * * * *	
4,4'-Isopropylidenediphenol alkyl (C_{12}–C_{15}) phosphites; the phosporus content is in the range of 5.2–5.6 weight percent.	For use only at levels not exceeding 1.0 percent by weight in rigid polyvinyl chloride as provided in § 121.4009 for water pipe and/or rigid vinyl chloride copolymers complying with §§ 121.2521, 121.2608, or 121.2609.
* * * * *	

(c) The use of the antioxidants and/or stabilizers in any polymeric substance or article subject to any regulation in this Subpart F must comply with any specifications and limitations prescribed by such regulation for the finished form of the substance or article.

8. In § 121.2591 by amending paragraph (a) (2) by revising the listing entry for "vinyl chloride" and amending paragraph (a) (4) by revising the listing entries for "polyvinyl chloride," "vinyl chloride copolymers complying with § 121.2521," and "vinyl chloride-vinyl acetate copolymers" to read as follows:

§ 121.2591 Semirigid and rigid acrylic and modified acrylic plastics.

* * * * *

(a) * * *

(2) * * *

Vinyl chloride (only in water pipe as permitted by § 121.4009).

* * * * *

(4) * * * Polyvinyl chloride (only in water pipe as permitted by § 121.4009). Vinyl chloride copolymers complying with § 121.2521 (only in water pipe as permitted by § 121.4009).

Vinyl chloride-vinyl acetate copolymers (only in water pipe as permitted by § 121.4009).

* * * * *

9. In § 121.2597 by revising the introductory paragraph to read as follows:

§ 121.2597 Polymer modifiers in semirigid and rigid vinyl chloride plastics.

The polymers identified in paragraph (a) of this section may be safely admixed, alone or in mixture with other permitted polymers, as modifiers in rigid vinyl chloride plastic food-contact articles prepared from vinyl chloride homopolymers for use as provided in § 121.4009 for water pipe and/or from vinyl chloride copolymers complying with § 121.2521, § 121.2608, and/or § 121.2609, in accordance with the following prescribed conditions:

* * * * * *

10. In § 121.2602 by adding a new paragraph (c) to read as follows:

§ 121.2602 Octyltin stabilizers in vinyl chloride plastics.

* * * * *

(c) The finished food-contact article is in the form of coatings, gaskets, cap liners, flexible tubing, plasticized films, or water pipe as permitted by § 121.4009.

11. In § 121.2605, by revising the introductory text of paragraph (a) to read as follows:

§ 121.2605 Polyhydric alcohol diesters of oxidatively refined (Gershtoffen process) montan wax acids.

* * * * *

(a) The polyhydric alcohol diesters identified in this paragraph may be used as lubricants in the fabrication of vinyl chloride plastic food-contact articles (coatings, gaskets, cap liners, flexible tubing, plasticized films, and water pipe as permitted by § 121.4009) prepared from polyvinyl chloride and/or from vinyl chloride copolymers complying with § 121.2521. Such diesters meet the following specifications and are produced by partial esterification of oxidatively refined (Gersthoffen process) montan wax acids by either ethylene glycol or 1,3-butanediol with or without neutralization of unreacted carboxylic groups with calcium hydroxide:

* * * * *

12. In § 121.2608, by revising paragraph (e) to read as follows:

§ 121.2608 Vinyl chloride-lauryl vinyl ether copolymers.

* * * * *

(e) *Other specifications and limitations.* (1) Vinyl chloride-lauryl vinyl ether copolymers may be used only in coatings, gaskets, cap liners, flexible tubing, and plasticized films, and in water pipe as permitted by § 121.4009.

(2) The vinyl chloride-lauryl vinyl ether copolymers identified in and complying with this section, when used as components of the food-contact surface of any article that is subject to a regulation in Subpart F of this Part 121, shall comply with any specifications and limitations prescribed by such regulation for the article in the finished form in which it is to contact food.

13. In § 121.2609 by redesignating paragraph (f) as paragraph (g) and adding a new paragraph (f) as follows:

§ 121.2609 Vinyl chloride-ethylene copolymers.

* * * * *

(f) Vinyl chloride-ethylene copolymers may be used only in coatings, gaskets, cap liners, flexible tubing, and plasticized films, and in water pipe as permitted by § 121.4009.

* * * * *

14. In § 121.2623 by revising paragraph (c) to read as follows:

§ 121.2623 Vinyl chloride-hexene-1 copolymers.

* * * * *

(c) *Other specifications and limitations.* (i) The vinyl chloride-hexene-1 copolymers identified in this section may be used in coatings, gaskets, cap liners, flexible tubing, plasticized films, and in water pipe as permitted by § 121.4009.

(ii) The vinyl chloride-hexene-1 copolymers identified in and complying with this section, when used as components of the food-contact surface of any article that is subject to a regulation in Subpart F of this Part 121, shall comply with any specifications and limitations prescribed by such regulations for the article in the finished form in which it is to contact food.

15. In Subpart H, by adding a new § 121.4009, to read as follows:

§ 121.4009 Vinyl chloride polymers.

(a) Vinyl chloride polymers may be safely used as a component of water pipe on an interim basis, pending the outcome of studies to determine whether vinyl chloride may reasonably be expected to be present, at the time of consumption, in potable water drawn from a system utilizing such pipe. The continued use of vinyl chloride polymers in water pipe is subject to the conditions in § 121.4000(c).

(b) Within 60 days of the effective date of this regulation, an interested person shall satisfy the commissioner in writing that studies have been undertaken that are adequate and appropriate to appraise the potential for the presence of vinyl chloride in potable water drawn from a system utilizing water pipe containing vinyl chloride polymers. These studies shall include: (1) Determination of the lowest attainable level of residual vinyl chloride in potable water pipe, (2) an investigation of the relationship between residual vinyl chloride in water pipe and the amount of vinyl chloride that may be present in water in such pipe under static conditions, and (3) an investigation of the level of vinyl chloride that may be present in water drawn from such a system.

Interested persons may, on or before November 3, 1975, submit to the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852, written comments regarding this proposal. Comments should be filed in quintuplicate (except that individuals may submit single copies), and should be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office Monday through Friday, from 9 a.m. to 4 p.m., except on Federal legal holidays.

Dated: August 27, 1975.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

[FR Doc.75-23241 Filed 8-29-75;8:45 am]

Social Security Administration

[20 CFR Part 405]

[Reg. No. 5]

FEDERAL HEALTH INSURANCE FOR AGED AND DISABLED

Proposed Conditions of Participation by Clinics, Rehabilitation Agencies, and Public Health Agencies

Correction

In FR Doc.75-16036 appearing at page 25938 in the issue of Thursday, June 19, 1975, a line was dropped from paragraph (p) of § 405.1730(b) in the first column of page 25943. Immediately preceding the word "rehabilitation" in the third line of (p) insert "furnished by a provider of services, a clinic,".

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[49 CFR Part 571]

[Docket 75-22; Notice 1]

EXTERIOR MOUNTED BICYCLE CARRIERS

Advance Notice of Proposed Rulemaking

This is an advance notice of proposed rulemaking, issued to solicit comments and information concerning hazards resulting from bicycle carriers mounted on the exterior of motor vehicles.

The Public Interest Research Group has petitioned the National Highway Traffic Safety Administration (NHTSA) to issue an advance notice of proposed rulemaking concerning exterior mounted bicycle carriers. The NHTSA believes that the request of the petitioner has merit, and that the protection derived from Federal Motor Vehicle Safety Standard No. 215, *Exterior Protection* (49 CFR 571.215), and future standards relating to pedestrian safety could be degraded by hazardously designed motor vehicle bicycle carriers.

Initial applicability of this proposed rulemaking is intended to encompass bicycle carriers for use with passenger cars, multipurpose passenger vehicles, trucks and buses with GVWR of 10,000 pounds or less.

The NHTSA is contemplating a rule which will:

1. Require all mounting hardware to be installed in such a manner as to minimize any hazard to pedestrians.

2. Reduce or eliminate sharp edges on bicycle carriers.

3. Prohibit bicycle, support arms from projecting beyond a specified distance from the exterior surface of the vehicle when the bicycle is not being transported.

4. Label all carriers to warn against installation on the front of vehicles.

Information concerning the following areas is specifically requested:

1. The extent of fatalities, injuries, and property damage resulting from exterior mounted motor vehicle bicycle carriers while the vehicle is either moving or parked.

2. Safety and hazard factors found in current designs for exterior mounted motor vehicle bicycle carriers.

3. Economic and other relevant data concerning bicycle carrier volume of sales, average unit price, number of manufacturers, and other similar information concerning market characteristics.

4. Motor vehicle insurance rates and coverage for vehicles equipped with exterior mounted bicycle carriers.

Interested persons are invited to submit information, views, and arguments on the areas described and on the general subject of exterior mounted motor vehicle bicycle carriers. Comments should refer to the docket number and be submitted to: Docket Section, National Highway Traffic Safety Administration, Room 5108, 400 Seventh Street, SW., Washington, D.C. 20590. It is requested but not required that 10 copies be submitted.

All comments received before the close of business on the comment closing date indicated below will be considered, and will be available for examination in the docket at the above address both before and after that date. The NHTSA will continue to file relevant material as it becomes available in the docket after the closing date, and it is recommended that interested persons continue to examine the docket for new material.

Comment closing date. December 2, 1975.

Proposed effective date. 1 year after publication of rule.

(Secs. 103, 119, Pub. L. 89-563, 80 Stat. 718 (15 U.S.C. 1392, 1407); sec. 102, Pub. L. 92-513, 86 Stat. 947 (15 U.S.C. 1912); delegations of authority at 49 CFR 1.51 and 501.8.)

Issued on August 27, 1975.

ROBERT L. CARTER,
Associate Administrator,
Motor Vehicle Programs.

[FR Doc.75-23280 Filed 9-2-75;8:45 am]

DEPARTMENT OF LABOR

Wage and Hour Division

[29 CFR Parts 603, 608, 609, 687]

[Administrative Order No. 639]

INDUSTRY COMMITTEES FOR INDUSTRIES IN PUERTO RICO

Changes in Order of Hearings of Industry Committees in Puerto Rico

Administrative Order No. 638, 40 FR 18519, set forth the order of hearings by Industry Committees Nos. 127-A through 127-D and Nos. 128-A through 128-F. At the request of certain interested parties and the agreement of other major parties and pursuant to the authority vested in me under section 5 of the

Fair Labor Standards Act of 1938 (29 U.S.C. 205), Reorganization Plan No. 6 of 1950 (3 CFR 1949–53 Comp., p. 1004) and 29 CFR part 511, the order of hearings of Industry Committees Nos. 127 and 128 is hereby changed as follows:

1. On October 14, 1975, the hearing of Industry Committee No. 127–D for the Gloves and Mittens Industry will follow the hearing of Industry Committee No. 127–A and the hearing of Industry Committee No. 127–B for the Hosiery Industry is changed to follow that of Committee No. 127–C. Accordingly, the sequence of hearings will be 127–A, D, C and B.

2. On October 28, 1975, the hearing of Industry Committee No. 128–B for the Handkerchief, Scarf and Art Linen Industry will commence first and be immediately followed by the hearing of Industry Committee No. 128–A for the Women's and Children's Industry. Accordingly, the sequence of hearings will be 128–B, A, C, D, E and F.

The hearings of the other Industry Committees remain unchanged as do the dates for filing prehearing statements, namely, October 4, 1975, for matters to be considered by Industry Committees No. 127, and October 18, 1975, for those to be considered by Industry Committee No. 128.

Signed at Washington, D.C., this 28th day of August, 1975.

JOHN T. DUNLOP,
Secretary of Labor.

[FR Doc.75-23333 Filed 9-2-75;8:45 am]

ENVIRONMENTAL PROTECTION AGENCY

[40 CFR Part 142]

[FRL 424-4]

DRINKING WATER STANDARDS IMPLEMENTATION AND STATE PROGRAM GRANT REGULATIONS

Extension of Time for Comments

On August 7, 1975, the Administrator of the Environmental Protection Agency (EPA) proposed regulations pursuant to the Public Health Service Act as amended by the Safe Drinking Water Act, for implementation of national interim primary drinking water standards and for grants to support State public water system supervision programs. Public hearings on the proposed regulations were scheduled for San Francisco, California, on September 3, and for Washington, D.C. on September 5. [40 FR 33224]

EPA has received a request from the Environmental Defense Fund, the Committee on Environmental Program and Projects of the League of Women Voters, and the Commission for the Advancement of Public Interest Organizations for a 21-day extension of time for written comments and for the scheduling of additional, later public hearings. The request indicates that the extension of time and additional hearings are needed to permit broader public participation in the rulemaking proceeding.

The proposed regulations have already been reviewed by EPA staff members with the National Drinking Water Advisory Council, numerous State representatives and members of public interest organizations. The public hearings were scheduled despite the fact that they are not required by the Safe Drinking Water Act or the Administrative Procedure Act, because EPA wishes to encourage public comments on these regulations.

There are, however, serious time restraints on the promulgation of these regulations. Section 1413(b) of the Public Health Service Act requires that the portion of the implementation regulations dealing with State primary enforcement authority be promulgated by September 11, 1975. As it is, that date will not be met. Moreover, in order to fulfill the Congressional intent that the States assume principal responsibility for enforcement of primary drinking water regulations, it is critical that the implementation and grant regulations be promulgated as soon as possible. Early promulgation is necessary to allow the States to develop programs qualifying for primary enforcement responsibility in time to exercise that responsibility by the effective date of the interim primary drinking water regulations.

Because of these time restraints, it is not possible to grant the request for later hearings, or to grant the full 21-day extension of time requested for written comments. However, EPA does continue to believe that it is important that these proposed regulations receive as much public scrutiny and comment as possible. Accordingly, there exists good reason for a two-week extension of time for the filing of written comments. EPA hereby extends the period for filing written comments on the proposed regulations to close of business on September 29, 1975.

Written comments regarding the proposed regulations shall be submitted in triplicate to the Office of Water Supply (WH–450), Environmental Protection Agency, Washington, D.C. 20460, Attention: Comment Clerk, Drinking Water Standards Implementation and Grant Regulations.

Secs. 1413, 1414, 1415, 1443, 1445, 1449 and 1450 of the Public Health Service Act, as amended by the Safe Drinking Water Act, Pub. L. 93-523, 42 U.S.C. 300f et seq., 88 Stat. 1660.

Dated: August 27, 1975.

JAMES L. AGEE,
Assistant Administrator for Water and Hazardous Materials.

[FR Doc.75-23348 Filed 9-2-75;8:45 am]

[40 CFR Part 162]

[FRL 394-6; OPP-30003]

PESTICIDE PROGRAMS

Regulations for State Registration of Pesticides To Meet Special Local Needs

Notice is hereby given that, pursuant to the authority of section 24(c) and section 25(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (hereinafter referred to as "FIFRA" or "the Act") the Administrator of the Environmental Protection Agency ("EPA") proposes to amend 40 CFR Part 162 by establishing a new Subpart B prescribing regulations applicable to State registration of pesticides to meet special local needs. The proposed regulations are set forth below. These proposed regulations are related to, and should be read in conjunction with, the proposed regulations applicable to State issuance of experimental use permits, which appear elsewhere in this issue of the FEDERAL REGISTER (40 FR 40545).

STATUTORY AUTHORITY

Authority for State registration of pesticides is provided by section 24(c) of FIFRA, as amended, which, in its entirety, reads as follows:

A State may provide registration for pesticides formulated for distribution and use within that State to meet special local needs if that State is certified by the Administrator as capable of exercising adequate controls to assure that such registration will be in accord with the purposes of this Act and if registration for such use has not previously been denied, disapproved, or canceled by the Administrator. Such registration shall be deemed registration under Section 3 for all purposes of this Act, but shall authorize distribution and use only within such State and shall not be effective for more than 90 days if disapproved by the Administrator within that period.

BACKGROUND

Prior to the enactment of the 1972 amendments to FIFRA, pesticides sold, distributed, and used entirely on an intrastate basis were not subject to Federal regulation. They were solely within the province of State regulatory activity. The Act, as amended, requires EPA registration of all pesticides, whether sold or distributed in interstate or intrastate commerce. EPA regulations applicable to registration under section 3 of the Act were published on July 3, 1975 (40 FR 28241). These final regulations are designated as 40 CFR Part 162, Subpart A.

In providing for EPA registration for all pesticides, the Congress recognized that there are many pesticide uses, particularly on minor pests and specialty crops, for which EPA registration has not been, and probably will not be requested. In many instances, this situation reflects the fact that pesticide manufacturers or formulators consider the cost of seeking and obtaining EPA registration of such uses to be disproportionate to potential profitability. Nevertheless, farmers and others rely on such minor uses as solutions to many locally important pest problems. In addition, it was recognized that there often are local conditions necessitating deviations from an EPA approved label for purposes of effective pest control or environmental protection.

The legislative history of the 1972 amendments plainly indicates that it was the intention of the Congress that section 24(c) be employed to help deal with minor or local use problems. Specifically, Senate Report No. 92-838, filed by the Committee on Agriculture and Forestry, dated June 7, 1972, said:

The purpose of this subsection is to give a State the opportunity to meet expeditiously

and with less cost and administrative burden on the registrant the problem of registering for local use a pesticide needed to treat a pest infestation which is a problem in such State but is not sufficiently widespread to warrant the expense and difficulties of Federal registration.

This view was reemphasized in Part II of Senate Report No. 92–838, dated October 3, 1972. A similar explanation of the purpose of section 24(c) appeared in the House of Representatives Report No. 92–511, dated September 25, 1971.

Special Local Need

FIFRA, as amended, no longer exempts intrastate products from its registration requirements. The previously quoted passage from Senate Report No. 92–838 clearly indicates that State registration is intended solely to provide a means of dealing with problems that arise, in part, because of gaps in EPA registrations. Accordingly, the proposed regulations define "special local need" in terms of the existence, safety and efficacy, and availability of EPA-registered pesticide products. Thus, where there is an existing or expected local or minor pest problem, a State agency certified under section 24(c) should be permitted to register one or more pesticide products under the following circumstances:

There is no EPA-registered pesticide product for the use in question, or

There is an EPA-registered pesticide product, but it is not available, e.g., cannot be obtained in sufficient quantity, or

There is an EPA-registered pesticide product which, nominally, is suitable but, if used in accordance with the label, would not be as safe or as efficacious under the local conditions.

It should be noted that "special local need" is defined so as to allow certified State agencies to register products containing plant regulators, defoliants, and desiccants as well, provided the registration satisfies one or more of the foregoing criteria.

Where a State agency issues a registration on the ground that no EPA-registered pesticide product would be safe or efficacious under the conditions of use within the State, the State agency should be prepared to show that the pesticide product(s) it has registered will, in fact, be more effective or less hazardous. Where there is any question, EPA will request supporting information under § 162.156(a) of the proposed regulations and will disapprove a State registration if the claims for it cannot be substantiated.

States are urged to examine the proposed definition of "special local need" in the context of the proposed regulations, as a whole. EPA believes that, in this context, it will be apparent that the definition is sufficiently broad to enable States to take care of many minor use problems (although it is recognized that the tolerance requirements of the Federal Food, Drug, and Cosmetic Act often will be a limiting factor).

It should be noted that the terms "EPA-registered" and "registered by EPA," throughout the proposed regulations, refer to registrations originally issued by EPA (as distinguished from State registrations which become Federal registrations if not disapproved by EPA). This means that a State will be allowed to register more than one product to meet a special need.

Limitations

The proposed regulations are designed to facilitate State issuance of specific types of registrations; however in accordance with the purposes and provisions of the Act, the proposed regulations set forth a number of limitations on the types of registrations which States may be authorized to issue. States will not be authorized to register pesticides containing active or inert ingredients not contained in any EPA-registered products.[1] It is the Agency's belief, based upon its Congressional mandate to protect man and the environment, that the decision to permit the introduction of new chemicals into the environment should be made by the Administrator. This is not to imply that a State could never obtain the technical capability to perform the review which the Administrator must undertake pursuant to section 3, FIFRA, to register a product containing a new chemical. But even if such detailed review were performed by a State, the Administrator would have to perform the same indepth review of such registrations, pursuant to his disapproval authority under section 24(c). This would result in duplication of efforts with the attendant duplicative costs. Additionally, EPA believes that pesticide producers would seldom seek State registration for a product containing a new chemical if, for the same effort, it can obtain a Federal registration and the increased market that accompanies such a registration. Accordingly, were States so authorized, they would be required to maintain extensive technical staffs whose services would be utilized on an occasional basis.

States will also not be authorized to issue registrations for pesticide products affected by suspension or cancellation action based on human health, environmental, or efficacy considerations; or pesticide products formerly denied registration by EPA. In this regard, the proposed regulations provide that States may not register products affected by cancellation or suspension actions of the types specified, except where specifically permitted to do so by the Administrator.[2] A requirement that uses which may result in residues on or in food and feed be covered by necessary tolerances, exemptions, or other clearances in accordance with the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301) is among the other limitations on State registration.

Checks on the adequacy of State registration programs are provided by requirements for EPA review and certification of State programs and EPA review of individual State registration actions. If disapproved by the Administrator, a State registration cannot remain effective for more than 90 days (but, if not disapproved, becomes a Federal registration and is thereafter subject to such EPA actions as suspension and cancellation under section 6). In addition, the proposed regulations provide for withdrawal of EPA certification in the event of a State's failure or refusal to carry out its registration program in accordance with the Act, as amended, or with the terms and conditions of EPA certification, or in the event that EPA repeatedly has to disapprove a State's registration actions.

In short, the proposed regulations offer the States a fair degree of latitude, but they are not open-ended. To some extent, they will have the effect of decentralizing responsibility for pesticide registration decisions that are only of local significance. State agencies are close to, and familiar with, the pest problems and environmental conditions that give rise to "special local needs". Potentially, they are in a position to respond more expeditiously and knowledgeably than EPA possibly could. Whether a particular State agency actually has that potential will be determined through EPA's review of the State plan. To receive certification, a State will have to show that the State agency responsible for pesticide registration meets EPA's requirements regarding availability and utilization of scientific and technical expertise, registration procedures, and legal authority.

Prerequisites for EPA Certification

EPA certification will not be an all-or-nothing authorization; rather, a State

[1] There may appear to be an inconsistency between the prohibition on State registration of products containing active or inert ingredients not contained in any EPA-registered products and the possibility of State registration of a "new product". In the context of EPA registration procedures, the term "new product" includes more than those products containing new chemicals. It also includes duplicative products of other producers as well as products containing the same active and inert ingredients but in different proportions.

[2] In all cases, State agencies will be prohibited from registering products or uses suspended or cancelled. With regard to uses not subject to the cancellation or suspension action, the Administrator will determine whether to permit State registration of such uses on a case by case basis. Where a broad scale suspension or cancellation action is involved, applicable to pesticides containing a particular active or inert ingredient, State registration of pesticide products containing these ingredients generally will be prohibited. Where suspension or cancellation action is based on considerations peculiarly applicable to particular uses of a pesticide, State registration of other uses generally will not be prohibited. State agencies generally will be able to register products or uses which were specifically taken into consideration in suspension or cancellation proceedings but were not suspended or cancelled.

agency will be certified to issue one or more types of registrations, depending primarily on its scientific expertise, registration procedures, and legal authority. Thus, it is possible that some States could be certified to issue all the types of registrations enumerated in the proposed regulations, while others might be certified only to issue specified types of amendments to EPA registrations.

Availability and utilization of scientific and technical expertise will be a major determinant of the scope of a State registration program certified by EPA. A designated State agency must either employ the necessary scientific and technical personnel or be able to utilize such personnel on a continuing basis through formal or informal working arrangements. Where such arrangements will be utilized, the State plan will have to identify specific individuals or groups, e.g., the Entomology Department of the State University, who can be called upon, as necessary, to review registration applications and otherwise provide advice and assistance in scientific and technical disciplines relevant to the types of registrations which the designated State agency is certified to issue. In all cases, the individuals or groups upon whom the designated State agency will depend for scientific and technical expertise should have professional experience with, and in-depth knowledge of, environmental and other conditions affecting pest control within the State.

A designated State agency will be expected to perform its own independent review of State registration applications. Obviously, the scope and depth of such reviews will depend, in each case, on the type of registration and on the nature and extent of differences from EPA registration of a similar product or use. In all cases, the State agency will be expected to make its decisions based on impartial evaluation of registration requests by qualified scientific and technical personnel (employed or otherwise utilized by the State agency) and, as appropriate, on relevant information from other sources. Through the review process, the State agency should ensure that registration requests are accompanied by sufficient supporting data (or, insofar as efficacy is concerned, appropriate statements from a State agricultural experiment station or other State or Federal agency), that pesticide composition (particularly if different from an EPA-registered product) is such as to warrant the claims made for the pesticide, that the directions for use (including any appropriate warnings and cautions) to meet special local needs are complete and intelligible, and that the product/use in question will not cause unreasonable adverse effects on man or the environment.

State Legal Authority

Adequacy of the State agency's legal authority will be another consideration. To be certified, a State agency must have authority to deny, amend, or revoke State registration whenever it appears that a State-registered pesticide or its labeling or other material required for registration does not comply with FIFRA or with EPA's regulations governing State registration or whenever such action is necessary to prevent unreasonable adverse effects on the environment (including man). This means, among other things, that the State agency must have authority to revoke a State registration because of acts which are unlawful under State law and under section 12 of the Act. States also are expected to have authority to undertake inspections and other activities necessary to determine whether State-registered products are being distributed and used in accordance with Federal and State law and the terms and conditions of State registration. To be certified, a State agency must also have legal authority to employ or otherwise utilize scientific and technical personnel, conduct its own independent review of registration applications, maintain complete records of State registration, and comply with the various other requirements of the proposed regulations. Any of the required legal authority can be derived from State statutes dealing specifically with pesticides or from other State statutes. The proposed regulations include a provision calling for submittal of an opinion by the State Attorney-General or legal counsel of the designated State agency on the extent to which the State agency has the requisite legal authorities. What is wanted here is a sufficiently detailed analysis to enable EPA to understand, particularly in areas where the legal authority is not entirely clear-cut, the reasoning behind the opinion. Following the publication of these proposed regulations, upon a request from a State, EPA will make an revaluation of States' legal authorities in the area of pesticide registration.

Other Relevant FIFRA Sections

To some extent, most sections of FIFRA are applicable to State registrations. The proposed regulations delineate the extent to which section 3 is applicable. They also provide that establishments in which State-registered products are produced must be registered in accordance with EPA's regulations under section 7 and must maintain books and records in accordance with EPA's regulations under section 8. State-registered products are subject to section 12, in which certain acts are declared to be unlawful, and section 25, which authorizes, among other things, EPA issuance of regulations affecting pesticide packaging and coloration.

Multiple State Registration

The proposed regulations do not include any explicit limitation on multiple State registration, i.e., registration in more than one State, of identical products. It is recognized, of course, that special local needs are not circumscribed by State boundary lines. Nevertheless, in reviewing registration applications, each State agency will be expected to make its own determination as to the existence of a special local need. Where identical products are registered in several States, EPA will review such registrations with particular attention to the question of whether they are consistent with the concept of special local need. Where it appears that a product registered by several States properly should be registered with EPA, appropriate steps toward this end will be taken. This note of caution is aimed at the use of State registration in a manner which is designed to circumvent, or has the effect of circumventing, the requirements of section 3(c)(1)(d) of the Act.

Use of Data

FIFRA imposes certain restrictions on the data which the Administrator may consider in support of an application for registration under section 3. Pursuant to section 3(c)(1)(D), the Administrator, in evaluating an application for registration, cannot consider data submitted in support of another application for registration under section 3, without the consent of the prior applicant, or a promise by the subsequent applicant to pay reasonable compensation for the use of such data. In drafting these proposed regulations, the Agency has carefully considered the question whether such a limitation on the consideration of previously submitted data is applicable to State registrations pursuant to section 24(c) of the Act.

Section 24(c) includes no express prohibition on the consideration of previously submitted data in support of State registration. Section 3(c)(1)(D) applies by its terms only to the Administrator of EPA and only to a limited type of action by the Administrator, i.e., the consideration of data in support of a subsequent application for registration. Other actions of the Administrator which might possibly involve consideration of data submitted by a previous applicant for registration (e.g., applications for an experimental use permit pursuant to section 5; cancellation or suspension actions pursuant to section 6; applications for emergency exemptions pursuant to section 18; and even section 3 registration actions; insofar as data might be considered to support denial of an application) are not covered by section 3(c)(1)(D), either expressly or by implication.

In consequence of the foregoing, the Agency has reached the conclusion that Congress did not intend section 3(c)(1)(D) to control the consideration of previously submitted data other than as provided by the language of that section itself. Since nothing in section 3(c)(1)(D) extends the operation of the section to State officials, the Agency has concluded that State officials are not subject to the restraints which section 3(c)(1)(D) imposes on the Administrator regarding the consideration of previously submitted data. The same result applies regarding the Administrator's "disapproval" authority under section 24(c). State special local needs registrations are valid from the date of their issuance by the State, unless disapproved. Thus, review by the Administrator pursuant to the disapproval authority in 24(c) is review for the purpose of terminating, not initiating, a registration. As such, the Adminis-

trator's action is analogous to review of an existing section 3 registration to determine whether or not to initiate suspension or cancellation action under section 6. It is clear that section 3(c)(1)(D) does not apply to section 6, and the same conclusion should also apply with equal force to review pursuant to the disapproval authority of section 24(c). Nor is a different conclusion required by the language in section 24(c) that a State registration "shall be deemed registration under section 3 for all purposes of this Act." This language is clearly addressed to the legal effect of a State 24(c) registration, and not to the procedures which must be followed by a State in registering a pesticide product, or in any disapproval action by the Administrator.

The conclusion that section 3(c)(1)(D) does not apply to section 24(c) is consistent with the policy behind section 24(c). As previously indicated, the legislative history of the 1972 amendments clearly indicates Congress' intent that section 24(c) be employed to deal with minor or local use problems "expeditiously and with less cost and administrative burden" [Senate Report No. 92-838, supra], than would be the case with an EPA registration under section 3 of the Act. Implementation at the State level of restrictions on the consideration of previously submitted data would complicate the registration process, and increase both costs and administrative burdens. In addition, the implementation of such restrictions might require the inclusion of substantial periods of delay in State registration processes. In this regard, the Agency notes that the procedure set out in an interim policy statement (38 FR 31862) implementing section 3(c)(1)(D) adds several months to the time required in certain circumstances to obtain a registration pursuant to section 3. Such delays might prevent the use of section 24(c) to respond expeditiously to special local pest problems, thus defeating another important purpose behind section 24(c).

Finally, the Agency recognizes that attempts might be made to avoid financial responsibility under section 3(c)(1)(D) by using multiple State section 24(c) registrations. As mentioned earlier, for this and other reasons the Agency will closely monitor situations where a product is registered for the same uses in several states, and will take appropriate action to ensure that the intent of the Act is properly served.

EFFECT OF STATE DENIAL AND REVOCATION

A State agency certified under section 24(c) is entitled to, and expected to, deny State registration whenever an application does not satisfy the requirements of Federal and State law and EPA's regulations. Such denial does not entitle an applicant to the remedies set forth in section 6 of the Act in cases of EPA denial. An applicant can, however, request EPA registration after being denied State registration, and his request would be treated in the same manner as would any other new application.

A State agency also is entitled to, and is expected to, revoke a State registration whenever it is in violation of Federal or State law or EPA's regulations. If such revocation occurs before the 90-day period allowed by the Act for EPA disapproval of a State registration, EPA may disapprove the State registration, in which case the remedies provided by section 6 of the Act will not be available to the registrant (for the reasons discussed below). If revocation occurs after the 90-day period, EPA, upon notification of the State revocation action, may initiate cancellation action under section 6, depending on the reasons for State revocation. If EPA issues a cancellation notice, then section 6 remedies will be available. To allow coordination of EPA and State action in such cases, the proposed regulations call for State consultation with EPA before a State registration is revoked.

EFFECT OF EPA DISAPPROVAL

The proposed regulations provide that EPA disapproval of a State registration shall not be considered a refusal to register within the meaning of section 3(c)(6) of the Act or a suspension or cancellation within the meaning of section 6. EPA has concluded that the Congress did not intend that, in such cases, the affected State registrant would have access to the remedies prescribed by these sections of the Act. The holder of a State registration disapproved by EPA always has the option of applying for EPA registration under section 3. Denial of EPA registration would, of course, make available the remedies under section 6. It is important to note that a State registration can be disapproved for various reasons, some of which would be inapplicable to consideration of a subsequent application for EPA registration, e.g., the State registration is not for a "special local need". In addition, an EPA registration action, in most cases, will result in a much more extensive record reflecting a more detailed exploration of pertinent issues. EPA believes that it is sound policy to limit the expensive and time-consuming section 6 procedures to those cases in which there has been such a thorough review. In the event of an EPA disapproval, EPA's notification to the State agency will include provisions for terminating shipment, sale, and use and/or use of existing stocks; such provisions will depend largely on the basis for disapproval.

OTHER STATE AUTHORITY

Section 24(a) provides that a State "may regulate the sale or use of any pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this Act". States do not need EPA certification to exercise this authority. Without certification under section 24(c), a State can impose special limitations or restrictions on the use of an EPA-registered pesticide in addition to those imposed through EPA registration, or even bar the use of an EPA-registered pesticide within the State. Nevertheless, the proposed regulations would allow States to request and receive certification for such purposes, since with such authority a State can ensure, for example, that any special directions for use within the State are communicated to pesticide users in supplementary labeling.

REGISTRATION INFORMATION

What State agencies certified under section 24(c) can and cannot register under the proposed regulations is keyed to the status of EPA registration, e.g., whether or not there is an EPA-registered product for a particular use. Accordingly, it is essential that States have easy access to information on EPA registrations. EPA currently is preparing a complete inventory of registered products; it will permit retrieval of information on chemicals, application sites, and pests. From this inventory, a State agency would be able to determine, for example, whether there are any products or chemicals registered for use against a particular pest on a particular crop. This inventory will provide information not only on products containing a single active ingredient but also on combination. In addition, if used in conjunction with the EPA Compendium of Registered Uses the inventory will offer quick access to information on label directions, unique limitations, special application information, and so on. It is anticipated that the inventory will be completed by mid-1975. Arrangements will be made to put it into the hands of State agencies as quickly as possible after its completion.

EPA also is planning to prepare a comprehensive list of inert ingredients contained in EPA-registered products (without cross-reference between products and inert ingredients). This list will be compiled during the re-registration process required by FIFRA and therefore will not be completed at least until late-1976. In the meantime, where a State agency needs information on the registration status of a particular inert ingredient, it will be able to obtain such information directly from EPA.

ENFORCEMENT POLICY

In certifying States to register products for special local needs pursuant to section 24(c) of the Act, EPA does not intend any concomitant grant of enforcement authority which would in any way curtail or preempt EPA enforcement of FIFRA. Notwithstanding State enforcement capabilities which may be established or enhanced as a result of the undertaking by that State to operate a pesticide registration program under section 24(c), EPA will continue to exercise its general enforcement responsibilities over pesticide products. Where enforcement activity involves a product bearing a section 3 registration which has arisen out of a section 24(c) State registration, EPA reserves the right to exercise its prosecutorial discretion in determining whether: (1) To proceed with Federal action where a State has declined to act; (2) To proceed with Federal action in

addition to State action; (3) To decline Federal action in the event or in the absence of State action.

Inflation Impact Analysis

On November 27, 1974, the President issued Executive Order 11821 (39 FR 41501) which requires each Agency to certify that the inflationary impact of any major regulation has been evaluated. The following discussion summarizes EPA's consideration of the inflationary impact of these regulations and focuses on the reasons why the Agency believes these proposed regulations do not constitute a "major action" within the meaning of Executive Order 11821 and OMB Circular No. A-107.

Pesticides are necessary to provide the nation with an abundant supply of food and fiber. The registration of pesticide products is required by FIFRA prior to their distribution or sale. As discussed in the preamble to the regulations implementing section 3 of FIFRA (40 FR 28248), the most significant potential cost associated with Federal registration is the cost of developing the data required in support of the registration. The regulations proposed herein for State registration of pesticides for special local needs will be economically beneficial to pesticide producers and users because these regulations provide a means of registering such pesticides which in many cases will require the production of less data and therefore will be less costly than would be the case for Federal registration. The Agency anticipates that most State registrations will not involve changed use patterns, and therefore will fall within § 162.155(d) of these proposed regulations. This provision requires the State to perform an efficacy review but authorizes it, in such circumstances, to base this review upon written findings and recommendations of scientific personnel (i.e., employees of a State agricultural experiment station), rather than upon the more extensive data required for Federal registration (see 40 CFR 162.8(b)). In those cases involving registration for new products or changed use patterns, these proposed regulations establish data requirements relating to human health and environmental hazards. However, such data would also be required by the Act to support Federal registration, so the impact of these proposed regulations in this regard is essentially neutral.

The Agency also observes that the vast majority of States currently have registration programs which license the distribution and sale of a pesticide in return for a fee. These programs may continue under FIFRA. To obtain authority under these proposed regulations to issue special local needs registrations not involving changed use patterns or new products, it will not be necessary to significantly augment existing State registration programs. As noted above, the Agency is of the opinion that authority of this variety is all that most States will request.

In summary, these proposed regulations provide a mechanism for State registration of pesticides for special local needs which in most cases is less costly and administratively burdensome than Federal registration, which would otherwise be required. In addition, States can obtain authority in most instances under these proposed regulations without any significant augmentation to existing programs. For these reasons the Agency believes these proposed regulations providing for State registration of pesticides to meet special local needs do not constitute a major action within the intent of the Executive Order and OMB Circular No. A-107.

Interim Certification

On July 3, 1975, final regulations for the registration, re-registration, and classification of pesticides pursuant to section 3 of the Act were published in the Federal Register (40 CFR Part 162, Subpart A) (40 FR 28241). These regulations became effective August 4, 1975. Since that date, States have been prohibited from issuing new registrations except under a program approved by the Administrator in accordance with section 24(c). However, States may renew any State registration already in effect, and the product concerned may be distributed and used solely within that State subject to the requirements of § 162.17(f) of the FIFRA section 3 regulations, if the State registrant submits a notice of application for EPA registration within sixty (60) days of the effective date of the section 3 regulations as required by § 162.17.

Since it did not prove possible to promulgate section 24(c) regulations prior to the effective date of the FIFRA section 3 regulations, some interruption in the authority of States to register pesticides has occurred. In order to prevent further disruption of State registration programs (particularly in relation to minor uses) during the course of this rulemaking proceeding, an interim certification procedure will be followed. However, it is unreasonable to expect States to develop and submit, on relatively short notice, plans for interim certification which fully satisfy the regulations proposed below. Even if this task could be accomplished, some procedure would have to be implemented to require States to amend their plans to reflect any changes or additions to the requirements when the section 24(c) regulations are made final. For these reasons, the following interim certification procedure has been adopted. This procedure will enable States intending to apply for section 24(c) authority to obtain interim certification to register pesticides to meet "special local needs," as defined in these proposed regulations. Interim certification will expire if the State has not submitted a plan pursuant to the final section 24(c) regulations within 60 days after the effective date of the section 24(c) regulations, or, if such a plan is submitted and it is disapproved by the Administrator, on the effective date of the Administrator's disapproval.

A State may request interim certification to register pesticides to meet special local needs at any time by having the Governor or Chief Executive Officer or their designee submit a request in writing to the Administrator. Such request shall include:

(1) Designation of the State agency which will be responsible for issuance of State registrations to meet special local needs;

(2) A list of the types of registration actions for which interim certification is requested [see proposed § 162.153(b)];

(3) A description of the registration procedures which will be followed by the designated State agency;

(4) A citation to the applicable State laws and regulations under which authority such registration actions will be issued; and

(5) An affirmation that the State intends, upon final promulgation of regulations under section 24(c), to request certification to register pesticides for special local needs.

The Administrator shall act on a request for interim certification as expeditiously as possible. The Administrator shall approve the request for interim certification if the State's request shows that the State is capable of exercising adequate controls to assure that registrations for special local needs issued by it will be in accord with the purposes of FIFRA. Where authority to issue rgistrations involving new products or changed use patterns (as defined in these proposed regulations) is requested, interim certification shall be granted only if the State registration procedures include a procedure for hazard determination sufficient to ensure that pesticide product(s) will not be registered if they would cause unreasonable adverse effects on the environment, when used as directed or in accordance with widespread and commonly recognized practice. The hazard determination procedure shall satisfy the requirements of §162.155(e) of these proposed regulations. Where authority to issue registrations which do not involve new products or changed use patterns is requested, interim certification shall be granted if the state registration procedures include a procedure for efficacy determination (i.e., to ensure that the composition of a pesticide is such as to warrant the claims made for it) which satisfies the requirements of § 162.155(d) of these proposed regulations.

The Administrator shall notify the designated State agency of his approval or denial of the request. Notice of approval or denial will also be published in the Federal Register. Public comment, however, will not be solicited with respect to requests for interim certification. In order to obtain interim certification a State must affirm its intention to submit a State plan for certification pursuant final section 24(c) regulations, and must do so within 60 days of the effective date of the final section 24(c) regulations or its interim certification authority will terminate. The Agency expects to expedite the publication of final section 24(c) regulations so that interim certification should be of limited duration. Adequate opportunity for public comment on State plans submitted pursuant

to final section 24(c) regulations is provided for in proposed § 162.58(c).

The Administrator may at any time amend, suspend, or withdraw his interim certification of a designated State agency if he determines that such State agency has not complied with the requirements, terms, or conditions of such interim certification. Prior to denying, amending, suspending, or withdrawing interim certification, the Administrator will furnish the designated State agency written notification of his intent to take such action and a statement of his reasons. In such cases, the State agency will be given an opportunity to comment on the proposed action.

A State which has received interim certification may register pesticides to meet special local needs (as defined in § 162.152(k) of the proposed regulations). The State may issue the types of registration actions set forth in the proposed § 162.153(b) for which it has requested and received interim certification. Interim special local needs registration programs shall be subject to the limitations contained in proposed §162.153(c). The provisions of § 162.156 of these proposed regulations pertaining to EPA review of State registrations shall apply. This section includes provisions for notification to EPA of registrations issued (§162.156(a)); provisions governing EPA disapproval actions (§162.156 (b) (c) and (e)); and certain FEDERAL REGISTER publication requirements regarding registrations involving changed use patterns (§162.156(d)). In addition, the labeling of a pesticide product registered pursuant to interim certification shall state "For Distribution and Use Only Within [Name of State]."

All registrations issued under the authority of an interim certification program shall be deemed registrations under section 3 unless disapproved within 90 days. As a condition of the granting of interim certification, the Administrator shall require assurances from the State that registrations issued pursuant to interim certification will be modified to satisfy any provisions in the final section 24(c) regulations regarding classification (see proposed § 162.155(f)), labeling (see proposed § 162.155(g)), coloration or discoloration (see proposed § 162.155(h)(2)), and packaging (see proposed § 162.155(h)(1)) within a reasonable period of time after the State receives final certification.

PUBLIC COMMENT

EPA invites all interested parties to submit comments on these proposed regulations. States, in particular, are urged to spell out their views in detail and to describe any special situations which may be difficult to handle under these proposed regulations. To be sure of receiving full consideration, all comments should reach EPA on or before October 3, 1975, and should bear the identifying notation OPP-30003. Comments should be filed in triplicate and addressed to the Federal Register Section, Technical Services Division (WH-569), Office of Pesticide Programs, Environmental Protection Agency, Room E-401, 401 M St. SW., Washington, D.C. 20460. All written comments will be available for public inspection at the Office of the Federal Register Section from 8:30 to 4 p.m., Monday through Friday.

Dated: August 26, 1975.

RUSSELL E. TRAIN,
Administrator.

It is proposed to amend 40 CFR Part 162 by establishing Subpart B, to read as follows:

Subpart B—Regulations for State Registration of Pesticides To Meet Special Local Needs

Sec.

AUTHORITY: Section 24(c) and section 25 (a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended by the Federal Environmental Pesticide Control Act of 1972 (86 Stat. 997).

Subpart B—Regulations for State Registration of Pesticides To Meet Special Local Needs

§ 162.150 Scope.

This Subpart sets forth regulations governing registration by a State of pesticide products formulated for distribution and use within such State to meet special local needs. It also sets forth regulations governing certification of State registration programs by the Administrator.

§ 162.151 Applicability.

This Subpart applies solely to State registration of pesticides to meet special local needs. It neither applies to, nor affects, any procedures by which a State licenses or otherwise approves or allows use within the State of EPA-registered pesticide products.

§ 162.152 Definitions.

Terms used in this Subpart shall have the meanings set forth in the Act and in Subpart A. In addition, as used in this Subpart, the following terms shall have the meanings set forth below:

(a) "Approved State Plan" means a State plan for registration of pesticides to meet special local needs that has been approved by the Administrator.

(b) "Certification" means the act, i.e., approval of the State plan, by which the Administrator authorizes a designated State agency to issue specified types of pesticide registrations.

(c) "Changed Use Pattern" means a significant change from a use pattern approved in connection with the registration of a pesticide product. Examples of significant changes include, but are not limited to, changes from nonfood to food use, outdoor to indoor use, ground to aerial application, terrestrial to aquatic use, and non-domestic to domestic use.

(d) "Designated State Agency" or "State Agency" means the State agency designated by State law or other authority to be responsible for registering pesticides to meet special local needs.

(e) "EPA" means the U.S. Environmental Protection Agency.

(f) "EPA-registered" and "registered by EPA" mean originally registered by EPA.

(g) "New Product" means a pesticide product not registered by EPA at the time of State registration.

(h) "Pesticide" means any substance or mixture of substances intended for preventing, destroying, repelling, attracting, or mitigating any pest, and any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant.

(i) "Pesticide product" means a pesticide offered for distribution and use, and includes any labeled container and any supplemental labeling.

(j) "Pest Problem" means:

(1) A pest infestation and its consequences, and the climate, soil, and other conditions of the pest infestation, or

(2) Any condition requiring the use of plant regulators, defoliants, or desiccants.

(k) "Special Local Need" means a pest problem (existing or likely to occur within a State) which cannot be effectively controlled because:

(1) There is no pesticide product registered by EPA for such use; or

(2) There is no EPA-registered pesticide product which, under the conditions of use within the State, would be as safe and/or as efficacious for such use within the terms and conditions of EPA registration; or

(3) An appropriate EPA-registered pesticide product is not available.

(l) "Use Pattern" means the manner in which a pesticide is applied and includes the following parameters of pesticide application:

(1) Target pest;
(2) Crop or animals treated;
(3) Application site; and
(4) Application technique and rate.

§ 162.153 State registration actions.

(a) *General.*—A designated State agency may be certified to issue one or more of the following types of registrations in order to meet special local needs, depending upon such State agency's capability to exercise adequate controls to assure that such registrations will be in accord with the purpose of the Act. Types of registrations which a State agency will not be certified to issue are set forth in paragraph (c) of this section.

(b) *Types of State Registration Actions.* A State may request certification of a designated State agency to issue the following types of registrations of pesticides formulated for use and distribution within the State to meet special local needs, subject to the limitations set forth in paragraph (c) of this section.

(1) To permit the use of new products.

(2) To amend EPA registrations for one or more of the following purposes:

(i) To permit use on additional crops or animals;

(ii) To permit use at additional sites;
(iii) To permit use against additional pests;
(iv) To permit use of additional application techniques or equipment;
(v) To permit use at different application rates; and
(vi) To prescribe special label directions for one or both of the following purposes:
(A) Preventing unreasonable adverse effects on man or the environment under local use conditions, or
(B) Providing for local use conditions affecting pesticide efficacy.
(3) To serve other purposes specifically identified in the approved State plan.

(c) *Limitations.* (1) A pesticide product registered by a State agency to meet a special local need shall be used only within such State and shall be regarded as "formulated for use and distribution within the State", regardless of where actually formulated, only if its container bears, or is accompanied by directions for its use to meet such special local need and, a statement identifying the State within which it is so registered. The establishment in which such product was produced shall be registered in accordance with regulations under section 7 of the Act and shall maintain books and records in accordance with regulations under section 8 of the Act.

(2) A designated State agency shall not issue any type of registration other than those authorized in the approved State plan and a State shall not issue a registration covering any of the following:

(i) A product containing an active or inert ingredient not contained in any EPA-registered product;

(ii) A product containing an active or inert ingredient, which ingredient was included in a product whose registration has been suspended or cancelled by EPA or is the subject of an EPA notice of intent to suspend or cancel because of human health, environmental or efficacy considerations with regard to such ingredient (except that a State may register certain uses of a product containing such an ingredient to the extent that the Administrator's order or notice of intent so provides);

(iii) A product or use which has been the subject of a notice of denial of registration published in the Federal Register pursuant to section 3(c) (6) of the Act; or

(iv) A product or use which can reasonably be expected to result in residues on or in food or feed unless the registration of such product or use is supported by the necessary tolerances, exemptions, or other clearances under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301).

(3) A registration issued by a State agency shall be valid for a maximum of five years from the date of its issuance and may be renewed.

§ 162.154 Considerations affecting issuance and withdrawal of certification.

(a) General: A State may request the Administrator to certify a designated State agency to issue one or more of the types of registrations set forth in § 162.153(b). The Administrator shall grant such a request if he determines, upon review of the State plan, that such State agency is capable of exercising adequate controls to assure that such registrations will be in accord with the purposes of the Act.

(b) Such determination shall be based on consideration of whether the State plan shows that such State agency: (1) Employs or otherwise utilizes scientific and technical personnel having expertise relevant to pest problems and environmental and other conditions affecting pest control within the State (and, where certification to register new products or products involving changed use patterns is requested, expertise relevant to product hazard determinations pursuant to § 162.155(e);

(2) Utilizes registration procedures which include its own independent review of registration applications;

(3) Maintains complete and accurate records of all State registrations, including applications and supporting data and documents reflecting the State agency's review of such applications and supporting data, copies of approved labeling, and any reports received concerning accidents or misuse; and

(4) Has adequate legal authority, including authority:

(i) To deny, amend, or revoke State registration when it appears that a State-registered pesticide or its labeling or other material required to be submitted does not comply with the provisions of the Act or this Subpart, or when necessary to prevent unreasonable adverse effects on the environment;

(ii) To undertake inspections at reasonable times, to determine whether State-registered products are being produced, distributed, and used in accordance with Federal and State law and the terms and conditions of State registration; and

(iii) To satisfy the requirements of paragraph (b) (1), (2), and (3) of this section and to comply in all other respects with the requirements of this Subpart.

(c) The Administrator may at any time amend, suspend, or withdraw his certification of a designated State agency if he determines that such State agency has not complied with the requirements of this Subpart or with the terms and conditions of such certification, e.g., if EPA repeatedly has disapproved registrations issued by such State agency.

§ 162.155 Product registration requirements.

(a) *General.* State registration requirements shall be generally consistent with EPA registration requirements as set forth in 40 CFR Part 162, Subpart A. EPA requirements need not be observed, however, to the extent that they involve consideration of factors not relevant to distribution and use within the State.

(b) *Registration statement.* An application for State registration of a pesticide product to meet a special local need shall include the name and address of the applicant and any other person whose name will appear on the labeling or in the directions for use; the name of the product; a complete copy of the labeling showing all claims made for the product and directions for its use to meet the special local need; the complete formula of the product; and a statement indicating whether:

(1) An EPA registration of, or experimental use permit for, the product has ever been sought, issued, denied, canceled, or suspended; and

(2) Registration of the product has ever been sought from, or denied or revoked by, another State.

(c) *Special local need determination.* In reviewing an application for State registration, the designated State agency shall determine that such State registration is related to a special local need, as defined in § 162.152(k). Where questions arise as to the availability of an appropriate EPA-registered pesticide, the State agency itself shall resolve such questions without consideration of economic benefit to pesticide producers or sellers. Where questions arise as to other factors bearing on the existence of a special local need, the State agency may rely upon scientific data, findings, or recommendations submitted in writing by a State agricultural experiment station or other State or Federal agency authorized by law to conduct pesticide research, pest control activities, or programs for the protection of environmental quality or natural resources.

(d) *Efficacy determination.* The State agency shall determine that the composition of a pesticide is such as to warrant the claims made for it in the application. The required determination shall be based on information submitted in writing in either or both of the following categories:

(1) Scientific data supplied by the applicant; or

(2) Scientific data or findings and recommendations of a State agricultural experiment station or other State or Federal agency authorized by law to conduct pesticide research, pest control activities, or programs for the protection of environmental quality or natural resources.

(e) *Product hazard determination.* In the case of an application involving a new product or changed use pattern, the State shall determine that (when considered in conjunction with any restrictions imposed pursuant to § 162.155(f)) the pesticide product will not cause unreasonable adverse effects on the environment when used as directed or in accordance with widespread and commonly recognized practice. The State shall make this determination based upon the data specified in 40 CFR 162.8(b)(4).

(f) *Classification.* EPA regulations spelling out procedures for pesticide classification appear at 40 CFR Part 162.11. State registered products shipped, distributed, or sold or offered or delivered for shipment, distribution, or sale after October 21, 1976, shall be classified as follows:

(1) A State registration for a pesticide product not involving a changed use pattern, shall be classified the same as the EPA-registered product/use.

(2) A State registration involving a new product or a changed use pattern shall be classified in accordance with 40 CFR Part 162.11.

(g) *Labeling requirements.* (1) Any new product registered by a State agency must bear a label satisfying the requirements of 40 CFR 162.10, and 40 CFR 162.153(c)(1).

(2) A State agency may not require or permit modification or elimination of any labeling approved in connection with EPA registration, except that EPA labeling shall be supplemented by directions for use to meet special local needs; such supplementary directions shall satisfy the requirements of 40 CFR 162.10(i) and 40 CFR 162.153(c)(1).

(3) Prior to issuing a registration, the designated State agency shall review and approve the labeling (including directions for use to meet special local needs) related thereto.

(h) *Coloration and packaging.* (1) Products registered by a State agency shall be subject to any standards which the Administrator may prescribe with respect to pesticide packaging pursuant to section 25(c)(3) of the Act.

(2) Products registered by a State agency shall be subject to any regulations which the Administrator may prescribe with respect to coloration and discoloration of pesticides pursuant to section 25(c)(4) of the Act, including the regulations set forth at 40 CFR 162.13.

§ 162.156 EPA Review of State registrations.

(a) *Notification.* (1) Within 10 days after issuing a registration, or an amendment thereto, the designated State agency shall send EPA written notification of such registration or amendment on a form supplied by EPA, accompanied by a copy of the approved labeling. Upon request, such State agency shall furnish EPA data in support of a registration or amendment.

(2) Within 30 days after issuing a registration or an amendment thereto, the designated State agency shall send EPA a copy of the final printed labeling.

(b) *Disapproval.* (1) A State registration shall be disapproved if:

(i) The registration is not for a special local need; or

(ii) The registration is not a type of registration that the State agency is certified to issue; or

(iii) The State agency did not follow the registration procedure set forth in the approved State plan; or

(iv) The State agency fails to furnish requested data in support of the registration; or

(v) Supporting data do not substantiate the State agency's indicated reasons for issuing the registration; or

(vi) The State-registered product or use will cause unreasonable adverse effects on the environment; or

(vii) The composition of the State-registered product is such as not to warrant the claims made for it; or

(viii) The registration has been revoked by the State; or

(ix) The registration is otherwise contrary to the Act or this Subpart.

(2) A disapproval may be rescinded if the State agency demonstrates that the cause of such disapproval has been corrected.

(c) *Effective date of disapproval.* State registration shall be deemed registration pursuant to Section 3 of the Act as of the effective date of such registration. The Administrator may disapprove a State registration and shall do so within 90 days of its effective date and, in the event of such disapproval, shall notify the State agency and the registrant of such action. Taking into account the reasons for such disapproval, the Administrator shall specify the termination date of a disapproved State registration and, if appropriate, provide for disposition of existing stocks of the product in question.

(d) FEDERAL REGISTER *notice.* Upon receipt of notice from a State of a registration involving a changed use pattern, EPA shall publish a notice in the FEDERAL REGISTER describing the registration in general terms, and inviting public comment thereon.

(e) *Effect of disapproval.* (1) A disapproval by the Administrator shall not be considered a refusal to register within the meaning of section 3(c)(6) of the Act and shall not be subject to the remedies prescribed therein.

(2) A disapproval by the Administrator shall not be considered a suspension or cancellation within the meaning of the Act and shall not be subject to the hearings and appeals provisions of Section 6 of the Act.

§ 162.157 State revocation of registration.

(a) *Consultation and notification.* Wherever practicable, a State agency shall consult with EPA prior to revoking a State registration. In all cases, the State agency shall send EPA written notification of a revocation within 10 days after the effective date of such revocation. Such notification shall include a brief explanation of the reasons for revocation.

(b) *Effect of revocation.* A State agency's revocation of a State registration may result in cancellation under section 6 of the Act.

§ 162.158 Certification procedures.

(a) *State requests.* A State may request certification at any time by having the Governor submit a State plan in writing to the Administrator. A copy should be provided to the appropriate EPA Regional Administrator. Such a State plan shall include:

(1) Designation of the State agency which will be responsible for issuance of State registration to meet special local needs;

(2) A list of the types of registration actions for which certification is requested;

(3) An opinion of the State Attorney General or the legal counsel of the designated State agency that the State has the requisite legal authorities outlined in § 162.154(b)(4), accompanied by copies of the applicable State laws and regulations;

(4) A description of the registration procedures which will be followed by the designated State agency; and

(5) A description of the functions and qualifications of scientific and technical personnel employed or otherwise utilized by the designated State agency for the purpose of reviewing registration applications.

(b) *Amendments.* A State may request that its certification be amended by the Administrator at any time. If the State is requesting authorization to issue additional types of registration, the request shall be accompanied by an appropriate amendment to its State plan.

(c) *EPA Certification.* (1) After receiving a State request for certification, EPA will publish a FEDERAL REGISTER notice of the request and invite interested parties to submit comments.

(2) EPA will approve or deny a request as expeditiously as possible and will attempt to do so within 90-days after receiving all the information considered necessary for proper review of the request. Notice of approval or denial will be published in the FEDERAL REGISTER.

(3) Prior to denying, amending, or withdrawing certification, the Administrator will furnish the affected State agency written notification of his intention to take such action and a statement of his reasons. In such case, the affected State agency will be given an opportunity to comment on the proposed action.

[FR Doc.75-23350 Filed 9-2-75;8:45 am]

[40 CFR Part 172]

[FRL 394-5]

EXPERIMENTAL USE PERMITS

Regulations for State Issuance

Notice is hereby given that, pursuant to the authority of section 5(f) and section 25(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended by the Federal Environmental Pesticide Control Act of 1972 (Pub. L. 92-516, 86 Stat. 973), the Administrator of the Environmental Protection Agency (EPA) proposes to amend 40 CFR Part 172 by establishing a new Subpart B prescribing regulations applicable to State issuance of experimental use permits. The proposed regulations are set forth below. They are related to, and should be read in conjunction with, the proposed regulations applicable to State registration of pesticides to meet special local needs, 40 CFR 162 Subpart B, which also appear today at FR 40 FR 40538.

STATUTORY AUTHORITY

Section 5(a) of FIFRA, as amended, authorizes the Administrator to issue an experimental use permit if he determines that the applicant needs such a permit in order to accumulate information necessary to register a pesticide under section 3. Regulations applicable to

EPA issuance of such permits were published on April 30, 1975 (40 FR 18780).

Under section 5(f), the Administrator may, under such terms and conditions as he may by regulation prescribe, authorize any State to issue an experimental use permit for a pesticide.

Summary of the Proposed Regulations

Under the FIFRA, as amended, experimental use permits may be issued for the purpose of allowing an applicant to accumulate the information necessary to register a pesticide. Under the regulations proposed below, State issuance of experimental use permits will be subject to the same constraints as State registration of pesticides to meet special local needs. A State will be permitted to issue permits only for the testing of pesticide products to allow for the accumulation of data necessary to support a registration which the State is certified to issue under section 24(c). Testing intended to provide data to support an application for a registration which a particular State is not certified to issue or to support an application which is intended to be submitted for federal registration may be conducted only under a federally issued experimental use permit. This limitation will not infringe upon any person's ability to obtain an experimental use permit. Where an experimental use permit cannot be issued by a State, the experimental program in question may qualify for a federal permit.

In general, a state agency that has been certified to issue special local needs registrations in one or more of the categories established by 40 CFR 162.53(b) should be capable of exercising authority for issuing experimental use permits for the development of data to support an application for registration in such category or categories. Accordingly, these regulations do not require significant augmentation of state programs, in terms of staffing or other resources, beyond what is required for authorization to register pesticides for special local needs pursuant to section 24(c) of the Act. Due to this fact, and the complementary nature of sections 5(f) and 24(c), States are encouraged to consolidate their requests in these two areas.

The regulations governing federal experimental use permits (40 CFR 172, Subpart A) define the circumstances when an experimental use permit will be required, and set out the standards and procedures which this Agency will follow in administering the federal experimental use permit program. That portion of 40 CFR 172, Subpart A which prescribes the circumstances when an experimental use permit will be required (40 CFR 172.3) is equally applicable to state experimental use permit programs pursuant to section 5(f) of the Act, and has been incorporated by reference in these regulations. Those parts of 40 CFR 172, Subpart A which set out standards and procedures for administering the federal program reflect the Agency's judgment as to the elements of an effective experimental use permit program. Accordingly, certain requirements of 40 CFR 172 Subpart A regarding standards and procedures have been included in these regulations, either by incorporation by reference or otherwise. However, in some respects these regulations give the states discretion to develop procedures different from those which the Agency has prescribed for the federal experimental use permit program (e.g. application procedures). In requesting EPA authorization of a State program, a state should demonstrate that the procedures which it has developed in these areas are reasonable and will ensure that permits will be issued and used in a manner generally consistent with the federal experimental use permit program.

Under the proposed regulations States will be required to furnish EPA with notification of the issuance of experimental use permits. This notification will make EPA aware of the prospective introduction of new pesticide uses and enable the Agency to furnish the States with advice and information, when appropriate, regarding such new product uses. The regulations also provide for EPA review and revocation of permits issued by a State. While the Act does not expressly confer disapproval authority, section 5(f) does authorize the Administrator to subject state experimental permit programs to such "terms and conditions" as he may by regulation impose. Authority to review and revoke state permits is included in these regulations as such a term or condition, in order to provide the agency adequate authority to supervise state programs to ensure that the purposes and goals of the Act are adequately served. It should be emphasized however, that where compelling reasons appear to exist for revocation or modification of a State permit, the Agency will consult with the State, and suggest that it take appropriate action. EPA authority will be used as a last resort, where action is necessary to prevent unreasonable adverse effects on man or the environment. The regulations further provide for notice and the opportunity for the permittee to contest the revocation.

State plans requesting authorization to issue experimental use permits will be acted upon expeditiously. If the Administrator proposes to reject a State plan, notice and opportunity for a hearing will be given to the affected state as required by the Act (sections 4(b) and 5(f)). States which have been granted authority pursuant to this Subpart will be expected to administer their experimental use permit programs consistent with the requirements set out herein. If the Administrator determines that a State program is not in compliance he may revoke the authorization to issue experimental use permits. In such instances notice and an opportunity for a hearing will be given to the state, as required by the Act.

Inflation Impact Analysis

On November 27, 1974, the President issued Executive Order 11821 (39 FR 41501) which requires each Agency to certify that the inflationary impact of any major regulation has been evaluated. The following discussion summarizes EPA's consideration of the inflationary impact of the proposed regulation and focuses on the reasons why the Agency believes this proposed regulation does not constitute a "major action" within the meaning of Executive Order 11821 and OMB Circular No. A-107.

The requirement for an experimental use permit is established by FIFRA. Section 5(f) provides for State issuance of experimental use permits for the purpose of gathering data necessary to support a State registration under section 24(c). Potential registrants may also, of course, apply to EPA for an experimental permit under 40 CFR 172 Subpart A. The State experimental use permit program outlined in these proposed regulations and the Federal experimental use permit program are essentially similar; the economic impact of these programs on the manufacturers, producers and consumers will be slight. Since certification under section 24(c) is a prerequisite to authorization under section 5(f), State resources required to obtain section 5(f) authority will, for the most part, be already available. Furthermore, it is anticipated that relatively few States will submit a State Plan under section 5(f) for authorization to issue experimental use permits.

For these reasons, the Agency believes these proposed regulations do not constitute a major action within the intent of the Executive Order and OMB Circular A-107.

Public Comment

EPA invites all interested parties to submit comments on the proposed regulations for State issuance of experimental use permits. To receive full consideration, comments must be received on or before October 3, 1975. Comments should be filed in triplicate and addressed to Information Branch, Office of Pesticide Programs, Environmental Protection Agency, Room E-421, Washington, D.C. 20460. All written comments filed pursuant to this Notice will be available for public inspection at the Information Branch during regular business hours, 8 a.m. to 4:30 p.m. daily.

Dated: August 26, 1975.

Russell E. Train,
Administrator.

40 CFR Part 172 is amended by establishing a new Subpart B, to read as follows:

Subpart B—State Issuance of Experimental Use Permits

Sec.

Authority: Secs. 5(f) and 25(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended by the Federal Environmental Pesticide Control Act of 1972 (86 Stat. 997).

Subpart B—State Issuance of Experimental Use Permits

§ 172.20 Scope.

This Subpart sets forth regulations governing State issuance of experimental use permits to allow persons to gather data necessary to register pesticides with the State in order to meet special local needs. It also sets forth regulations governing authorization of State experimental use permit programs by the Administrator.

§ 172.21 Definitions.

Terms used in this Subpart shall have the meanings set forth in the Act and in 40 CFR 172.1 and 40 CFR 162.152.

§ 172.22 General.

(a) The scope of the requirement for an experimental use permit (within the meaning of "pesticide" as defined in the Act) is set forth in 40 CFR 172.3, which is hereby incorporated by reference in this Subpart.

(b) Pesticide products under experimental use permits may not be sold or distributed other than through participants and, if sold or distributed through participants, may be used only at an application site of a cooperator and in accordance with the terms and conditions of the experimental use permit.

(c) Establishments in which pesticide products under State experimental use permits are produced shall be registered in accordance with regulations under Section 7 of the Act and shall maintain books and records in accordance with regulations under Section 8 of the Act.

§ 172.23 State issuance of permits.

(a) General: Upon approval of the State plan by the Administrator, the designated State agency may issue, amend, renew, deny or revoke experimental use permits subject to such terms and conditions as may be provided in the authorization.

(b) A designated State agency shall not issue any experimental use permit:

(1) For any pesticide product or use for which the State is not certified to issue a special local need registration pursuant to Section 24(c) of the Act (40 CFR 162 Subpart B).

(2) For any pesticide product or use for which State registration is prohibited under 40 CFR 162.153(c)(2)(i)–(iv); or

(3) For use of a pesticide product in an amount or an application to an area in excess of that necessary to gather data in support of an application for State registration.

§ 172.24 Administration of state programs.

(a) State experimental use permit programs shall be generally consistent with the federal experimental use permit program, as set forth in 40 CFR 172, Subpart A.

(b) Procedures leading to issuance: (1) An application for an experimental use permit shall be made in writing, and shall contain sufficient information to enable the State to determine whether use pursuant to the permit would be in accordance with the purposes of the Act and this Subpart.

(2) Labeling: (i) New products shall bear labeling satisfying the requirements of 40 CFR 172.6(a). The designated State agency may approve the use of the experimental program as directions for use, if such program is to be distributed with the product.

(ii) The designated State agency may permit an EPA or state registered pesticide to be used under an experimental use permit to gather data necessary to support a registration for a modified or additional use with supplemental labeling as approved by it. In exercising this discretion, the designated State agency shall ensure that the supplemental labeling and the registered label together satisfy the requirements of 40 CFR 172.6(a).

(3) Duration: State experimental use permits shall be issued for a specified period of time (normally one year), depending upon the nature of the pest problem and the requirements of the testing program submitted. The designated State agency should require the applicant to propose a suitable duration of the permit commensurate with the program submitted. The designated State agency may renew, extend or amend a permit, if circumstances warrant.

(4) Limitations: The designated State agency shall impose such limitations in the permit as are necessary to protect health and the environment, including limitations on quality, sites, areas, and other parameters of pesticide use.

(c) *Program surveillance and reporting of data:* (1) The permittee shall supervise the test program and evaluate the results of testing at each site of application. The designated State agency shall require the permittee to report to it immediately any adverse effects from use of, or exposure to, the pesticide.

(2) Reports: (i) During the course of the program, the designated State agency shall require the permittee to submit such reports (both special and periodic) as are necessary to effectively supervise the progress of the program to prevent unreasonable adverse effects on man or the environment. The designated State agency shall also require the permittee to submit a final report at the conclusion of the program.

(ii) Where applicable, reports shall be made to the U.S. Department of Agriculture, Animal and Plant Health Inspection Service, as required by 40 CFR 172.8(c).

(3) Inspection: The designated State agency shall require the permittee or participants in the experimental use program to allow any authorized representative of the designated State agency, upon presentation of official identification, to enter at any reasonable time, any premises involved in the testing program to inspect and to determine whether there has been compliance with the terms and conditions of the permit.

§ 172.25 EPA review.

(a) *Notification of state action.* (1) Within 10 days after the issuance of an experimental use permit, the designated State agency shall notify EPA of such issuance by forwarding a copy of such permit and a description of the experimental program to be conducted under the terms of the permit.

(2) Within 10 days after amendment or revocation of an experimental use permit by a State, the designated State agency shall notify EPA in writing of such amendment or revocation. Such notice shall include a brief explanation of the reasons for the amendment or revocation. Where amendments to permits include changes in the approved labeling, the designated State agency shall also forward a copy of the amended labeling.

(3) EPA shall give notice in the FEDERAL REGISTER of State issuance of experimental use permits, or amendments thereto.

(b) *Reports.* The designated State agency shall submit such reports to EPA in such form and containing such information as EPA may from time to time require.

(c) *Revocation by EPA.* (1) The Administrator may revoke an experimental use permit issued under this Subpart if he finds:

(i) Its terms and conditions are being violated;

(ii) Its terms and conditions are inadequate to avoid unreasonable adverse effects on the environment;

(iii) New evidence which demonstrates that any tolerance will be inadequate to protect the public health, or that any exemption from the requirement for a tolerance is no longer appropriate; or

(iv) A failure to meet any other provision of the Act or this Subpart.

(2) Prior to revoking a state experimental use permit, the Administrator shall consult with the State which issued the permit.

(3) The Administrator shall notify the permittee in writing of such revocation.

(4) The permittee shall notify all participants of such revocation as soon as possible after he receives notice of revocation.

(5) The revocation of a permit shall not preclude the Administrator from initiating civil or criminal sanctions for the violations of the permit conditions or otherwise as authorized by law.

(6) Hearings: (i) If an experimental use permittee wishes to contest the revocation of any such permit, he shall, within 20 days after receipt of notice of such revocation, file with the Administrator a written request for an opportunity to confer with the Administrator (or his designee).

(ii) Within 20 days after such conference, the permittee shall be notified of the Administrator's final decision.

§ 172.26 Authorization.

(a) A State may, by submitting a State Plan, request the Administrator to authorize the designated State agency to issue experimental use permits to allow persons to gather the data necessary to support the State registrations of pesticides to meet special local needs.

(b) The Administrator may grant such authorization if the State Plan establishes that the designated State agency:

(1) Has been certified to issue registrations of pesticides to meet special local needs within the requirements of 40 CFR 162 Subpart B;

(2) Has adequate legal authority, including authority:

(i) To issue experimental use permits, subject to limitations necessary for the protection on public health and the environment,

(ii) To supervise the use pursuant to an experimental use permit, as provided in § 172.24(c),

(iii) To deny an experimental use permit if it determines that a permit is not justified, or that the issuance of the permit would cause unreasonable adverse effects on the environment,

(iv) To amend or revoke an experimental use permit, if it finds:

(A) Its terms and conditions are being violated,

(B) Its terms and conditions are inadequate to avoid unreasonable adverse effects on the environment,

(C) Any required tolerance has been revoked by EPA, or any exemption from the requirement for a tolerance has been withdrawn by EPA, or

(D) A failure to meet any other provision of the Act or this Subpart.

(v) To comply in all other respects with the requirements of this Subpart; and

(3) Utilizes procedures for the review of permit applications, and for the supervision of use pursuant to a permit program that are adequate to assure that the State program will be administered in accordance with the purposes of the Act or this Subpart.

(c) Revocation: The Administrator may at any time revoke the authorization of a State to issue experimental use permits if he determines that the designated State agency has not complied with the requirements of this Subpart or with the terms and conditions of such authorization.

§ 172.27 State plans.

(a) A State may request authorization to issue experimental use permits at the time it requests certification under section 24(c) or at any time thereafter. States shall request authorization by having the Governor submit a State plan in writing to the Administrator. A copy should be provided to the appropriate EPA Regional Administrator.

(b) None of the information provided in support of a request for EPA certification to issue special local need registrations need be duplicated in the State plan for the purpose of requesting authorization to issue experimental use permits.

(c) A State Plan shall include: (1) Designation of the State agency responsible for the administration of the State experimental use permit program;

(2) An opinion of the State Attorney General or the legal counsel of the designated State agency that the State has the requisite legal authorities as set forth in Section 172.26(b)(2) of this Subpart, accompanied by copies of the applicable State laws and regulations;

(3) A description of procedures the designated State agency will follow:

(i) To review experimental use permit applications, to ensure that experimental use permits will be issued in accordance with the terms and conditions of the authorization, the Act, and this Subpart, and

(ii) To supervise use pursuant to the permits, to ensure that permits are used in accordance with their terms and conditions, the Act, and this Subpart.

(d) After receiving a State plan, EPA shall publish a FEDERAL REGISTER notice thereof and invite interested parties to comment thereon.

(e) EPA shall approve or reject the State plan as expeditiously as possible and shall attempt to do so within 90 days after receipt of all information considered necessary for proper review of the State plan.

(f) Notices of approval, intention to reject, rejection, intention to revoke, and revocation shall be published in the FEDERAL REGISTER.

(g) Prior to rejecting or revoking authorization, the Administrator shall notify the State in writing of his intention to take such action and shall afford the State the opportunity for a hearing as provided in section 4(b) of the Act.

[FR Doc.75-23349 Filed 9-2-75;8:45 am]

FEDERAL DEPOSIT INSURANCE CORPORATION

[12 CFR Part 337]

APPROVAL AND RECORD KEEPING REQUIREMENTS PERTAINING TO INSIDER TRANSACTIONS

Notice of Proposed Rule Making

1. Notice is hereby given that the Board of Directors (the "Board") of the Federal Deposit Insurance Corporation ("Corporation"), pursuant to the authority in sections 7(a), 8(a), 8(b), 8(e), 9 Tenth, 1820(b) and 1820(c)) is considering the addition of a new § 337.3 to Part 337 of Title 12 of the Code of Federal Regulations. The purpose of the proposed regulation is to curb abuses arising out of the dealings of insiders with insured nonmember banks through the establishment of procedures which will insure that bank boards of directors supervise such transactions effectively and which will better enable Corporation examiners to identify and analyze such transactions.

The experience of the Corporation indicates that many banks have suffered significant loan losses, loss of revenue, excessive costs, and other substantial economic detriment as a result of ill-considered transactions with insiders. The need for more vigorous supervision of such transactions by boards of directors and bank supervisory agencies is indicated by the fact that abusive self-dealing has been the primary cause or a significant contributing cause in more than half of all bank failures since 1960, including the failure of 29 nonmember insured banks. The most dramatic example of the consequences of abusive self-dealing is the 1973 failure of United States National Bank, San Diego, California, for which the Corporation has already had to establish a reserve of $150 million for losses to the deposit insurance fund. Review of existing and past "problem" bank cases reveals a similar predominance of insider overreaching as a source of serious difficulty. Moreover, an insider transaction that is not effected on an "arm's length" basis may lead to a diminution of earnings and an erosion of capital, even where the immediate result is not the bank's failure or its designation as a "problem" institution. It follows, therefore, that insider transactions whose terms and conditions cannot be justified under all the circumstances surrounding the transaction, increase the risk of loss to depositors and ultimately to the deposit insurance fund. In addition, such transactions represent a diversion to insiders of resources that properly belong to all shareholders on a pro rata basis.

The proposed regulation would seek to minimize the risk of such abuse in insured nonmember banks by requiring meaningful board of directors review of significant insider transactions and by requiring the maintenance of certain records designed to facilitate internal control and examiner analysis of these transactions. In addition, the proposed regulation lists some of the factors which the Corporation would consider in determining whether an insider transaction or group of insider transactions indicates the presence of an "unsafe or unsound" banking practice and what kind of corrective supervisory action is warranted.

Although the Corporation has determined that insider transactions require special supervision by bank boards of directors and close scrutiny by the Corporation's examiners, this determination does not mean that all transactions with insiders or their interests are detrimental to the bank in question, or that they should be discouraged. Rather, the focus of the proposed regulation is the establishment of internal bank procedures which will minimize the potential for abuse that inheres in the context of insider transactions. At the same time, the Corporation has sought to avoid unrealistic prohibitions or unduly burdensome requirements.

The regulation would apply to all insured State nonmember banks. It defines an "insider" as any director; officer or employee in a position to influence a bank's management or policies; or any other person who has direct or indirect control over the voting rights of more than five percent of the shares of any class of voting stock of a bank. An insider transaction is considered to be any business transaction between an insured State nonmember bank or a subsidiary of such a bank and an insider, certain close relatives of the insider, a related corporation, or interests of the insider. An insider transaction would also encompass any transaction between the bank and a non-insider where the trans-

action is made in contemplation of the person becoming an insider or where the transaction ultimately inures to the benefit of an insider, or persons related to an insider. Certain routine transactions are expressly excluded from the coverage of the proposed regulation, and public comment is invited particularly with respect to other transactions which might also appropriately be excluded.

Under the proposed regulation, the board of directors of each insured State nonmember bank would be required to review and approve each insider transaction involving assets or services having a fair market value greater than a specified amount which varies with the size of the bank. Although not specifically required by the proposed regulation, prior review and approval is desirable and should occur except under circumstances which render such review and approval clearly impractical. Where prior review and approval by the board of directors is clealy impractical, subsequent action should occur as soon as possible.

The inclusion of a schedule of minimum dollar amounts that will trigger the approval requirement is based upon a determination that effective board of directors review is possible only if the number of transactions subject to review is limited. Accordingly, the Corporation proposes to require approval only for those insider transactions which, alone or taken in the aggregate, are deemed significant relative to the size of the bank. This determination also reflects the fact that the impact of a transaction of a given size will vary depending, among other things, on the size of the bank. However, the inclusion of such a schedule is not intended to suggest that insider overreaching involving a transaction smaller than the minimum amount will not be the subject of examiner comment or corrective action on the part of the Corporation.

For the purpose of applying the review and approval requirement schedule, the proposed regulation provides for the aggregation of insider transactions. Aggregation would operate in one of two ways, depending upon the nature of the insider transaction. First, any insider transaction which is a loan or other extension of credit would be aggregated with the outstanding balances of all other loans or extensions of credit involving the same insider.[1] Second, any insider transaction which is not a loan or other extension of credit would be aggregated with all similar transactions involving the same insider which have occurred during the twelve months preceding such transaction. Accordingly, when the amount of such transactions, aggregated according to the appropriate method, reaches the prescribed minimum amount in the schedule, board of directors review and approval would be required. The purpose of this provision is to avoid circumvention of the proposed review and approval process by effecting a series of transactions none of which involves an amount greater than the scheduled minimum but which, in the aggregate, are significant.

In order to facilitate examiner review of insider transactions and to foster effective internal controls over such transactions by the bank itself, the proposed regulation would impose two record keeping requirements. First, the minutes of the meeting where approval of an insider transaction or group of insider transactions is given would be required to reflect the nature of the transaction, the parties to the transaction, that such review was undertaken and approval given, the names of individual directors who voted to approve or disapprove the transaction, and, in the case of negative votes, an optional statement by each dissenting director of his or her reasons for voting to disapprove the proposed insider transaction. Second, the proposed regulation would require each bank to maintain a separate file on all insider transactions involving the same insider for which review and approval is required under paragraph (b). Such files would contain all documents and other material relied upon by the board in approving each transaction, including the name of the insider, the insider's position or relationship that causes such person to be considered an insider, the date on which the transaction was approved by the board, the type of insider transaction and the relevant terms of the transaction, any other pertinent facts which serve to explain or support the basis for the board's decision, and any statements filed by directors who voted not to approve the transaction setting forth their reasons for such vote.

In order to facilitate compliance with its approval and review requirements, the proposed regulation would require an insider having knowledge of a proposed insider transaction with which he or she is involved to give timely notice of such transaction to the bank's board of directors. Also, when the bank itself becomes aware of the existence of a completed insider transaction which has not been reviewed and approved in compliance with the regulation, the bank would be required to report such transaction promptly to the FDIC Regional Director with jurisdiction over the bank.

Finally, the proposed regulation makes clear that formal compliance with its review and approval requirements neither relieves the bank of its obligation to conduct its operations in a safe and sound manner nor prevents the Corporation from taking whatever supervisory action it deems necessary and appropriate with respect to any insider transaction or group of insider transactions, including the institution of formal proceedings under section 8 of the Federal Deposit Insurance Act. In addition, the proposed regulation sets forth the factors which will be considered by the Corporation's Board of Directors in determining whether such transaction or transactions indicate the presence of unsafe or unsound banking practices. These factors include: whether, because of preferential terms and conditions, such insider transactions are likely to result in significant loan losses, excessive costs, or other significant economic detriment which would not occur in a comparable arm's length transaction with a person of comparable creditworthiness or otherwise similarly situated; whether transactions with an insider and all persons related to that insider are excessive in amount, either in relation to the bank's capital and reserves or in relation to the total of all transactions of the same type; and whether from the nature and extent of the bank's insider transactions it appears that certain insiders are abusing their positions with the bank.

2. The proposed new § 337.3 reads as follows:

§ 337.3 Insider transactions.

(a) *Definitions.* (1) *Bank.* The term "bank" means an insured State nonmember bank and any subsidiary controlled by such bank.

(2) *Person.* The term "person" means a corporation, partnership, association, or other business entity; any trust; or any natural person.

(3) *Control.* The term "control" (including the terms "controlling," "controlled by," and "under common control with") means the possession, directly or indirectly, of the power to direct or cause the direction of management and policies of a person, whether through the ownership of voting securities, by contract, or otherwise.

(4) *Insider.* The term "insider" means any officer or employee in a position to influence management or policies, any director, or any other person who has direct or indirect control over the voting rights of more than five percent of the shares of any class of voting stock of a bank.

(5) *Persons related to an insider.* The term "person related to an insider" means any person controlling, controlled by or under common control with an insider, and, in the case of a natural person:

(i) An insider's spouse;

(ii) An insider's parent or stepparent, child or stepchild, or sibling; and

(iii) Any other relative who lives in an insider's home.

(6) *Insider transaction.* The term "insider transaction" means any business transaction or series of related business transactions between a bank and:

(i) An insider of the bank;

(ii) A person related to an insider of the bank;

(iii) Any other person where the transaction is made in contemplation of such person becoming an insider of the bank; or

(iv) Any other person where the transaction inures to the benefit of an insider or a person related to an insider.

(7) *Business transaction.* The term "business transaction" includes, but is

[1] For the purposes of the proposed regulation, an insider transaction "involves" a given insider if the transaction in question is between the bank and (a) such insider; (b) a person related to such insider; (c) such insider prior to his or her becoming an insider but made in contemplation of that event; and (d) any other person where the transaction inures to the benefit of such insider or a person related to such insider.

not limited to, the following types of transactions:

(i) Loans or other extensions of credit;

(ii) Purchases of assets or services from the bank;

(iii) Sales of assets or services to the bank;

(iv) Use of the bank's facilities, its real or personal property, or its personnel;

(v) Trust activities;

(vi) Leases of property to or from the bank; and

(vii) Payment by the bank of commissions and fees, including brokerage commissions and consultant, architectural and legal fees.

For the purpose of this regulation, the term does not include routine deposit account activities, safekeeping transactions, credit card transactions, or transactions which involve the purchase from or sale to an insider and all persons related to that insider of property used in the normal conduct of the bank's business where the aggregate fair market value of all such property purchased or sold in any 12-month period does not exceed $1,000.

(b) *Approval and Disclosure of Insider Transactions.* An insider transaction, either alone or when aggregated in accordance with the provisions of paragraph (c) of this section, involving assets or services having a fair market value amounting to more than:

(1) $10,000 if the bank has less than $25,000,000 in total assets;

(2) $20,000 if the bank has at least $25,000,000 and not more than $100,000,000 in total assets;

(3) $50,000 if the bank has more than $100,000,000 and not more than $500,000,000 in total assets; or

(4) $100,000 if the bank has more than $500,000,000 in total assets

must be specifically reviewed and approved by the bank's board of directors.[1] The minutes of the meeting where approval is given must indicate the nature of the transaction, the parties to that transaction, that such review was undertaken and approval given, and the names of individual directors who voted to approve or disapprove the transaction. In the case of negative votes, a brief statement of each dissenting director's reason for voting to disapprove the proposed insider transaction must be included in the minutes if its inclusion is requested by the dissenting director.

[1] Where a transaction is part of a series of related transactions with the same insider or persons related to such insider, such as drawdowns under a line of credit, approval of each transaction will not be necessary so long as the bank's board of directors approves the entire series of such transactions, and so long as the minutes of the meeting where approval is given clearly show that the board approved the specific terms and conditions under which each transaction would take place and that approval was granted only upon the condition that the entire series of transactions would be subject to appropriate restrictions, including limitations as to time and aggregate amount.

(c) *Aggregation of insider transactions.* For the purposes of paragraph (b) of this section, insider transactions will be aggregated with other insider transactions which involve the same insider in the following manner:

(1) *Loans or other extensions of credit.* Any loan or other extension of credit will be aggregated with the outstanding balances of all other loans or extensions of credit which involve the same insider.

(2) *Other insider transaction.* Any insider transaction which is not a loan or extension of credit will be aggregated with all other such insider transactions which involve the same insider and have occurred during the twelve months preceding such transaction.

(d) *Bank files maintained for insider transactions.* Each bank shall maintain a separate file on all insider transactions involving the same insider for which review and approval is required under paragraph (b) of this section. Such files shall contain all documents and other material relied upon by the board in approving each transaction, including the name of the insider, the insider's position or relationship that causes such person to be considered an insider, the date on which the transaction was approved by the board, the type of insider transaction and the relevant terms of the transaction, any other pertinent facts which serve to explain or support the basis for the board's decision, and any statements submitted for the file by directors who voted not to approve the transaction setting forth their reasons for such vote.

(e) *Discovery of insider relationship.* When a bank becomes aware of the existence of an insider relationship after entering into a transaction for which approval would have been required under paragraph (b) of this section, the bank shall promptly report such transaction to the Regional Director of the Corporation in charge of the Region in which the bank is headquartered.

(f) *Knowledge of proposed insider transactions.* Any insider, having knowledge of a proposed insider transaction between the bank and:

(1) Such insider;

(2) A person related to such insider; or

(3) Any other person where the transaction inures to the benefit of such insider or a person related to an insider.

shall give timely notice of such transaction to the bank's board of directors.

(g) *Supervisory action in regard to certain insider transactions.* Notwithstanding compliance with the review and approval requirements of paragraph (b) of this section, the Corporation will take appropriate supervisory action against the bank, its officers or its directors when the Corporation determines that an insider transaction, alone or when aggregated with other insider transactions, is indicative of unsafe or unsound practices. Such supervisory action may involve institution of formal proceedings under section 8 of the Federal Deposit Insurance Act. Among the factors which the Corporation will consider in determining the presence of unsafe or unsound banking practices involving insider transactions are:

(1) Whether, because of preferential terms and conditions, such insider transactions are likely to result in significant loan losses, excessive costs, or other significant economic detriment which would not occur in a comparable arm's length transaction with a person of comparable creditworthiness or otherwise similarly situated;

(2) Whether transactions with an insider and all persons related to that insider are excessive in amount, either in relation to the bank's capital and reserves or in relation to the total of all transactions of the same type; and

(3) Whether, from the nature and extent of the bank's insider transactions, it appears that certain insiders are abusing their positions with the bank.

3. This notice is published in accordance with the provisions of 5 U.S.C. section 553(b) and 12 CFR §§ 302.1, 302.2 and 302.3 regarding notice and public participation.

4. All interested persons are invited to submit comments in writing on or before October 31, 1975 to Alan Miller, Executive Secretary, Federal Deposit Insurance Corporation, 550 17th Street, NW., Washington, D.C. 20429. The Corporation is particularly interested in public comment on the practicality of the proposed requirements and whether or not they meet the need for more effective supervision of this type of transaction. All written comments will be made available for public inspection during regular business hours at the Office of the Executive Secretary, Room 6108, at the above address.

By Order of the Board of Directors, August 28, 1975.

[SEAL] ALAN R. MILLER,
Executive Secretary.

[FR Doc.75-23345 Filed 9-2-75;8:45 am]

SECURITIES AND EXCHANGE COMMISSION

[17 CFR Part 210]

[Release Nos. 33-5608, 34-11608, 35-19137]

REPLACEMENT COST DATA

Proposal To Require Disclosure

In January 1974 in Accounting Series Release No. 151 (39 FR 2085), the Commission called attention to the problems caused by inflation in the interpretation and use of financial statements prepared on the basis of the historical monetary cost data currently required by generally accepted accounting principles. At that time the Commission urged supplemental disclosure of data showing the magnitude of "inventory profits" which it defined in the release as the difference between the historical cost of goods sold and the current replacement cost of such goods at the time of sale. The Commission has observed very little response to this specific suggestion in communications between registrants and investors, nor has it seen any significant

evidence of systematic attempts to quantify the effect of changing current costs on the economics of a registrant's business, despite the fact that prices and the rate of inflation increased substantially in 1974.

While the current general rate of inflation has been reduced from 1974 levels, it still persists at a rate substantially above historical norms for the United States. In addition, the general rate of inflation does not reflect the impact of price changes on a particular company. The impact of such price changes may be substantially greater or less than that indicated by an average or general rate of inflation encompassing all price changes in an economy since it is characteristic of an inflationary economy that specific price relationships realign rapidly and unevenly relative to the general rate of inflation.

In the light of the current rate of inflation and price changes, therefore, the Commission has concluded that it is necessary to propose amendments to its Regulation S–X (17 CFR Part 210) which would require registrants to disclose in the footnotes to financial statements the current cost at the end of the reporting period of replacing inventories and productive capacity as well as the cost of sales and depreciation, depletion, or amortization expense computed on the basis of replacement cost during the reporting period. The Commission believes that these data will make it possible for investors to obtain a better understanding of the current costs of operating the business which cannot be obtained from historical cost financial statements taken alone and that such an understanding is necessary in order to make informed investment decisions. Under current conditions, the Commission is not prepared to conclude that the basic accounting model needs to be changed to reflect replacement cost or other current value data in lieu of historical cost data in the financial statements. In addition, it notes that this is one of the matters being investigated by the Financial Accounting Standards Board in connection with the Board's inquiry into the conceptual framework for financial statements. The Commission believes that such a fundamental change in the basic accounting model should only be made, if at all, after such a study. At the same time, it believes that the absence of any current cost or value information is a significant shortcoming for users of financial data about business activities, and it feels that these proposed requirements for supplemental information will materially assist financial statement users in the interim.

The Commission also notes that in Securities Act Release No. 5427 issued in 1973 (38 FR 28948) it proposed footnote disclosure of cost of sales on a replacement cost basis with the primary objective of obtaining some measure of comparability among companies using different historical cost methods of computing cost of sales. No final rules encompassing those proposals have yet been adopted. Although the principal focus of the rules proposed herein is to provide current economic data, an additional benefit will be to provide information which will assist investors in comparing companies which use alternative methods for cost of sales and depreciation permitted under current generally accepted accounting principles.

While the Commission's objective in proposing these rules is to improve investment decision making, it believes the data will also be useful to managers for internal purposes and to macro-economic decision makers who have responsibility for determining economic policies which affect business activities.

In addition, the Commission has noted the development of proposals to permit business entities to calculate depreciation for tax purposes on the basis of current replacement cost.[1] Such an approach would reflect in the calculation of taxable income the current value of capital consumed. The development of regular replacement cost data on a systematic basis for reporting to investors will enable the makers of tax policy to determine explicitly the effect of present taxes on economic capital and to estimate the impact of alternatives. It would also assist corporations in creating a data base which may ultimately be used for tax reporting purposes.

Finally, analysis of the data provided in supplemental footnote disclosure and the experience gained by registrants in preparing the data should assist the Financial Accounting Standards Board in making determinations concerning changes in the framework for financial reporting.

In proposing these rules, the Commission is fully aware that there will be many problems of implementation and that the cost of developing the required information may be significant. Guidelines for implementation of the rules proposed herewith accompany the proposal. The Commission welcomes comments on these guidelines as well as on the rules, and it urges registrants to use the relatively long comment period to experiment in the application of the rules and guidelines to their particular circumstances and to report the results of these experiments to the Commission. The Commission is particularly interested in receiving information about specific problems in implementing the proposals, receiving suggestions about the least costly means of developing the required data, and obtaining specific data with respect to the cost of implementation supported by exhibits showing how such costs were estimated.

The Commission wishes to emphasize that it recognizes that the data proposed to be required herein will require the use of a substantial number of estimates and judgments in its preparation. The objectivity which exists when data are developed by accumulating the results of many specific transactions will not exist in this case. Data preparers will generally have to make use of estimating and sampling techniques in developing specific indices (or making use of specific indices now available) that cover certain specific types of goods and services, judge the appropriateness of grouping certain assets together for revaluation, determine the frequency with which indices should be updated, and the like. Due to the lack of definitive standards at this time, the resulting computations will inevitably result in greater subjectivity than is the case with traditional accounting information. The Commission believes that, as experience is gained, greater objectivity can be achieved and more specific computational guidelines can be developed. However, it also believes that the resulting data at present will be sufficiently specific and of great utility to investors and that it is not appropriate to wait for great computational refinement before presenting such information to financial statement users.

In this connection, comments are specifically solicited concerning whether the note containing these data should be labelled "unaudited," at least initially. Such an approach may communicate to investors the lack of objective standards and precision inherent in the data. It may also reduce the cost of presenting the data by reducing the procedures which would have to be followed by independent public accountants if the footnote data were not so labelled. On the other hand, it may reduce the reliability of the information in an area where the accountant's judgment may be particularly needed.

The Commission also specifically solicits comments on the desirability of initially requiring these data only from those companies which exceed a particular size criterion as well as comments on what appropriate size criterion might be used. The proposed requirement might apply, for example, only to companies whose total sales or total assets exceed $50 million. In this fashion, large companies with more sophisticated accounting systems and more extensive stockholder groups would initially present these data, and the rule could be extended to smaller registrants after more experience is gained in its implementation.

Commission action. The Commission hereby proposes to amend Part 210 (Regulation S–X) of 17 CFR Chapter II by adding to § 210.3–16 paragraph (w) as given below.

§ 210.3–16 General notes to financial statements. (See Release No. AS–4.)

* * * * *

(w) *Current replacement cost information.* (1) The current replacement cost of inventories at each fiscal year end for which a balance sheet is presented shall be stated. If current replacement cost exceeds net realizable value at that date, that fact shall be stated and the amount of the excess disclosed.

(2) For the two most recent fiscal years, state the approximate amount

[1] See, for example, the report of the Committee of Inquiry into Inflation and Taxation, chaired by Professor Russell Mathews and appointed by the Prime Minister of Australia in 1974.

which cost of sales would have been if it had been calculated by estimating the current replacement cost of goods and services sold at the times when the sales were made.

(3) State the estimated current cost of replacing the productive capacity together with the current net replacement cost represented by the depreciable, depletable and amortizable assets on hand at the end of each fiscal year for which a balance sheet is presented.

(4) For the two most recent fiscal years, state the approximate amount of depreciation, depletion and amortization which would have been accrued if it were estimated on the basis of average current replacement cost of productive capacity. For purposes of this calculation, economic lives or salvage values currently used in calculating historical cost depreciation, depletion or amortization shall generally be used. For assets being depreciated, depleted or amortized on a time expired basis, the straight-line method shall be used in making this calculation. For assets depreciated, depleted or amortized on any other basis (such as use), that basis shall be used for this calculation.

(5) Describe the methods used in determining the amounts disclosed in paragraphs (w) (1) through (4) of this section. Describe what consideration, if any, was given in determining the answers to paragraphs (w) (1) and (2) of this section to the related effects on direct labor costs, repairs and maintenance, utility and other indirect costs as a result of the assumed replacement of productive capacity. Where the economic lives or salvage values currently used in historical cost financial statements are not used in paragraph (w)(4) of this section above, an explanation of other bases used and the reasons therefor shall be disclosed. If depreciation, depletion or amortization expense is a component of inventory costs or cost of sales, indicate that fact and cross-reference the answer for this paragraph in paragraph (w)(2) of this section in order to avoid potential duplication in the use of these data.

(6) Furnish any additional information—such as the historical customary relationships between cost changes and changes in selling prices, the difficulty and related costs (including financing) which might be experienced in replacing productive capacity—necessary to prevent the above information from giving misleading implications.

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GUIDELINES FOR THE IMPLEMENTATION OF PROPOSED RULE 3-16(W)

Introduction. Although it is relatively easy to set forth the broad concepts underlying the determination of replacement cost computation for inventories, cost of sales, depreciable, depletable and amortizable assets, and depreciation, depletion and amortization expense, it is recognized that no simple rules can be devised that would cover the application of such concepts in all situations which may arise. Accordingly, the following guidelines are offered as further clarification of replacement cost concepts as used herein and as an aid to judgments required during implementation of such concepts. These guidelines are not intended to be either rigorous or exhaustive.

General guidelines. There appear to be various points of view concerning how the effects of inflation on a business entity should be measured. Some suggest that the best approach is to adjust all data prepared on a historical monetary unit basis by some index reflecting the composite effect of price changes throughout the economy so as to reflect historical costs on the basis of purchasing power units. Others believe that the impact of inflation on a particular entity cannot be determined without considering the specific price changes experienced by that entity in an inflationary economic environment which is typically characterized by wide dispersion in price movements. There are also those who believe that both effects should be considered by analyzing changes in specific prices affecting the firm in terms of the proportion which results from general changes in purchasing power and the proportion which results from other factors.

In proposing limited supplemental disclosure of replacement costs, the Commission is requiring the presentation of data which reflect the impact of specific price changes on the firm. In so doing, the Commission is not reaching the conclusion that data reflecting historical costs on the basis of general purchasing power units would not be useful, nor is it suggesting that these data would not be valuable in analyzing specific price changes. At the present time, however, the Commission is not proposing to require the presentation of data on a general purchasing power basis.

The basic objective of the Commission in proposing to require replacement cost data is to give investors information about the current economics of business operations rather than the value of business assets. The disclosures proposed do not represent a current value approach, although presumably assets measured by current cost will more closely approximate current value than will historical cost data. Accordingly, the proposal does not require disclosures related to assets other than inventories and certain depreciable, depletable or amortizable assets which represent the operating assets of a business. It does not propose supplemental disclosures in regard to monetary assets or liabilities, investments held for monetary gain rather than operating use, or goodwill. Similarly, if assets not essential to operations (e.g., an abandoned plant or excess land) are included in fixed assets, such assets, if significant, should be set forth separately on the balance sheet and no supplemental replacement cost data need be reported in accordance with the proposed rules. Such nonessential assets have also been characterized as severable assets which may be disposed of without impairing the firm's operating objectives and commitments. Such assets are generally not depreciated, depleted or amortized and are carried on the financial statements at the lower of cost or net realizable value. In cases where net realizable value is materially above cost and the intention to dispose of the assets exists, additional disclosure of the net realizable value would ordinarily be desirable.

In addition, the release does not propose to require revised financial statements even on a supplemental basis, nor does it require the specific disclosure of the effect on net income of applying replacement cost methods. Accordingly, although "holding gains and losses" are implicit in asset balances computed on a replacement cost basis, this release does not attempt to deal with the issue of whether or not such amounts should be recognized in the statement of operations. It is noted that the issue of what constitutes appropriate treatment of gains and losses currently is a cause for great debate, which is part of the study of the conceptual framework for financial statements now being undertaken by the Financial Accounting Standards Board. The disclosure of selected asset balances and expense items indicating the impact of price changes on these elements of the entity will serve as highly useful information until these issues are resolved and more comprehensive reporting procedures are developed.

The definition of replacement cost. For purposes of this release, replacement cost is the lowest amount that would have to be paid in the normal course of business to obtain an asset of equivalent operating or productive capability. In the case of depreciable, depletable or amortizable assets, gross and net replacement cost should be distinguished. Gross replacement cost is the total estimated current cost of replacing total productive capacity at the end of the year while net replacement cost is the gross replacement cost adjusted for the already expired service potential of such assets. Similarly, reproduction cost, which is the cost to replace an existing asset in identical form but at current price levels, should be distinguished. Frequently replacement cost and reproduction cost are considered interchangeable. When there is no change in technology (affecting the output of the asset) or materials (affecting the input costs of the asset), both methods should provide the same results. When such changes have occurred, however, replacement cost is a more accurate representation of asset value since it gives recognition to both functional and technological obsolescence. This distinction will be discussed further below.

One of the objectives inherent in the replacement cost approach is to measure the cost of maintaining the operating capability or productive capacity of the entity. Accordingly, it is the current cost associated with retaining the existing potential of the entity for providing goods and/or services. The concept does not necessarily imply that assets used up in operations will be or would have to be replaced with other identical assets.

In theory, replacement cost is applied on an item-for-item, transaction-by-

transaction basis. In practice specific indices are frequently applied to various asset groupings during the accounting period such that replacement cost and specific price level indexing methods become variants of one another. At present there is no generally available set of indices which appear useful to all entities or various operating segments of the entity. In determining replacement costs, the use of available public indices (e.g., wholesale price indices) is encouraged whenever possible since it will simplify implementation and will enhance the objectivity of the information. Data preparers will have to exercise judgment in determining whether such indices are an appropriate measure of the impact of price changes on the entity. In other cases data preparers will have to generate indices internally and will have to exercise judgment in grouping assets appropriately; in determining whether price changes for one, a few, or all assets in the group will be used to update the indices; and in deciding how frequently indices will have to be updated. A brief description of the assumptions and methods used is required under the proposed rule.

Replacement cost methods require the use of a number of estimates. Although in many cases these estimates may be statistically derived and thus objectively verifiable to some degree within the entity, the current lack of detailed standards will call for considerable judgment by data preparers. Until more experience is gained more detailed standards are not warranted and flexibility in dealing with implementation problems is encouraged along with a general description of the method used. Accordingly, it is recognized that the lack of detailed objective standards from outside the firm will frequently mean that replacement cost data will not be fully comparable between firms. Nevertheless, it is expected that replacement cost data will enhance comparability when compared with the variations that exist in current generally accepted accounting principles for inventories and depreciation which vary widely and lack detailed objective criteria for application. Although flexibility is encouraged, criteria adopted by the entity should be consistently applied. Any subsequent change in criteria should be disclosed when the impact of such a change is significant. In this way users of the information will be able to more accurately appraise the major impacts of price changes on the operations of a particular entity over time.

Occasionally entities engage in projects with relatively fixed terms. Examples of such projects are long-term construction contracts or contract research and development programs. Frequently assets associated with such projects have no utility apart from that project and are thus related to only the one particular production cycle contemplated under the particular project. Where this is the case the going concern or continuity of operations assumption implicit in the replacement cost method is not applicable. Accordingly, it is believed that in the usual case such assets are most appropriately valued on a historical cost basis.

Certain regulated companies have argued that any change in accounting valuation methods is inappropriate to such companies since their rate base is determined on some other basis. However, information about the impact of price changes on such companies should be provided since it appears relevant in appraising the rate-making process and in assessing the results and future prospects of such companies.

In the case of entities whose operations are denominated in foreign currencies, replacement cost calculations should be made on the basis of current costs in those currencies. In translating those data for purposes of the disclosures required under this rule, the exchange rate at the balance sheet date should be used for asset balances while the rates during the period should be used for computing expenses recognized during that period.

Some specific problems which may be encountered in the application of replacement cost concepts to the four specific disclosures proposed to be required by this release are discussed below.

Inventory. The amount shown for inventories in the footnote disclosure proposed to be required by this release is the replacement cost determined at each date for which a balance sheet is presented. Such data will not be changed in subsequent periods. For example, replacement cost of year-end 1974 inventory will be based on 1974 year-end prices and not revised in the following year when the statements are presented again on a comparative basis.

For purchased inventories, replacement cost should be based on current buying prices having regard to normal order quantities and supply conditions. When it is difficult or impractical to determine current buying prices on an item-by-item basis, it is frequently possible to approximate replacement costs through the application of specific price indices to the original or previously adjusted costs. Similar calculations are currently made in computing dollar-value LIFO inventory adjustments. For work in process and finished goods inventories, reference may be made to current reproduction costs for the particular inventories. This usually requires the maintaince of some form of a standard cost system. Standard costs realistically set and regularly updated to reflect current input costs, rates and operating conditions ordinarily constitute a reasonable approximation of replacement costs. This procedure will typically require a revaluation of depreciable, depletable or amortizable assets on a replacement cost basis. Standard cost systems based on the historical cost of productive facilities will generally not provide the appropriate data without adjustment.

As previously noted, considerable judgment will be needed in selecting and/or developing appropriate indices; in placing some, all, or none of the assets to be indexed into groups with relatively homogeneous cost characteristics; and in establishing the frequency (and method, if internally derived) of updating indices. The establishment of indices ordinarily will require the use of statistical techniques. During the period, indices for raw materials can be revised regularly (usually monthly or quarterly depending on the volatility of price changes) based on a sample of major input categories. For work in process and finished goods it is possible to regularly update standard cost formulae for a single product which is representative of a large product group and, in this manner, index the standard cost formulae for the entire product group. Periodic testing of the estimates and assumptions used in such approaches will facilitate increased accuracy in the selection and development of indices. Such approaches have been used in practice and it appears that the key to the development of increasingly useful information to management and shareholders is the refinement of indices through experience over time.

Obsolete or discontinued inventory items should be set forth separately and not included in replacement cost calculations. These items are not part of the continued production process and thus are not essential to the continuing of business operations.

If a company has as part of its continuing production process long-term supply contracts at a fixed price or at a price which accretes at a rate substantially below market price, the actual price paid under the contracts should be used in determining replacement costs. Where the amounts of inputs acquired under the contracts are a substantial part of the production process, the nature and term of such contracts should be disclosed.

Where the firm's current buying price at the end of the period is based upon a supply contract of short duration and does not reflect year-end market prices, estimated current market price rather than the firm's current contract buying price should be used.

Cost of sales. The amount shown for cost of sales should be based on current replacement costs determined during the course of the reporting period. Frequently such costs will constitute estimated average replacement costs based on indices and/or standard cost formulae used during the period. Accordingly, the same methods described in the Inventory Guidelines will be used to compute cost of sales. It should be noted, however, that more accurate estimates will typically be achieved by more frequent updating of indices and standard costs being applied.

In developing estimation techniques, the objective should be to determine the cost of replacing goods at the time sales were made. This will result in an investor being able to see the relationship between sales and cost of sales on a current basis. Computing cost of goods sold on the basis of end-of-period replacement cost of all goods sold during the period will not meet the objectives of this disclosure since it would not provide information about the

relationships between sales during the reporting period and cost of sales at the time when such sales were made and thus would not indicate the impact of price changes on operations during the period. To the extent that the relationships which exist on a replacement cost basis during the period are not indicative of the relationships existing at the end of the period or which are anticipated, such facts should be disclosed.

To the extent that cost of sales in the historical financial statements includes costs of individual projects of a unique sort which do not require the acquisition of goods and services which are regularly used in the registrant's production process, such as is the case in many research projects and in some construction projects accounted for on a percentage of completion basis, the historical cost of these projects should be used. If, however, such projects require the use of standard inputs acquired during the course of the project, current input cost data should be developed even if the end products produced are unique or unusual in nature.

Depreciable, depletable or amortizable assets. The amount shown for depreciable, depletable or amortizable assets at the end of the period should be based on replacement costs determined at that time. Such data should not be changed in subsequent periods when the statements are presented again on a comparative basis.

Ordinarily the current gross replacement cost along with current net replacement cost (as earlier defined) should be disclosed. Whenever such assets are revalued on the basis of their current replacement cost, it will be necessary to make an adjustment to accumulated depreciation in order to properly reflect service potential used up in prior periods expressed in terms of replacement cost at the current balance sheet date. For purposes of the disclosure required in this release this catch-up adjustment should not be included in revalued expense items called for by this release.

Certain intangible assets such as licenses, franchises and the like generally should be valued at replacement cost if they are of an essential nature to business operations. For other intangibles having unique characteristics (such as patents, trademarks and the like) historical cost may be used. Goodwill would not be included in the revaluation process due to lack of any objective criteria for evaluating it on an ongoing basis.

Other useful distinctions may be drawn. For example, specific assets may be distinguished by whether they are general purpose (e.g., standard machine tools) or special purpose (e.g., custom tools or processes). Replacement costs for general purpose tools may be determined directly (item-for-item at current replacement costs) or by reference to specific indices for an equivalent asset or group of equivalent assets. Special purpose and highly unique assets may be valued on the basis of estimated reproduction costs for the specific asset or on the basis of estimated unit costs to replace the asset with one that has an equivalent function (e.g., buildings may be classified by type and valued by a standard unit cost per square foot to replace that type of building).

Wherever possible, management should attempt to value specific assets. However, when various assets are used in an integrated or interdependent manner, it may be necessary to consider them as one item to determine their replacement cost. In such instances it is frequently possible to view such assets as an inseparable group and to value the group on the basis of the total number of units of output which can be produced by that group times the current per-unit replacement cost for the most efficient substitute available for producing such units. Such valuation may have to be adjusted for such factors as the physical size of the substitute or the utility of the increased output. It is recognized that a recurring problem will be determining what constitutes a most efficient substitute.

Related to that problem is the difficulty of valuing an asset on the basis of equivalent operating or productive capability. The necessity for determining an equivalent function arises because of technological innovations that make the most efficient replacement asset one that has similar output but different rates or quality of output, or because of the lack of availability of a strictly equivalent asset. There is no ready solution to these problems and the simplest answer is that considerable judgment may be required to determine equivalent functionality. One approach that has been used is to establish a basis of equivalent outputs. For example, the current replacement cost of a particular asset owned by the entity would be half the price of the nearest equivalent asset that would be purchased as a replacement in the ordinary course of business and that has double the capacity. In other instances, management may have to look at the overall utility of a particular asset to the entity. For example, even if automobiles have been substantialy technologically improved, the relevant factor may be that the entity needs one unit of transportation. In such a case no consideration should be given to technological improvements in the replacement automobile.

For purposes of this release, land is generally excluded from replacement cost considerations since in the ordinary case land is either not used up in the productive process or it is held as an investment and is not essential to continued operations. However, it should be noted that in some circumstances current values for land held by the entity may be of substantial importance in appraising the investment value of that entity. Although this situation is not directly contemplated by this release, entities are encouraged to disclose estimated current values for such land where such values vary significantly from historical cost, as well as the basis or method used for establishing the current value of such land. Entities supplying such information will ordinarily be expected to demonstrate to the staff of the Commission that such values are reasonably derived.

A special problem in applying the replacement cost concept occurs when attempting to value natural resource reserves. It is not meaningful to measure the cost of reproducing the specific mines or wells which comprise the depletable assets of a natural resource company. In this case, therefore, it will normally be necessary to estimate the cost of purchasing the existing mineral reserves owned by the company. Frequently it is possible to make such an estimate on the basis of the value of comparable reserves available in the market place with adjustments as deemed appropriate. Professional engineers are known to make such determinations. However, where in the judgment of management such values are not an appropriate reflection of current values or such values cannot be reasonably obtained, current values determined on some other basis may be used in addition to or in lieu of replacement cost methods. Where this is the case, disclosure of the methods used along with the reasons for using them and an explanation of the meaning of the resulting valuation will be required. Once again, entities supplying such information will ordinarily be expected to demonstrate to the staff of the Commission that such values are reasonably derived.

Financing leases as defined by Accounting Series Release No. 147 [38 FR 29215] should be treated as capitalized for purposes of revealing assets in accordance with this release.

As previously discussed, assets held as part of a particular project which is expected to have a relatively fixed and nonrecurring production cycle should normally be valued on the basis of historical cost.

Depreciation, depletion and amortization amounts. The disclosure of the supplemental footnote data in regard to depreciation, depletion and amortization expense should be based on the estimated current replacement costs during the period. For assets used throughout the period, the replacement cost data may be based on the average of replacement cost at the beginning and the end of the period. Approximations may be used for assets acquired during the period.

In calculating the expense amount, a straight-line method should be used, generally based on the same useful life and proportionate salvage value as that used for historical cost statements. In circumstances where assets are valued on the basis of the replacement cost of the most efficient substitute and where the useful life or proportionate salvage value of such a substitute varies significantly from the useful life or proportionate salvage value being used in historical cost statements for the asset being valued, it may be necessary to adjust such lives or salvage values to appropriately reflect the cost of replacing such an asset. The nature and reason for such an adjustment should be disclosed where its overall impact would be significant.

The straight-line method is specified to achieve comparability. In so specifying, it is recognized that any basis of measuring depreciation, depletion or amortization of a cost base is essentially a system of allocation rather than valuation. The assumptions used here provide for a systematic and rational basis for making such allocations.

Comment period and proposed effective date. Because of the significance of this proposal, comments will be received until January 31, 1976.

The proposal supersedes amendments to 17 CFR 210.5-02-6 originally made in Securities Act Release No. 5427 [38 FR 28948] (October 4, 1973; Securities Exchange Act Release No. 10420, Public Utility Holding Company Act Release No. 18110, Investment Company Act Release No. 8023) to the extent that such proposals have not been adopted to date.

The foregoing are proposed to be adopted pursuant to Sections 6, 7, 8, 10 and 19(a) [15 U.S.C. 77f, 77g, 77h, 77j, 77s] of the Securities Act of 1933; Sections 12, 13, 15(d) and 23(a) [15 U.S.C. 78l, 78m, 78o(d), 78w] of the Securities Exchange Act of 1934; and Sections 5 (b), 14 and 20(a) [15 U.S.C. 79e, 79n, 79t] of the Public Utility Holding Company Act of 1935.

All interested persons are invited to submit written comments on the proposals on or before January 31, 1976. The communications should be addressed to the Secretary, Securities and Exchange Commission, Washington, D.C. 20549, and should be referenced to File No. S7-579. All comments will be available for public inspection.

By the Commission.

GEORGE A. FITZSIMMONS,
Secretary.

AUGUST 21, 1975.

[FR Doc.75-23299 Filed 8-2-75;8:45 am]

[17 CFR Parts 230, 270]

[Release Nos. 33-5607, IC-8894, File No. S7-578]

SALES LOAD VARIATIONS DURING PERIODIC "OPEN SEASONS"

Proposed Permission

Notice is hereby given that the Securities and Exchange Commission has under consideration the adoption of Rule 22d-4 [17 CFR 270.22d-4] under section 22(d) of the Investment Company Act of 1940 (the "Act") [15 U.S.C. 80a-22 (d)] to exempt from section 22(d), subject to certain conditions, sales of redeemable securities issued by a registered investment company to persons who are shareholders of the company or of a company whose shares are underwritten by the same underwriter. Rule 22d-4 would be adopted by the Commission pursuant to the authority granted the Commission by sections 6(c), 38(a), and 22(d) of the Act [15 U.S.C. 80a-6(c), 80a-37(a), 80-22(d)] and sections 2(10)(b) and 19(a) of the Securities Act of 1933 [15 U.S.C. 77b (10)(b), 77s(a)].

Section 6(c) provides that the Commission by rule, regulation or order may exempt any person or transaction or any class of persons or transactions from any provision of the Act if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Section 38(a) of the Act authorizes the Commission to issue such rules as are necessary or appropriate to the exercise of powers conferred on it in the Act.

Section 2(10) of the Securities Act of 1933, which defines "prospectus", excepts certain notices containing limited information from that definition and authorizes the Commission to permit such other information in such excepted notices by rules or regulations deemed necessary or appropriate in the public interest and for the protection of investors. Section 19(a) of that Act gives the Commission authority, among other things, to make such rules and regulations as may be necesary to carry out the provisions of that Act.

Background. Pursuant to a request of Congress, the Commission staff conducted a study of the possible consequences of the repeal of section 22(d).[1] On November 4, 1974, the Commission announced it had determined not to recommend repeal.[2] Instead, it set forth a comprehensive program to revise the laws and regulations affecting the distribution of open-end investment companies.[3] The Commission's program was based on a study, "Mutual Fund Distribution and section 22(d) of the Investment Company Act of 1940" (the "Report"), prepared by its Division of Investment Management Regulation. This is the sixth in a series of releases designed to implement that program.[4]

Proposed Rule 22d-4. Purposes. Section 22(d) of the Act prohibits a registered investment company, its principal underwriter, or a dealer from selling any redeemable security issued by such registered investment company to any person except at a public offering price described in the prospectus.[5]

Proposed Rule 22d-4 would provide an exemption from section 22(d) for an investment company issuing redeemable securities and for its underwriter and dealers to permit offers of shares to shareholders of the company, or of companies whose shares are underwritten by the same underwriter, at a reduced or no sales load, described in the prospectus, at the same time that shares were being offered at full sales loads to new investors.

The proposed rule allows companies and underwriters, at their option, to reduce or eliminate sales loads charged on fund shares to certain fund shareholders. Offers may be made under the rule by a company to its shareholders and shareholders of other companies in the same mutual fund complex. One of the purposes of the proposed rule would be to allow mutual funds and their underwriters to permit, where they deem it desirable, repeat investors of load mutual funds to share in the distribution economies that may accompany additional sales to fund shareholders.

Flexibility in Marketing. The rule has been drafted to give broad flexibility to funds and their principal underwriters in designing marketing strategies for selling to existing shareholders. The Report had suggested that such a rule contain certain features such as a required one year holding period, a limit on the availability of an open season offer, and a limit on the amount of shares which could be purchased to an amount already owned. It also suggested that periodic payment contractual plans be excluded from the rules' coverage at least until completion of the plan.[6] Rather than prescribe all such limitations, the Commission prefers to publish the proposed rule in a form which would leave to the funds and their underwriters the opportunity to proscribe whatever limitations they deem appropriate.

For example, as proposed, the rule could permit them to hold more than one open season during a year. The duration

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[1] Report of the Staff of the Securities and Exchange Commission on the Potential Economic Impact of a Repeal of Section 22(d) of the Investment Company Act of 1940 (Nov. 1972).

[2] Letter transmitting "Report on Mutual Fund Distribution and Section 22(d) of the Investment Company Act of 1940" to U.S. Senate Committee on Banking, Housing and Urban Affairs. See also, Investment Company Act Rel. No. 8570, (Nov. 4, 1974).

[3] Letter of transmittal, *supra.*

[4] Investment Company Act Rel. No. 8568 (Securities Act Rel. No. 5536) (Nov. 4, 1974) [39 FR 39868], announced the adoption of an amendment to Rule 134 relating to investment company advertising. Investment Company Act Rel. No. 8571 (Securities Act Rel. No. 5537) (Nov. 4, 1974) [39 FR 40789], announced proposed revisions of the Statement of Policy. Investment Company Act Rel. No. 8569 (Nov. 4, 1974) [39 FR 40281], announced the adoption of an amendment to Rule 22d-1 to permit quantity discounts and other reductions in, or eliminations of, the sales load for certain group purchases of investment company securities. The fourth release, Investment Company Act Rel. No. 8878 (August 7, 1975) [40 FR 33970] provides certain exemptions from Section 22(d) for variable annuity contracts. Further amendment of Rule 134 was effectuated pursuant to Investment Company Act Rel. No. 8824 (Securities Act Rel. No. 5591) (June 16, 1975) [40 FR 27442].

[5] The Commission has previously adopted two rules to codify certain administrative interpretations of Section 22(d) and certain orders for exemption from the restrictions or variations in the sales load on redeemable securities. Rule 22d-1 was adopted in 1958. Investment Company Act Rel. No. 2798 (Dec. 2, 1958) [23 FR 9601]. Paragraph (h) was subsequently amended by Investment Company Act Rel. No. 6347 (Feb. 8, 1971) [36 FR 2965]. Rule 22d-1 was further amended by Investment Company Act Rel. No. 8569 (Nov. 4, 1974) [39 FR 40281]. Rule 22d-2 was adopted in 1974. In addition, as indicated in footnote 2, page 3, *supra*, Rule 22d-3, adopted in 1975, provides certain exemptions for variable annuity contracts, Investment Company Act Rel. No. 8878 (August 7, 1975) [40 FR 33970].

[6] Report at 13, 93-97.

of the open season could be 30 days or whatever period in excess of 30 days they deem to be desirable. It could even be continuous. No limitations on the amount of shares that might be purchased would be required in the rule. Setting any such limitations would also be left to funds and their principal underwriters. If they wish, they could make an unlimited offer, or they could limit the offer to an amount equal to the number or value of shares of funds in the complex already owned by existing shareholders or some lesser amount.

The Commission specifically requests comments on the need for and desirability of including any such limitations in the rule.

The proposed rule also would preserve the flexibility of funds and their underwriters to reward dealers for services rendered to fund shareholders. For example, if a fund and its underwriter decided to offer shares under such a rule at a reduced load, they would be free to pass on all or a portion of that load to dealers who render continuing service to shareholders who purchase under the rule.

Notice to Shareholders. The proposed rule would require that offers be preceded by notice to shareholders. Included in the information to be furnished to shareholders would be an explanation of how to calculate any maximum amount of shares that may be purchased pursuant to the offer. The notice would not need to be accompanied by a prospectus if it satisfied the requirements of Rule 134 under the Securities Act of 1933. To avoid any question of whether the notice would be covered by that rule, a specific provision would be added to Rule 134 permitting written notices of the terms of an offer which meets the requirements of Rule 22d–4.[1]

Commission action: (1) It is proposed to amend Part 270 of Chapter II of Title 17 of the Code of Federal Regulations by adding a new § 270.22d–4.

§ 270.22d–4 Exemption from section 22(d) with respect to certain investments by open-end investment company shareholders.

A registered investment company which is the issuer of redeemable securities (the "company"), a principal underwriter, or a dealer therein may offer shares of the company to shareholders of the company or shareholders of companies whose shares are underwritten by the same underwriter ("offeree shareholders") at a reduced price described in the prospectus of the company reflecting reduction or elimination of the regular sales loads charged by the company, provided that:

(a) At least thirty days before the offer becomes effective, offeree shareholders are furnished with a written notice of the terms of an offer made under the rule which is dated and includes information concerning the:

(1) Duration of the offer;

(2) Sales load, if any, charged on purchases;

(3) Method of calculating any maximum amount of shares that may be purchased by an offeree shareholder pursuant to the offer; and

(4) Procedures to be followed in ordering shares pursuant to the offer; and

(b) Offeree shareholders have owned shares for at least six months and any such offer remains in effect for at least 30 days.

NOTE.—A notice containing statements limited to the information set forth in paragraph (a) of this rule and otherwise complying with Rule 134 under the Securities Act of 1933 need not be accompanied by a prospectus.

(2) It is proposed to amend paragraph (a)(3)(iii) of § 230.134 of Chapter II of Title 17 of the Code of Federal Regulations as follows (bracketed portions denote optional material).

§ 230.134 Communications not deemed a prospectus.

* * * * *

(a) * * *

(3) * * *

(iii) In the case of an investment company registered under the Investment Company Act of 1940, the company's classification and subclassification under the Act, whether it is a balanced, specialized, bond, preferred stock or common stock fund and whether in the selection of investments emphasis is placed upon income or growth characteristics, and a general description of an investment company including its general attributes, methods of operation and services offered provided that such description is not inconsistent with the operation of the particular investment company for which more specific information is being given, identification of the company's investment adviser, any logo, corporate symbol or trademark of the company or its investment adviser and any graphic design or device or any attention-getting headline, not involving performance figures, designed to direct the reader's attention to textual material included in the communication pursuant to other provisions of this Section; and with respect to an investment company issuing redeemable securities whose registration statement under this Act is effective, (A) a description of such company's investment objectives and policies, services, and method of operation; (B) identification of the company's principal officers; (C) the year of incorporation or organization or period of existence of the company, its investment adviser, or both; (D) the company's aggregate net asset value as of the most recent practicable date; (E) the aggregate net asset value as of the most recent practicable date of all registered investment companies under the management of the company's investment adviser; (F) any pictorial illustration which is appropriate for inclusion in the company's prospectus and not involving performance figures; (G) descriptive material relating to economic conditions, or to retirement plans or other goals to which an investment in the company could be directed, but not directly or indirectly relating to past performance or implying achievement of investment objectives; and (H) a written notice of the terms of an offer which meets the requirements of Rule 22d–4 under the Investment Company Act of 1940 (17 CFR 270.22d–4) Provided that, (*1*) if any printed material permitted by clauses (A) through (H) of this paragraph is included, such communication shall also contain the following legend set in a size type at least as large as, and of a style different from, but at least as prominent as, that used in the major portion of the advertisement:

For more complete information about (Name of Company) including charges and expenses [get] [obtain] [send for] a prospectus [from (Name and Address)] [by sending this coupon]. Read it carefully before you invest or [pay] [forward funds] [send money].

or, (2) if any material permitted by clauses (A) through (G) of this paragraph is used in a radio or television advertisement, such communication shall also contain the following legend given emphasis equal to that used in the major portion of the advertisement:

For more complete information about (Name of Company) including charges and expenses [get] [obtain] [send for] a prospectus [from (Name and Address)]. Read it carefully before you invest or [pay] [forward funds] [send money].

For purposes of clause (B) of this paragraph (a)(3)(iii), "principal officers" means the president, secretary, treasurer, any vice-president in charge of a principle business function and any other person who performs similar policy making functions for the company on a regular basis. In the case of two or more registered investment companies having the same investment adviser or principal underwriter, the same information described in this paragraph (a)(3)(iii) may be included as to each such company in a joint communication on the same basis it is permitted in communications dealing with individual companies under this paragraph (a)(3)(iii).

* * * * *

All interested persons are invited to submit written statements of views and comments on the adoption of proposed Rule 22d–4 and the proposed amendment to Rule 134 in triplicate to George A. Fitzsimmons, Secretary, Securities and Exchange Commission, 500 N. Capitol Street, Washington, D.C. 20549 on or before October 15, 1975. They should refer to File No. S7–578. All such communications will be available for public inspection in the Public Reference Room, 1100 L Street, NW., Washington, D.C.

By the Commission.

[SEAL] GEORGE A. FITZSIMMONS,
Secretary.

AUGUST 19, 1975.

[FR Doc.75-23282 Filed 9-2-75;8:45 am]

[1] On November 4, 1974, and June 16, 1975, the Commission amended Rule 134 to expand the scope of material permitted in Rule 134 Communications. Investment Company Act Rel. No. 8568 (Securities Act Rel. No. 5536) (Nov. 4, 1974) [39 FR 39868], and Investment Company Act Rel. No. 8825 (Securities Act Rel. No. 5591) (June 16, 1975) [40 FR 27442]. Companies using Rule 134 must, however, comply with the legend and other requirements of Rule 134 as amended.

notices

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF STATE

[Public Notice 461; Delegation of Authority No. 107-3]

DEPUTY COORDINATOR, REFUGEE AND MIGRATION AFFAIRS

Delegation of Contract Authority

By virtue of the authority contained in Section 4 of the Act of May 26, 1949 (63 Stat. 111; 22 U.S.C. 2658), as amended, and by virtue of the authority vested in me by Delegation of Authority No. 107-2 (Public Notice No. 454, 40 FR 27956, July 2, 1975), I hereby redelegate to the Deputy Coordinator, Refugee and Migration Affairs, the functions and authority vested in me with respect to negotiation, execution, amendment and termination of contracts.

This Delegation of Authority amends Delegation of Authority No. 107-2 of July 2, 1975 and is effective August 18, 1975.

[SEAL] J. M. WILSON, Jr.,
Coordinator for Humanitarian Affairs.

AUGUST 15, 1975.

[FR Doc.75-23221 Filed 9-2-75;8:45 am]

[Public Notice CM-5/89]

ADVISORY COMMITTEE OF THE INTER-AMERICAN TROPICAL TUNA COMMISSION

Meeting

The Advisory Committee to the United States Section of the Inter-American Tropical Tuna Commission will meet Thursday, September 18, 1975, in the auditorium of the Southwest Fisheries Center, National Marine Fisheries Service, 8604 La Jolla Shores Drive, La Jolla, California at 10 a.m. The agenda items are: 1975 fishing experience and outlook, 1976 preliminary fishery outlook, domestic and international fleet development, recent significant developments in countries fishing in the eastern tropical Pacific, review of efforts to internationalize the tuna/porpoise problem, and options for Paris and longer range positions.

The meeting will be open to the public, and those attending may participate in the discussion subject to instructions of the Chairman.

Dated: August 25, 1975.

LEO N. SCHOWENGERDT,
Acting Deputy Assistant Secretary.

[FR Doc.75-23219 Filed 9-2-75;8:45 am]

[Public Notice CM-5/88]

STUDY GROUP 2 OF THE U.S. NATIONAL COMMITTEE FOR THE INTERNATIONAL RADIO CONSULTATIVE COMMITTEE (CCIR)

Meeting

The Department of State announces that Study Group 2 of the U.S. National Committee for the International Radio Consultative Committee (CCIR) will meet on September 24, 1975, at 9:30 a.m. in Room 521J, Federal Office Building 10B, 7th and Independence Avenue, SW., Washington, D.C.

Study Group 2 deals with matters relating to the communications for scientific satellites, space probes, spacecraft, exploration satellites (e.g., meteorological and geodetic), and to interference problems concerning the radioastronomy and radar astronomy services. The purpose of the meeting will be a final review of work programs in preparation for the international meeting of Study Group 2, Geneva, March 1976.

Members of the general public may attend the meeting and join in the discussions subject to instructions of the Chairman. Admittance of public members will be limited to the seating available.

Dated: August 25, 1975.

GORDON L. HUFFCUTT,
Chairman, U.S. CCIR National Committee.

[FR Doc.75-23220 Filed 9-2-75;8:45 am]

DEPARTMENT OF DEFENSE

Department of the Air Force

ADVISORY COMMITTEE ON THE AIR FORCE HISTORICAL PROGRAM

Meeting

The Advisory Committee on the Air Force Historical Program will meet at the James Forrestal Building, Washington, D.C. on September 18-19, 1975.

The purpose of the meeting is to examine the mission, scope, progress, and productivity of the Air Force Historical Program and make recommendations thereon for the consideration of the Secretary of the Air Force.

The meeting will be open for public attendance, and will begin at 10 a.m. on both dates, in Room 8E-069, James Forrestal Building. Among the topics on the tentative agenda during the meeting are: Air Force Historical Progress and Problems, Contract Histories, Organizational Changes, Personnel Plans, and Current Status of Historical Projects.

If additional information is desired, contact HQ USAF (AF/CHO), Washington, D.C. 20314, telephone 693-73944.

JAMES J. SHEPARD,
Col, USAF,
Director of Administration.

[FR Doc.75-23206 Filed 9-2-75;8:45 am]

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[Wyoming 49454]

WYOMING

Application

AUGUST 25, 1975.

Notice is hereby given that pursuant to section 28 of the Mineral Leasing Act of 1920, as amended (30 U.S.C. 185), Northwest Pipeline Corporation has applied to amend right-of-way grant W-49454 to construct a natural gas pipeline across the following lands:

SIXTH PRINCIPAL MERIDIAN, WYOMING

T. 16 N., R. 93 W.,
Sec. 10, S½SE¼, NW¼SE¼, and W½NE¼;
Sec. 15, NE¼NE¼, SW¼SE¼, and E½SW¼;
Sec. 22, NW¼NE¼;
Sec. 23, NE¼SE¼ and S½SE¼;
Sec. 24, NW¼SW¼.

The pipeline will be a part of the Barrel Springs Gathering System in Carbon County, Wyoming.

The purpose of this notice is to inform the public that the Bureau will be proceeding with consideration of whether the application should be approved and, if so, under what terms and conditions.

Interested persons desiring to express their views should send their name and address to the District Manager, Bureau of Land Management, P.O. Box 670, Rawlins, Wyoming 83201.

PHILIP C. HAMILTON,
Chief, Branch of Lands and Minerals Operations.

[FR Doc.75-23211 Filed 9-2-75;8:45 am]

National Park Service

DIRECTIVE FOR THE PLANNING PROCESS OF THE NATIONAL PARK SERVICE

The National Park Service hereby publishes, for purposes of obtaining public comment, Directive 75-2, "The Planning Process of the National Park Service," dated August 1975. The directive will replace material in Part IV, Section 6 of Service Activity Standards related to planning in existing units of the Na-

tional Park System. The Director, National Park Service, will approve the directive upon completion of public review and comment and appropriate action thereto.

Interested persons are asked to provide their comments to the Director, National Park Service, Interior Department, 18th and C Street, N.W., Washington, D.C. 20240, within forty-five (45) days after publication of this notice.

Dated: August 29, 1975.

GARY EVERHARDT,
Director,
National Park Service.

THE PLANNING PROCESS OF THE NATIONAL PARK SERVICE UNITED STATES DEPARTMENT OF THE INTERIOR, AUGUST 1975

CONTENTS

INTRODUCTION

Planning is a process of imagining and evaluating possible futures. The steps involved in this process—the identification of problems and definition of goals, the gathering of information about resources, the design of strategies for solving problems and achieving goals, and the assessment of these strategies—are all directed toward one end: to provide a rational basis for determining the best future.

In the National Park Service, planning is conducted to determine the future of the nationally significant areas that have been set aside as units of the National Park Service. The purpose of this planning is to develop alternative strategies for achieving the stated management objectives of national parks, to assess these strategies, and to provide decisionmakers with sufficient data to allow selection and implementation of the most suitable and feasible strategy.

The National Park Service planning process has evolved throughout the years in response to the perceived needs of the times. However, in recent years rapidly changing conditions have prompted thorough reexamination, and in some cases redesign, of this process. The following principles are today considered both relevant and requisite to conscientious planning:

Park Service planning must comply with the provisions of the National Environmental Policy Act of 1969 and other pertinent statutes, and it must reflect concern with the spirit as well as the letter of these laws.

The public must be encouraged, and given opportunities, to participate in the planning process. Further, a public record must be maintained to document this process.

The planning process must be flexible in order to adapt to changing management needs and budgetary and manpower limitations. A mechanism must be developed that will allow *regular* assessment of each park's planning needs. The planning process must also include a feedback system for self-correction, so that unrealistic objectives and strategies can be identified and culled, and more viable ones can be developed.

The long-standing policy of employing a multidisciplinary team to accomplish planning tasks must be reemphasized.

More emphasis must be placed on the gathering of sufficient information for thorough assessment of alternative strategies, for forecasting the consequences of these strategies, and for making final decisions.

The planning process involves six essential steps (the documents produced at the end of each step are shown in parentheses):

The development of management objectives designed to achieve a park's purpose (statement for management)

The identification of planning tasks required to achieve the objectives (outline of planning requirements)

The specification of a method for conducting the programmed planning tasks (task directive)

The collection of required information about the natural, cultural, and socioeconomic environment of the park (information base)

The development of alternative strategies for meeting the management objectives, and the analysis of their probable consequences (environmental assessment)

The selection of the most acceptable strategy, the amplification of the proposals included in this strategy, and the assessment of consequences as required (plan and, where necessary, environmental statement)

The following sections discuss the planning documents mentioned above, and indicate the tasks, procedures, and responsibilities involved in preparing these documents.

STATEMENT FOR MANAGEMENT

PURPOSE AND CONTENTS

The first document to be prepared as part of the planning process is the statement for management. Each park must have an approved statement for management, which is subject to annual review and revision.

The statement for management can be used to guide short- and long-term management of the park and to determine the nature and extent of planning required to meet the park's management objectives. In the absence of more specific planning documents, the statement for management provides a general framework for directing park operations and communicating park objectives to the public.

The statement for management includes the following sections:

Purpose of the Park

Each park must be managed to preserve park resources and provide for environmentally compatible public use in accordance with existing National Park Service management policies and the park's purpose. The purpose is normally defined in, or deduced from, its enabling legislation or other legal documents providing for its establishment (reports from congressional hearings, memoranda of agreements, presidential proclamations, secretarial orders). In clarifying the purpose of the park, other generally applicable guidelines, such as those found in the Antiquities Act of 1906, the Act establishing the National Park Service (August 25, 1916), and the Historic Sites Act of 1935, may be utilized. The Park Purpose section should also identify all relevant legal documents, and copies of these documents should be appended to the statement for management.

Because many National Park Service areas were authorized decades ago when different environmental and social conditions existed, park purpose should be carefully reexamined during the preparation of statements for management for such areas. If necessary, corrective legislation to redefine park purpose should be proposed.

Significance of Park Resources

This section includes a concise description of the resources that prompted the park's inclusion in the National Park System.

Influences on Management

The section on inter- and extra-park influences begins with the identification of legislative and administrative constraints on management and use of the park. Relevant statements from the park's enabling legislation, from state and local ordinances, and from memoranda of agreement with federal, state, and local agencies or private interests are either quoted or paraphrased.

Second, regional influences are identified and described. These influences may include resources and their uses, environmental problems, and any organizations or activities outside the park's boundaries that affect and/or are affected by the park. Groups having particular interest in the park, planning commissions, transportation systems, research projects, and professional societies or organizations are examples of subjects to be discussed.

Third, a brief description of the events, trends, or processes within the park that influence and/or are influenced by day-to-day or long-term management is included. Unusual changes in visitor use patterns or concession operations, and deterioration of critical natural or cultural resources are examples of relevant topics.

Land Classification

This section defines *existing* management zones in the park, and briefly de-

scribes the management strategy for each zone (see section dealing with land classification in Chapter II of NPS Management Policies). If the park contains more than one management zone, a map is prepared on a topographic base to show the locations of the zones.

Management Objectives

The management objectives are the heart of the statement for management. All decisions concerning the management, use, and development of the park are directed toward achieving these objectives and fulfilling the park's purpose. The management objectives provide a framework for conserving park resources and for accommodating environmentally compatible public use in accordance with existing National Park Service management policies.

Essentially, the management objectives are a list of desired conditions. Because they spell out *ends* rather than *means*, they do not preclude alternative planning strategies. Rather, they provide a framework that enables planners and managers to work toward fulfilling the park purpose, while applying Park Service policy. In fact, in some cases, the management objectives may be park-specific restatements of more general Park Service management policies.

Management objectives are grouped into two broad categories:

Resource Preservation and Management

Objectives in this category concern natural and cultural resources such as wildlife, soils, vegetative communities, water, and historic and archeological structures and sites.

Visitor Use

Objectives for visitor use concern information, interpretation, activities, programs, services (including concessions where appropriate), and safety and protection requirements. These objectives should focus on the unique park values to be communicated to visitors, the kinds and levels of visitor activities and services, and the required regulation or control of uses.

PROCEDURES AND RESPONSIBILITIES

As stated, each park must have an approved statement for management. The regional director schedules the preparation of this document, providing assistance to the park as necessary. The superintendent is responsible for the actual preparation of the statement.

Prior to approval, the draft statement for management must be made available for public review and comment for a period of no less than 30 days. Following public review, and modification of the document as necessary, the draft statement is submitted to the Director for policy review. When cleared, it is transmitted for approval by the regional director.

The approved statement for management is subject to annual review, during which it is revised as necessary. Any revisions must be reviewed and approved, following the same procedure as for the original statement.

Planning documents must reflect the purpose, objectives, constraints, and policies indicated in the statement for management. Thus, if conditions change or new information is brought to light during the planning process rendering the statement for management out-of-date, the statement must be revised, reviewed for compliance with existing policy, and approved.

An impact analysis is not prepared on the statement for management because the statement provides information and policy guidance only, and does not in itself authorize actions. Proposed actions are subject to impact analysis and public scrutiny during the planning process.

The approved statement for management is distributed by the superintendent to interested citizens, concessioners, and park employees. The public is notified of the statement's availability through local and regional news media.

The superintendent and regional director are authorized to continue or initiate *only* the following actions based on an approved statement for management:

Management actions that cause no significant changes in the park environment and that reflect the approved management objectives. Major actions affecting the capacity of an area for public use or resulting in irretrievable environmental impacts cannot be implemented without appropriate advance planning.

Improvement or rehabilitation of existing facilities for maintenance or refurbishment purposes, or minor improvements to fulfill health and safety requirements. Upgrading of visitor accommodations, construction of facilities to meet existing or projected public needs (such as parking lots and utilities), or other similar actions cannot be initiated.

Resurfacing and normal maintenance of roads and trails. Realignment, upgrading, or changing the status of roads and trails, except for emergency and safety purposes, is not authorized.

OUTLINE OF PLANNING REQUIREMENTS

PURPOSE AND CONTENT

The outline of planning requirements provides the rationale for planning, special studies, and planning-related research within the park, and defines the planning tasks required to achieve the management objectives. The OPR is developed by the park superintendent, who then meets with the regional director—and various professional personnel as appropriate—to discuss planning needs and establish planning priorities. The purpose of the meeting is to evaluate the needs defined in the OPR and to determine which, if any, require programmed planning. In cases where the park's needs can be met without programmed planning, professional consultation or other assistance may be recommended. The regional director reviews all OPR's for parks within the region, arranging their planning requirements in priority sequence, and then submits the OPR's and a proposed regional planning program to the Washington office where national priorities are established.

The outline of planning requirements contains:

A statement of the problem or situation for which planning is required.

A list of the tasks and information needed during the next 5 years to resolve the problem or improve the situation.

Identification of who will be responsible for accomplishing the planning tasks.

Cost estimates for the tasks involved.

A list of all plans currentl yin effect.

PROCEDURES AND RESPONSIBILITIES

The draft OPR is prepared by the superintendent—with assistance from regional office staff—following approval of the statement for management by the regional director. After the draft OPR is developed, reviewed, and revised according to regional recommendations, it is reviewed by representatives of the regional office, Denver Service Center, and Harpers Ferry Center who are involved in preparing the development and professional-services program. The OPR, as modified during this meeting, is approved by the regional director and submitted to the Washington office along with the proposed regional planning program. The OPR is reviewed and revised annually according to the same procedure.

Each park must have a current OPR, even if it calls for no planning during the designated 5-year period. Following approval of the OPR by the regional director, a Development Package Proposal (NPS Form 10-238) is prepared for each approved planning task or package of tasks. All previously prepared Development Package Proposals related to planning that are not approved in the new OPR are immediately considered null and void, and are removed from the program files.

TASK DIRECTIVE

PURPOSE AND CONTENT

Once a planning task is approved and programmed, a task directive is required. The task directive (formerly the planning directive) defines the focus, magnitude, components, and schedule of the planning task to be accomplished, as well as the nature of the planning product. It is an agreement between the regional director and those who are to perform the task, and provides an understanding of what is required in terms of dollars, personnel commitments, steps to be taken, information to be gathered, presentations to be made, documents to be produced and copies required, and projected completion dates. The task directive indicates the procedures for complying with statutory requirements, as well as for public participation. Disciplines required to complete the task are identified, as are informational needs and the proposed means of securing data in a timely fashion.

PROCEDURES AND RESPONSIBILITIES

The task directive is prepared by the office that has been assigned the task, in

consultation with management and professional personnel as appropriate. Following concurrence between the superintendent and the responsible official of the assigned office, the task directive is transmitted to the regional director for approval. Any revisions to the directive must also be reviewed and approved.

INFORMATION BASE

Systematic park planning requires relevant information concerning:

The biological, physical, cultural, and socioeconomic environment of the park and its vicinity.

The capability of facilities in and near the park to support existing and projected uses.

Visitor characteristics and their influence on park use.

To allow systematic planning, an information base (formerly the resources basic inventory) is assembled prior to or coincident with the initiation of identified planning tasks. The information base is essential for estimating the capability of parklands to support use without unacceptable resource impairment or a significant decrease in the quality of the visitor experience. It provides the basis for land classification, for the identification, analysis, and comparison of alternative planning strategies, and for specific decisions on management, use, interpretation, and development of the park.

The kinds and amount of information required depend on the nature of the park's resources, the objectives of the planning effort, and the adequacy and relevance of the information already available to planners. Judgment must be exercised to ensure that the data gathered are pertinent to the planning task at hand and that funds and manpower are not expended unnecessarily in procuring, storing, and evaluating marginally related or excessively detailed information.

The OPR and the task directive indicate informational needs for a given planning task, and fix responsibility for securing the data. Information and data requirements identified during planning require revision of the task directive and approval of appropriate Development Package Proposals (NPS Form 10-238).

DEVELOPMENT, ANALYSIS, AND SELECTION OF ALTERNATIVE STRATEGIES

The development and analysis of alternative strategies is the basic activity of planning. By analyzing the strategies that they have developed, planners ensure that they have considered all the viable ways of achieving the management objectives and have identified both the beneficial and adverse consequences of implementing each strategy. The analysis facilitates objectivity in planning and decisionmaking, and may result in the identification of additional conditions or problems that require changes in the management objectives or planning tasks. Opportunties for public participation are made available while the analysis is in progress.

The analysis of alternative strategies may include some or all of the following activities, each of which is documented in appropriate files:

Analyzing management objectives to ensure that they are not outdated, and are valid objectives—not solutions or approaches. New objectives are formulated, evaluated, and approved, as necessary.

Developing alternative strategies for meeting the objectives.

Identifying and quantifying the effects of alternative strategies on natural and cultural resources.

Analyzing socioeconomic and political implications.

Analyzing effects on visitors and on the kinds and amounts of public use of the park.

Analyzing the effects on park management.

Estimating costs, manpower requirements, and timeframes.

Preparing an environmental assessment.

Status reports, informational brochures, charts, tables, specific analyses, and graphic displays may be prepared during the analysis of alternative strategies to communicate facts or proposals to the public, to identify decisionmaking factors, or to facilitate evaluation and culling of strategies by planners and decisionmakers (see figure 1).

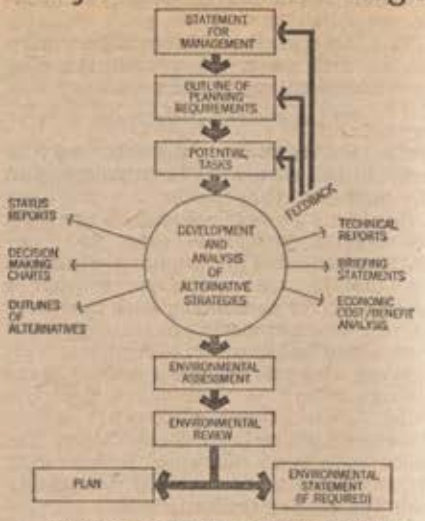
ENVIRONMENTAL ASSESSMENT

The end product of the analysis of strategies is the environmental assessment, which indicates the cost, feasibility, timeframe, environmental consequences, and other implications of the reasonable alternative strategies remaining at the end of the analysis. This document is prepared by the office assigned the planning task and is made available for public review. It is then used by decisionmakers in selecting the strategy or strategies that will constitute the subsequent plan. As a result of public review, considerations may be identified that have been overlooked or insufficiently emphasized in the analysis. These considerations should be noted, evaluated, and incorporated where appropriate before the document is submitted to decisionmakers.

ENVIRONMENTAL REVIEW

When all phases of the analysis are complete, the environmental assessment is transmitted to the regional director who weighs and evaluates the alternative strategies, determining whether their environmental consequences are significant or controversial. An environmental review, outlining the rationale for selecting one or more strategies and rejecting others, is then prepared by the regional director. The relative importance of environmental, technical, monetary, managerial, and other considerations is discussed. A determination is made as to whether the selected strategies constitute a major federal action with significant or controversial environmental impacts. If so, a commitment is made to prepare an environmental statement. If not, the decision not to prepare an environmental statement is documented.

The Development and Analysis of Alternative Strategies



PLANS AND ENVIRONMENTAL STATEMENTS

Upon completion of the environmental review, a park plan is prepared for use as a management tool and as a public statement of National Park Service management intentions. If required, an environmental statement is also prepared concurrently with the plan.

PLANS

The general management plan (formerly the master plan) is the parkwide plan for meeting the management objectives of the park. It charts a long-range strategy for resources management, visitor use, and development at a level of detail that will facilitate implementation of proposed actions. The general management plan also defines what is required to ensure compliance with relevant legislation and administrative policies and procedures.

The park's regional context is carefully considered when preparing the general management plan. Reciprocal influences between the park and its surroundings are identified, and the means of harmonizing these influences are proposed wherever possible. For some parks, regional influences and problems may be minimal and may not require any action. However, where these influences are of sufficient magnitude, joint planning with adjacent agencies, organizations, and other entities with jurisdiction in the region may be desirable, and is recommended (see Management Policies, Section II-6).

The GMP contains the park's statement for management—as revised during the planning effort—and three interrelated parkwide plans:

The resources management plan, outlining methods for protecting, perpetuating, and preserving natural and cultural resources.

The visitor use plan, outlining the methods for interpreting park resources, for providing for visitor use and safety, and for supplying information and support services.

The general development plan, outlining development necessary to accomplish the resources management plan and visitor use plan.

In a large park, implementation plans dealing with specific sites or subjects may be required to supplement the parkwide GMP; such additional plans, upon completion and approval, become part of the GMP. In a small park, the GMP may be sufficiently detailed to eliminate the need for implementation plans.

Complete general management plans are normally prepared only for parks where anticipated major changes in present use and/or development require preparation of parkwide planning strategies. This would apply to:

Recently authorized parks

Parks without approved master plans

Parks where existing plans are outdated

For parks with adequate GMP's (or master plans), planning requirements are generally limited to site- or subject-specific implementation plans.

Implementation plans may focus on, but need not be limited to:

Management of one or more wildlife species within the park's ecosystem

Management of natural and prescribed fires

Backcountry use and its regulation

Management of vegetation

Detailed guidelines for ongoing maintenance of historic resources

Development in specific areas of the park

Interpretive programs and media

Concession needs and contracted visitor services

Furnishing of historic structures

Determination of the suitability of parklands for wilderness designation

Legislative proposals for boundary adjustments, land use changes, increases in authorized funding for land acquisition, development, etc.

Studies and research on carrying capacities, visitor use, historic structures, transportation, etc.

The general management plan (or its independently prepared components) and all implementation plans are subject to policy review in the Washington office prior to approval by the regional director.

ENVIRONMENTAL STATEMENTS

The National Park Service planning process must be consistent with the provisions of the National Environmental Policy Act of 1969 (83 Stat. 852). NEPA compliance requires:

A systematic, interdisciplinary approach to planning, and objective consideration of environmental values

Full involvement of other agencies and the public during the planning process

Procurement and use of relevant environmental information in analyzing alternative strategies

Recordkeeping on planning activities as a basis for decisionmaking and preparation of documents

Preparation of an environmental statement when the plan as a whole constitutes a major federal action or entails significant or controversial impacts

When required, an environmental statement (EIS) is prepared concurrently with the plan and following the selection of strategy or strategies by decisionmakers. Although similar in scope to the environmental assessment, the environmental statement does not include information on costs, feasibility, or other considerations that are not directly related to the park environment. Its contents are limited to detailed considerations of the effects of the plan and its reasonable alternatives on the physical, ecological, and socioeconomic components of the park's environment. The environmental statement provides for review of environmental effects before final decisions are made. The comments of the public and from other agencies help ensure that environmental considerations are given sufficient weight in the decisionmaking process and that changes are made in the plan where appropriate.

More specific information on environmental statements is provided in existing National Park Service guidelines for preparation and review of environmental assessments and environmental statements.

Other Compliance Requirements

National Park Service planning must reflect awareness of and consistency with a wide variety of legislative and executive requirements.

All planning efforts must comply with the requirements of Section 106 of the National Historic Preservation Act of 1966 (16 U.S.C. § 470f) and Executive Order 11593 of May 13, 1971, "Protection and Enhancement of the Cultural Environment" (36 FR 8921), which require all federal agencies to nominate to the National Register of Historic Places potentially eligible historic properities under their control and to consult with State Historic Preservation Officers and the Advisory Council on Historic Preservation on plans affecting properties on or potentially eligible for the National Register. The Advisory Council's "Procedures for the Protection of Historic and Cultural Properties" (36 CFR Part 800) govern agency compliance with Section 106 and E.O. 11593.

Among the other laws and orders that are relevant to National Park Service planning are the following:

The National Park Service Organic Act of 1916, as amended (16 U.S.C. § 1).

The Wilderness Act of 1964, as amended (16 U.S.C. § 1131).

The Department of Transportation Act of 1966, as amended (49 U.S.C. 1653 (f)).

The Fish and Wildlife Coordination Act of 1934, as amended (16 U.S.C. § 661).

The Endangered Species Act of 1973 (16 U.S.C. § 1531).

The Federal Water Pollution Control Act, as amended (33 U.S.C. § 1251).

The Airport and Airway Development Act of 1970 (49 U.S.C. § 1701).

Executive Order 11752, "Prevention, Control, and Abatement of Environmental Pollution at Federal Facilities" (38 FR 34793–97).

The Water Resources Planning Act of 1965 (42 U.S.C. § 1962).

The Marine Protection, Research, and Sanctuaries Act of 1972 (33 U.S.C. § 1402; 16 U.S.C. § 1431).

The Coastal Zone Management Act of 1972 (16 U.S.C. § 1451).

Executive Order 11296, "Evaluation of Flood Hazard in Locating Federally Owned or Financed Buildings, Roads, and Other Facilities, and in Disposing of Federal Lands and Properties (36 F.R. 10663).

The Land and Water Conservation Fund Act of 1965, as amended (16 U.S.C. § 460*l*–4).

The Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (42 U.S.C. § 4601).

The Wild and Scenic Rivers Act, as amended (16 U.S.C. § 1271).

The Clean Air Act, as amended (42 U.S.C. § 1857).

The Noise Control Act of 1972 (42 U.S.C. § 4901).

Office of Management and Budget Circular A–95.

National Trails System Act (16 U.S.C. § 1241).

PUBLIC INVOLVEMENT

The goal of public involvement in the planning process is to reach better decisions. Citizen participation is considered a cornerstone of National Park Service planning and management.

Public involvement is valuable in the search for basic data, the identification of goals and problems, and the formulation of alternative planning strategies. It also aids in establishing a two-way exchange of information between the public and the agency, in promoting public understanding of decisions, in identifying public values that influence management decisions, and in educating the public about the park, about management capabilities, and about what park management can and cannot do.

Public involvement is first solicited during the formulation of management objectives, and subsequently during the development of alternative strategies to meet these objectives. Participation is particularly important during the analysis of strategies, when input from the public may have a significant effect on the planning effort.

The first step in establishing effective public involvement is to identify affected parties, in order to ensure broad cross-sectional representation. Next, steps must be taken to make certain that all concerned individuals and groups receive advance notice of opportunities for involvement. At the end of the planning effort, all contributions from the public must be summarized in a systematic, objective, viable, and traceable manner.

Responsible National Park Service officials must be frugal in expending time and energy on public involvement. Every effort must be tailored to the situation. The forms of involvement vary according to the requirements of the particular planning task. Methods of public in-

volvement include, but are not limited to:

Public meetings
Workshops
Presentations to groups
Ad-hoc committees
Advisory groups
Key contacts with opinion leaders
Analysis of incoming mail
Direct mailings from the Park Service to the public
Questionnaires and surveys
Behavioral observations of park visitors
Reports from key park staff
News Releases and mass media
Analysis of mass media
Day-to-day contacts with visitors and the public

Normally, one or more informal workshops are held during the analysis of strategies stage. Formal public meetings on draft plans and associated environmental statements are optional.

More specific guidelines for public involvement are laid down in Thomas A Heberlein's *Principles of Public Involvement—A Primer for Park Service Planners and Managers* (Department of Rural Sociology, University of Wisconsin, Madison, Wisconsin, 1975).

When a general management plan is in preparation, opportunities for public involvement are normally announced in the FEDERAL REGISTER and in local news media at the inception of the planning effort, at the end of the strategies analysis when the document displaying the strategies and their consequences is made available, and at the time the draft plan is released for public review. At the minimum, announcements in the FEDERAL REGISTER must be made prior to the selection of strategies as the plan's proposals and following completion of the draft plan.

For implementation plans, opportunities for public involvement are announced in the FEDERAL REGISTER and in local news media at the time the draft plan is made available for public review. During the preparation of these plans, other opportunities may be announced, as appropriate.

Specific responsibilities for public involvement are as follows:

FEDERAL REGISTER notices: regional office

Notices in local news media: park

Planning and coordination of formal public meetings and regional workshops: regional office, with assistance (as requested) from the park and the Denver Service Center

Planning and coordination of informal workshops in the park or its immediate vicinity: park

Maintaining a log of the names and addresses of interested or potentially interested individuals, as well as key contacts in organizations and agencies: park

Arranging professional consultations for the purpose of acquiring technical information for plans: responsible office (region, Denver Service Center, Harpers Ferry Center, or park)

Arranging consultations for the primary purpose of determining public sentiment, as well as sources of existing or potential controversy: park

Maintaining a record of all public consultations: responsible office (region, Denver Service Center, Harpers Ferry Center, or park)

RECORD OF PLANNING

For each planning effort, the planning team captain is responsible for keeping a cumulative record of the planning activities. No information is prepared specifically for this file; it is simply an aggregation of the material used and prepared during the planning effort. The availability of this record to the public will be determined in response to individual requests pursuant to the Freedom of Information Act.

The record contains the collections of material in various stages of completion, such as rough drafts, tapes of public meetings, or finished documents. It is arranged in the following order:

The *statement for management* file contains:

The management statement, revisions occurring while plan is in progress, reasons for revising management objectives, and approval dates

The *outline of planning requirements* file contains:

The outline of planning requirements, revisions occurring while plan is in progress, and reasons for revisions

The task directive, changes occurring while plan is in progress, and reasons for changes

Copies of Development Package Proposals (NPS Form 10–238) relevant to the planning effort

The *information base* file contains:

Bibliographic citations for information used in the planning effort, along with the location of each reference

New information prepared specifically for the planning effort (surveys, research reports, summaries of data analyses, interpretations of existing information, sketches, tables, charts, maps, photographic plates). Raw data files and voluminous reports are kept separately and referenced.

Previous planning documents or portions thereof that influence the planning effort

The *analysis of alternative strategies* file contains:

The description of the park and regional environment.

Capability and desirability analyses, if appropriate.

Alternative land classification zoning plans, if appropriate.

Alternative strategies.

Environmental impacts of alternative strategies.

Other consequences of alternative strategies (engineering, feasibility, costs, and political, managerial, and other implications not related to the park environment).

The *record of public involvement* file contains:

Written correspondence between the Park Service and the public.

groups (dates and attendance indicated) and similar material from public meetings, workshops, and presentations to groups (dates and attendance indicated).

Results of consultations with interested groups (dates indicated)

Results of consultations with professional experts (dates indicated)

News releases
News articles
Questionnaires and results
Analyses of public involvement

Address list for all involved organizations and members of the public

The *consultation with outside agencies* file contains:

The dates, subject matter, and results of consultations with local, state, and federal agencies, arranged chronologically by agency. Documentation should include identification of existing and potential conflicts, as well as agreements to resolve them, if any.

Written correspondence between the Park Service and outside agencies, arranged chronologically by agency.

The *record of statutory compliance* file contains:

A record of all actions taken specifically to comply with legislation, executive orders, and requirements in the *Code of Federal Regulations*, including but not limited to:

Surveys and studies conducted or commissioned

Consultations with state and federal agencies (dates and purpose only)

Chronological history of preparation and review of environmental documents issued to comply with NEPA, Section 106 (NHPA), E.O. 11593, as well as existing guidelines of CEQ and DOI.

Actions recommended in the plan specifically to comply with statutory requirements relating to design of facilities or land use.

The *memoranda* file contains:

All National Park Service memoranda relating to the particular planning effort, arrange chronologically

Glossary of Terms

Analysis of alternative strategies—The principal activity of planning in which planners formulate, analyze, and cull alternative strategies for meeting the park's management objectives, and identify the beneficial and adverse consequences of implementing each strategy.

Development Package Proposal (NPS Form 10–238)—A programming vehicle for parks to describe and justify their planning and development needs.

Environmental assessment—A formal documentation of the analysis of alternative strategies describing the strategies and indicating all the potential consequencies of implementation. (This document is normally prepared and made available for public review at the end of the strategies analysis.)

Environmental statement (EIS)—A formal documentation of the environmental impacts of implementing the plan (the strategy or strategies selected by decisionmakers) and its reasonable alternatives prepared in accordance with applicable NPS, CEQ, and DOI guide-

lines for complying with the National Environmental Policy Act of 1969. An EIS is made available for review by the public and other agencies upon completion of any plan which constitutes a major federal action with significant or controversial environmental effects.

Environmental review—A written analysis prepared by the responsible official outlining the rationale for selecting one or more alternative strategies as proposals to be included in the subsequent plan, and indicating whether an environmental statement is required.

General management plan (formerly master plan)—A long-range parkwide plan for preservation and use of park resources identifying strategies for resource management, visitor use, and development directed toward achieving the park's management objectives.

Information base (formerly resources basic inventory)—Information necessary for preparing the statement for management or a plan. The information base varies in scope and complexity according to the requirements of the planning effort.

Management objectives—Desired conditions to be achieved within the park.

Outline of planning requirements—A park-specific documentation of programmed planning needs, which states the problems, defines the required tasks, identifies the office assigned the tasks, and arranges in-park planning requirements in priority sequence.

Record of planning—A complete record (filed) of planning activities, including the statement for management, the outline of planning requirements, the information base, the analysis of alternative strategies, the record of public involvement, consultations with outside agencies, the record of statutory compliance, and memoranda.

Statement for management—A document prepared by the park superintendent identifying the purpose of the park, the significance of its resources, the influences on management, the existing management zones (land classification), and management objectives.

Task directive (formerly planning directive)—A written contractual agreement between the regional director and the office assigned the planning task establishing the focus, scope, schedule, personnel and funding commitments, required documents, and any other requirements of that task.

INDEX

[FR Doc.75-23379 Filed 9-2-75;8:45 am]

Office of the Secretary

OUTER CONTINENTAL SHELF

Geological and Geophysical Exploration

1. On December 11, 1974, Acting Secretary of the Interior John C. Whitaker issued a notice concerning "Outer Continental Shelf—Geological and Geophysical Exploration" which was published in the FEDERAL REGISTER on December 16, 1974 (39 FR 43562). This notice is a supplement to that notice. Permits for geological exploration shall continue to be subject to the provisions of the notice as published on December 16, 1974. Permits for geophysical exploration shall in the future include the provisions of the "Permit and Agreement for Outer Continental Shelf Geophysical Exploration", which shall be used as an interim measure until the final publication of regulations on geological and geophysical exploration on the outer Continental Shelf in 30 CFR Part 251. Copies of the new Permit and Agreement may be obtained from the appropriate Area Oil and Gas Supervisors of the Geological Survey.

Each person holding a permit for geophysical exploration issued since November 1, 1974, will be informed by letter by the appropriate Area Oil and Gas Supervisor that he may substitute the new Permit and Agreement for his existing permit. The new Permit and Agreement will provide appropriate protection for confidential geophysical data submitted by permittees. A failure to comply with the requirements for submission of data will cause the Department to take appropriate steps necessary to obtain the requested data.

2. Consequently, sections 2, 3, and 4 of the notice published on December 16, 1974, are no longer applicable to geophysical exploration.

3. The addresses of the Area Oil and Gas Supervisors are as follows:

For areas off the Atlantic Coast—Harry A. Dupont, Area Oil and Gas Supervisor, Eastern Area, USGS, Suite 316, 1825 K Street, NW., Washington, D.C. 20244; telephone number (202) 343–4685.

For areas in the Gulf of Mexico—Harry McAndrews, Area Oil and Gas Supervisor, Gulf of Mexico Area, Office of Resource Evaluation and Analysis, USGS, P.O. Box 7944, Metairie, Louisiana 70011; telephone number (504) 680–9341.

For areas off the coast of the States of California, Oregon, and Washington—Fred J. Shambeck, Area Oil and Gas Supervisor, Pacific Area, USGS, Room 7744, Federal Building, 300 No. Los Angeles Street, Los Angeles, California 90012; telephone number (213) 688–2846.

For areas off the State of Alaska—Rodney A. Smith, Area Oil and Gas Supervisor, Alaska Area, USGS, P.O. Box 259, Anchorage, Alaska 99510; telephone number (907) 278–3571.

Dated: August 27, 1975.

KENT FRIZZELL,
Acting Secretary of the Interior.

[FR Doc.75-23293 Filed 9-2-75;8:45 am]

DEPARTMENT OF AGRICULTURE

Forest Service

SOUTH FORK SALMON RIVER PLANNING UNIT

Availability of Final Environmental Statement

Pursuant to Section 102(2)(C) of the National Environmental Policy Act of 1969, the Forest Service, Department of Agriculture, has prepared a final environmental statement for the South Fork Salmon River Planning Unit, Boise National Forest and Payette National Forest, Idaho. The Forest Service report number is USDA-FS-FES (Adm) R4-75-11.

The environmental statement identifies and evaluates the probable effects of the land use plan for the South Fork Salmon River Planning Unit on the Boise and Payette National Forests in south-central Idaho. The purpose of the plan is to allocate National Forest lands within the unit to specific resource uses and activities; establish management objectives; document management direction, decisions, and necessary coordination between resource uses and activities; and provide for the protection, use, and development of the various resources within the planning unit. The plan provides for minimization of adverse effects. Minor adverse effects from some development activities will be temporary stream sedimentation and short periods of air pollution. All resource activities will be monitored so that tolerable levels of sedimentation will not be exceeded in the South Fork Salmon River.

Recreation opportunities will remain about the present level. A total of 64,800 acres has been designated as new wilderness study areas and an additional 142,090 acres will remain unroaded. About 14,710 acres presently undeveloped may be developed.

The plan provides for a low to moderate level of consumption resource uses with significant areas remaining undeveloped with options for future management remaining open.

This final environmental statement was transmitted to CEQ on August 26, 1975.

Copies are available for inspection during regular working hours at the following locations:

USDA, Forest Service, South Agriculture Bldg., Room 3230, 12th St. and Independence Ave., S.W., Washington, D.C. 20250.

Regional Planning Office, USDA, Forest Service, Federal Building, Room 4403, Ogden, Utah 84401.

Forest Supervisor, Boise National Forest, 1075 Park Boulevard, Boise, Idaho 83706.

Forest Supervisor, Payette National Forest, Forest Service Building, P.O. Box 1026, McCall, Idaho 83638.

District Forest Ranger, Krassel Ranger District, McCall, Idaho 83638.

District Forest Ranger, Cascade Ranger District, Cascade, Idaho 83611.

A limited number of single copies are available upon request to Forest Supervisor Edward C. Maw, Boise National Forest, 1075 Park Boulevard, Boise, Idaho 83706 and Forest Supervisor William B. Sendt, Payette National Forest, Forest Service Building, P.O. Box 1026, McCall, Idaho 83638.

Copies of the environmental statement have been sent to various Federal, State, and local agencies as outlined in the CEQ Guidelines.

Dated: August 26, 1975.

D. A. SCHULTZ,
Acting Director,
Regional Planning and Budget.

[FR Doc.75-23300 Filed 9-2-75;8:45 am]

Rural Electrification Administration

QUAKER STATE TELEPHONE CO.

Proposed Loan Guarantee

Under the authority of Public Law 93-32 (87 Stat. 65) and in conformance with applicable agency policies and procedures as set forth in the REA Bulletin 320-22, "Guarantee of Loans for Telephone Facilities," dated Fabruary 4, 1975, published in proposed form in the FEDERAL REGISTER, September 16, 1974, (Vol. 39 No. 180, pages 33228-33229) notice is hereby given that the Administrator of REA will consider providing a guarantee supported by the full faith and credit of the United States of America for a loan in the approximate amount of $11,500,000 to the Quaker State Telephone Company, Pine Grove, Pennsylvania. The loan funds will be used to finance the construction of facilities to extend telephone service to new subscribers, and improve telephone service for existing subscribers.

Legally organized lending agencies capable of making, holding and servicing the loan proposed to be guaranteed may obtain information and details of the proposed project from Mr. Harold J. Marshall, President, Quaker State Telephone Company, Pine Grove, Pennsylvania.

To assure consideration, proposals must be submitted (within 30 days of the date of this notice) to Mr. Harold J. Marshall. The right is reserved to give such consideration and make such evaluation or other disposition of all proposals received, as Quaker State Telephone Company and REA deem appropriate. Prospective lenders are advised that it is anticipated that financing for this project will be available from the Federal Financing Bank under a standing loan commitment agreement with the Rural Electrification Administration.

Copies of the REA Bulletin 320-22 are available from the Director, Information Services Division, Rural Electrification Administration, U.S. Department of Agriculture, Washington, D.C. 20250.

Dated at Washington, D.C., this 25 day of August, 1975.

DAVID A. HAMIL,
Administrator,
Rural Electrification Administration.

[FR Doc.75-23254 Filed 9-2-75;8:45 am]

Soil Conservation Service

NIBBS CREEK WATERSHED PROJECT, VIRGINIA

Availability of Final Environmental Impact Statement

Pursuant to Section 102(2)(C) of the National Environmental Policy Act of 1969; Part 1500 of the Council on Environmental Quality Guidelines (38 FR 20550, August 1, 1973); and Part 650 of the Soil Conservation Service Guidelines (39 FR 19650, June 3, 1974); the Soil Conservation Service, U.S. Department of Agriculture, has prepared a final environmental impact statement (EIS) for the Nibbs Creek Watershed Project, Amelia County, Virginia, USDA-SCS-EIS-WS-(ADM)-75-1(F)VA.

The EIS concerns a plan for watershed protection, flood prevention and municipal and industrial water supply. The planned works of improvement provide for conservation land treatment, 1 multiple-purpose reservoir with capacity for floodwater retarding and municipal and industrial water.

The final EIS has been filed with the Council on Environmental Quality.

A limited supply is available at the following location to fill single copy requests:

Soil Conservation Service, USDA, Room 9026, Federal Building, 400 North 8th Street, Richmond, Virginia 23240.

(Catalog of Federal Domestic Assistance program No. 10.904, National Archives Reference Services.)

SHELDON G. BOONE,
Acting Deputy Administrator for Water Resources, Soil Conservation Service.

AUGUST 26, 1975.

[FR Doc.75-23205 Filed 9-2-75;8:45 am]

DEPARTMENT OF COMMERCE

Domestic and International Business Administration

AUBURN UNIVERSITY, ET AL.

Applications for Duty-Free Entry of Scientific Articles

The following are notices of the receipt of applications for duty-free entry of scientific articles pursuant to Section 6 (c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Public Law 89-651; 80 Stat. 897). Interested persons may present their views with respect to the question of whether an instrument or apparatus of equivalent scientific value for the purposes for which the article is intended to be used is being manufactured in the United States. Such comments must be filed in triplicate with the Director, Special Import Programs Division, Office of Import Programs, Washington, D.C. 20230, within 20 calendar days after the date on which this notice of application is published in the FEDERAL REGISTER.

Amended regulations issued under cited Act, (40 F.R. 12253 et seq., 15 CFR 701,

1975) prescribe the requirements applicable to comments.

A copy of each application is on file, and may be examined during ordinary Commerce Department business hours at the Special Import Programs Division, Department of Commerce, Washington, D.C. 20230.

Docket number: 76-00090-01-77095. Applicant: Auburn University, Chemistry Department, Auburn, Alabama 36830. Article: PS-10 Photoelectron Spectrometer and Heated Probe. Manufacturer: Perkin-Elmer, United Kingdom. Intended use of article: The article is intended to be used for basic research in the electronic structure of matter and chemical bonding. The materials to be studied are organic compounds which are usually solid at room temperature. Experiments to be conducted are measurements of the photoelectron spectra of a free (gas phase) molecules. In addition, the article will be used by graduate students in basic research as partial fulfillment of the requirements for a dissertation for the degree of Doctor of Philosophy. The article will also be used for demonstration and student use in applied spectroscopy courses. Application received by Commissioner of Customs: August 20, 1975.

Docket number: 76-00089-33-77030. Applicant: University of Pennsylvania, School of Medicine, Department of Physiology, 37th and Hamilton Walk (A303 Richards Bldg.), Philadelphia, Pa. 19174. Article: NMR Spectrometer, Model CPS-2 and Probe Head. Manufacturer: Spin-Lock Electronics Ltd., Canada. Intended use of article: The article is intended to be used to characterize the mole fractions and NMR relaxation times of the several different populations of potassium within a variety of cells, including those from human lymphocytes, urinary bladder of the toad, frog striated muscle and rat lymphocytes. The relationship of the NMR properties of potassium to physiologically significant changes in tissue activity will be studied. Application received by Commissioner of Customs: August 20, 1975.

Docket number: 76-00088-84-23500. Applicant: Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460. Article: Type 122 Noise Dosimeter, and Type 129 Calibrator. Manufacturer: Computer Engineering Labs., United Kingdom. Intended use of article: The article is intended to be used for gathering personal noise exposure levels within transportation systems. Application received by Commissioner of Customs: August 20, 1975.

Docket number: 76-00091-33-46040. Applicant: Temple University, Health Science Center, Department of Pathology, 3400 North Broad Street, Philadelphia, Pa. 19140. Article: Electron Microscope, Model HU-12A. Manufacturer: Hitachi Ltd., Japan. Intended use of article: The article is intended to be used for research concerned with the fine structure of various aspects of cancer including squamous cell carcinoma in which the attachment zones at the cell surfaces are of considerable importance. Of particular interest is the evaluation of decreased numbers of attachment zones such as desmorsomes in noncancerous squamous epithelium invasive squamous cell carcinoma and cell carcinoma in-situ. The article is also intended to be used in studies designed to reveal the presence of virus in the cell tissue. Application received by Commissioner of Customs: August 20, 1975.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials.)

RICHARD M. SEPPA,
Acting Director,
Special Import Programs Division.

[FR Doc.75-23252 Filed 9-2-75;8:45 am]

AURA, INC.

Decision on Application for Duty-Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Public Law 89-651, 80 Stat. 897) and the regulations issued thereunder as amended (40 FR 12253 et seq, 15 CFR 701, 1975).

A copy of the record pertaining to this decision is available for public review during ordinary business hours of the Department of Commerce, at the Office of Import Programs, Department of Commerce, Washington, D.C. 20230.

Docket number: 75-00131-10-35600. Applicant: Aura, Inc., P.O. Box 26732, Tucson, Arizona 85726. Article: Concave UV Diffracting Grating. Manufacturer: Jobin-Yvon Optical Systems, France. Intended use of article: The article is intended to be used for comparison with standard ruled gratings. If they prove superior to the ruled gratings, the holographic gratings will be utilized in the ultraviolet spectrometer instrument aboard the Mariner spacecrafts to Jupiter and Saturn in 1977.

Comments: No comments have been received with respect to this application. Decision: Application approved. No instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, is being manufactured in the United States. Reasons: The National Bureau of Standards (NBS) advises in its memorandum dated August 8, 1975 that the article is a UV diffraction grating of the holographic type and as such it is pertinent to the applicant's intended purposes. NBS also advises that it knows of no domestic holographic grating of equivalent scientific value to the foreign article for such purposes as the article is intended to be used.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials.)

RICHARD M. SEPPA,
Acting Director,
Special Import Programs Division.

[FR Doc.75-23246 Filed 9-2-75;8:45 am]

COLORADO STATE UNIV.

Decision on Application for Duty-Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Public Law 89-651, 80 Stat. 897) and the regulations issued thereunder as amended (40 FR 12253 et seq., 15 CFR 701, 1975).

A copy of the record pertaining to this decision is available for public review during ordinary business hours of the Department of Commerce, at the Office of Import Programs, Department of Commerce, Washington, D.C. 20230.

Docket number: 75-00558-99-74600. Applicant: Colorado State University, Physics Department, College Avenue, Fort Collins, Colorado 80521. Article: 24 Channel Store Unit for a Malvern High Speed Correlator. Manufacturer: Precision Devices and Systems Ltd., United Kingdom. Intended use of article: The article is an accessory to an existing Malvern High Speed Correlator which is intended to be used to increase the resolution and flexibility of the system which will be used to determine and analyze the correlation spectrum of the laser light scattered from the turbulent flow (either laboratory flow or the real atmospheric flow) under investigation.

Comments: No comments have been received with respect to this application. Decision: Application approved. No instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, is being manufactured in the United States. Reasons: The application relates to a compatible accessory for an instrument that had been previously imported for the use of the applicant institution. The article is being furnished by the manufacturer which produced the instrument with which the article is intended to be used and is pertinent to the applicant's purposes. The Department of Commerce knows of no similar accessory being manufactured in the United States, which is interchangeable with or can be readily adapted to the instrument with which the foreign article is intended to be used.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials.)

RICHARD M. SEPPA,
Acting Director, Special
Import Programs Division.

[FR Doc.75-23247 Filed 9-2-75;8:45 am]

Applications for Duty-Free Entry of Scientific Articles

The following are notices of the receipt of applications for duty-free entry of scientific articles pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Public Law 89-651; 80 Stat. 897). Interested persons may present their views with respect to the question of whether an instrument or apparatus of

equivalent scientific value for the purposes for which the article is intended to be used in being manufactured in the United States. Such comments must be filed in triplicate with the Director, Special Import Programs Division, Office of Import Programs, Washington, D.C. 20230, within 20 calendar days after the date on which this notice of application is published in the FEDERAL REGISTER.

Amended regulations issued under cited Act, (40 FR 12253 et seq., 15 CFR 701, 1975) prescribe the requirements applicable to comments.

A copy of each application is on file, and may be examined during ordinary Commerce Department business hours at the Special Import Programs Division, Department of Commerce, Washington, D.C. 20230.

Docket number: 75-00077-33-46070. Applicant: Cornell University, New York State Veterinary College, Pathology Department, Multicategorical Research Wing, Ithaca, New York 14850. Article: Scanning Electron Microscope, Model HHS-2R, and accessories. Manufacturer: Hitachi Ltd., Japan. Intended use of article: The article is intended to be used for the following research:

(1) Reproductive studies involving research on infertility,

(2) Research on collagen diseases and wound healing,

(3) Cancer research on characterization of cancer cells, invasive growth, and cell surface characteristics that relate to the phenomenon of cellular contact inhibition,

(4) Immunology research, in which the article permits the recognition and differentiation of the various cell types which participate in immunological responses,

(5) Gastroenterology research in which the characteristics of the absorptive surfaces of the cells that line the digestive tract are related to gastrointestinal functional states and diseases,

(6) Bone pathology, in which the processes of osteoid deposition and subsequent mineralization are followed,

(7) Eye pathology, especially disease of the cornea, and

(8) Study of the early embryo, and the first stages of implantation.

In addition, the article will be used in courses in veterinary medicine for basic instruction in cellular morphology, membrane structure, and immunology. Application received by Commissioner of Customs: August 18, 1975.

Docket number: 76-00081-33-46040. Applicant: National Institute of Health, NINCDS, Surgical Neurology Branch, 9000 Rockville Pike, Bethesda, Md. 20014. Article: Electron Microscope, Model EM 201C, and accessories. Manufacturer: Philips Electronics Instruments, NVD, The Netherlands. Intended use of aricle: The article is intended to be used for biological research projects involving the peripheral nervous system and the central nervous system. Two interests include the study of cell membrane changes which accdmpany degeneration and regeneration in the PNS and the study of synaptic function in epileptogenic models in the CNS. Application received by Commissioner of Customs: August 18, 1975.

Docket number: 76-00082-33-90000. Applicant: Rush-Presbyterian-St. Luke's Medical Center, 1753 West Congress Parkway, Chicago, Illinois 60612. Article: EMI Scanner Body System (Prototype Design) and accessories. Manufacturer: EMI Limited, United Kingdom. Intended use of article: The article is intended to be used for computerized tomography studies of cancer, benign infections, blood clots, and cirrhosis in human patients. Experiments will be conducted by means of a tiny beam of x-radiation, numerous detectors, and a fast computer. Application received by Commissioner of Customs: August 18, 1975.

Docket number: 76-00083-75-68495. Applicant: University of California, Los Alamos Scientific Laboratory, P.O. Box 990, Los Alamos, NM 87545. Article: Mechanical circulating pump. Manufacturer: SRTI, France. Intended use of article: The article is intended to be used for the separation of deuterium-tritium mixtures by low temperature distillation. Experiments to be conducted will include all experiments relative to the design and operation of an efficient deuterium-tritium distillation system together with associated pump, valves, pipes and tritium handling procedures and materials as an integral portion of the Intense Neutron Sources (a national facility for radiation damage studies). Application received by Commissioner of Customs: August 18, 1975.

Docket number: 76-00084-33-90000. Applicant: Memorial Hospital, 1901 Arlington Street, Sarasota, Florida 33579. Article: EMI Scanner System with Magnetic Tape System. Manufacturer: EMI Limited, United Kingdom. Intended use of article: The article is intended to be used by staff radiologists, neurosurgeons, and neurologists for frequent studies for papers and article for submission to appropriate journals. In addition, the articles will be used to maintain a teaching file for continuing the education of these physicians. Students seeking degrees as Radiology Technicians will be instructed on the article and will be taught how to perform scans using the equipment. Application received by Commissioner of Customs: August 18, 1975.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials.)

RICHARD M. SEPPA,
Acting Director,
Special Import Programs Division.

[FR Doc.75-23251 Filed 9-2-75;8:45 am]

GEORGE WASHINGTON U.

Decision on Application for Duty-Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Public Law 89-651, 80 Stat. 897) and the regulations issued thereunder as amended (40 FR 12253 et seq., 15 CFR 701, 1975).

A copy of the record pertaining to this decision is available for public review during ordinary business hours of the Department of Commerce, at the Office of Import Programs, Department of Commerce, Washington, D.C. 20230.

Docket number: 75-00495-33-46040. Applicant: The George Washington University, Department of Pathology, 2300 Eye Street, NW., Washington, D.C. 20037. Article: Electron Microscope, Model EM 10. Manufacturer: Carl Zeiss, West Germany. Intended use of article: The article is intended to be used in fine structural studies of brain tissue from Rhesus monkey fetuses infected with live influenza virus. These ultrastructural studies are part of a broader investigation of the teratogenic potential of viruses for man using a primate model. The article will also be used to conduct a basic course entitled "Introduction to Electron Microscopy" in which students are to be provided with a working knowledge in the basic techniques of electron microscopy, including the actual operation of the transmission electron microscope. In addition, the article will be used in the field of diagnostic pathology.

Comments: No comments have been received with respect to this application. Decision: Application approved. No instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, is being manufactured in the United States. Reasons: The foreign article provides distortion free micrographs over a magnification range 100 to 200,000× without a pole-piece change. The most closely comparable domestic instrument available is the Model EMU-4C electron microscope currently supplied by the Adam David Company (Adam David). When the article was ordered the Model EMU-4C with its standard pole-piece, had a specified range from 1,400 to 240,000 magnifications. For survey and scanning, the lower end of this range could be reduced to 200 magnifications or less. But the continued reduction of magnification induced an increasingly greater distortion. The domestic manufacturer suggests in its literature on the Model EMU-4C that for highest quality, low magnification electron micrographs, an optional low magnification pole-piece providing 500-7000× should be used. It is noted that changing the pole-piece on the Model EMU-4C requires a break in the vacuum of the column that induces the danger of contamination which would very likely lead to the failure of the experiment.

The Department of Health, Education, and Welfare (HEW) advises in its memorandum dated August 1, 1975 that distortion free micrographs at low magnifications (100×) immediately followed by high magnification examinations at 200,000× without a pole-piece change is pertinent to the applicant's purposes. HEW also advises that the magnification

range without pole-piece change of the domestic Model EMU-4C is not scientifically equivalent to that of the foreign article for the applicant's intended use.

We, therefore, find that the Model EMU-4C is not of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used.

The Department of Commerce knows of no other instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, which is being manufactured in the United States.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials.)

RICHARD M. SEPPA,
Acting Director,
Special Import Programs Division.

[FR Doc.75-23250 Filed 9-2-75;8:45 am]

NORTHWESTERN UNIV.

Decision on Application for Duty-Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Public Law 89-651, 80 Stat. 897) and the regulations issued thereunder as amended (40 FR 12253 et seq, 15 CFR 701, 1975).

A copy of the record pertaining to this decision is available for public review during ordinary business hours of the Department of Commerce, at the Office of Import Programs, Department of Commerce, Washington, D.C. 20230.

Docket number: 75-00490-33-43400. Applicant: Northwestern University, Auditory Physiology Laboratory, Frances Searle Building, Evanston, Illinois 60201. Article: Automatic Stepping Micromanipulator and Electron Control Unit. Manufacturer: AB Transvertex Co., Sweden. Intended use of article: The article is intended to be used in experiments concerned with the study of bioelectric phenomena in the auditory system. Specifically, the electrical activity generated in response to sound by the sensory receptor cells and fibers of the auditory nerve are investigated. The overall purpose of these experiments is to delineate the energy conversion processes that take place in the inner ear which mediate hearing.

Comments: No comments have been received with respect to this application. Decision: Application approved. No instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, is being manufactured in the United States. Reasons: The foreign article provides remote control, freedom from creep, discrete stepping motion (4 micron increments), and a two micrometer step capability.

The Department of Health, Education, and Welfare (HEW) advises in its memorandum dated August 1, 1975 that the capabilities of the article described above are pertinent to the applicant's intended purposes. HEW also advises that it knows of no domestic instrument of equivalent scientific value to the foreign article for such purposes as the article is intended to be used.

The Department of Commerce knows of no other instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, which is being manufactured in the United States.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials.)

RICHARD M. SEPPA,
Acting Director,
Special Import Programs Division.

[FR Doc.75-23248 Filed 9-2-75;8:45 am]

U. OF CALIF., BERKELEY

Decision on Application for Duty-Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Public Law 89-651, 80 Stat. 897) and the regulations issued thereunder as amended (40 FR 12253 et seq., 15 CFR 701, 1975).

A copy of the record pertaining to this decision is available for public review during ordinary business hours of the Department of Commerce, at the Office of Import Programs, Department of Commerce, Washington, D.C. 20230.

Docket number: 75-00535-01-47500. Applicant: University of California, Lawrence Berkeley Laboratory, East End of Hearst Avenue, Berkeley, California 94720. Article: Monochromator Type THR 1500. Manufacturer: Jobin-Yvon, France. Intended use of article: The article is intended to be used in a laser isotope separation program to resolve chemiluminescence generated in chemical reactions, as well as to make basic spectroscopic measurements on uranium molecular vapors. Isotope shifts of materials being investigated will be measured and characteristic emission spectra will be recorded. The objective pursued in the course of these investigations is the identification and measurement of critical parameters of spectral lines suitable for use in commercial processes for laser photoseparation of isotopes.

Comments: No comments have been received with respect to this application. Decision: Application approved. No instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, is being manufactured in the United States. Reasons: The foreign article provides a specification of a monochromator with a resolution capability in excess of 1:270,000 in the first order. The National Bureau of Standards (NBS) advises in its memorandum dated August 12, 1975 that it knows of no domestic instrument that provides a resolution in first order greater than 1:100,000. NBS also advises that (1) the greater resolution of the article is pertinent to the applicant's intended purposes and (2) it knows of no instrument of equivalent scientific value to the foreign article for such purposes as the article is intended to be used which is being manufactured in the United States.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials.)

RICHARD M. SEPPA,
Acting Director,
Special Import Programs Division.

[FR Doc.75-23249 Filed 9-2-75;8:45 am]

FOREIGN AVAILABILITY SUBCOMMITTEE OF THE NUMERICALLY CONTROLLED MACHINE TOOL TECHNICAL ADVISORY COMMITTEE

Open Meeting

Pursuant to the provisions of the Federal Advisory Committee Act, 5 U.S.C. App. I (Supp. III, 1973), notice is hereby given that a meeting of the Foreign Availability Subcommittee of the Numerically Controlled Machine Tool Technical Advisory Committee will be held on Monday, October 6, 1975 at 1:00 p.m. in Room 4833, Main Commerce Building, 14th and Constitution Avenue, NW., Washington, D.C.

The Numerically Controlled Machine Tool Technical Advisory Committee was initially established on January 3, 1973. On December 20, 1974, the Acting Assistant Secretary for Administration approved the recharter and extension of the Committee for two additional years, pursuant to Section 5(c)(1) of the Export Administration Act of 1969, as amended, 50 U.S.C. App. Sec. 2404(c)(1) (Supp. III, 1973) and the Federal Advisory Committee Act. The Foreign Availability Subcommittee of the Numerically Controlled Machine Tool Technical Advisory Committee was initially established on July 10, 1973. On July 15, 1975, the Director, Office of Export Administration approved the reestablishment of the Subcommittee, pursuant to the charter of the Committee.

The Committee advises the Office of Export Administration, Bureau of East-West Trade, with respect to questions involving technical matters, world-wide availability and actual utilization of production and technology, and licensing procedures which may affect the level of export controls applicable to numerically controlled machine tools, including technical data related thereto, and including those whose export is subject to multilateral (COCOM) controls. The Foreign Availability Subcommittee was formed to determine the extent of foreign capability in numerically controlled technology.

The agenda for the meeting is:

(1) Opening remarks by the Subcommittee Chairman.

(2) Presentation of papers or comments by the public.

(3) Discussion of definitive work program of the Subcommittee:

(a) Specific topic areas to be addressed.

(b) Role of industry and government representatives.

(c) Time frame to undertake the work program.

The meeting will be open for public observation and a limited number of seats will be available to the public. To the extent time permits members of the public may present oral statements to the Subcommittee. Written statements may be submitted at any time before or after the meeting.

Copies of the minutes of the meeting will be available upon written request addressed to the Freedom of Information Officer, Room 3100, Domestic and International Business Administration, U.S. Department of Commerce, Washington, D.C. 20230.

For further information, contact Mr. Charles C. Swanson, Director, Operations Division, Office of Export Administration, Domestic and International Business Administration, Room 1620, U.S. Department of Commerce, Washington, D.C. 20230, telephone: A/C 202/967-4196.

Dated: August 28, 1975.

RAUER H. MEYER,
Director, Office of Export Administration, Bureau of East-West Trade, U.S. Department of Commerce.

[FR Doc.75-23279 Filed 9-2-75;8:45 am]

NEW TECHNOLOGY SUBCOMMITTEE OF THE NUMERICALLY CONTROLLED MACHINE TOOL TECHNICAL ADVISORY COMMITTEE

Open Meeting

Pursuant to the provisions of the Federal Advisory Committee Act, 5 U.S.C. App. I (Supp. III, 1973), notice is hereby given that a meeting of the New Technology Subcommittee of the Numerically Controlled Machine Tool Technical Advisory Committee will be held on Monday, October 6, 1975 at 9 a.m. in Room 4833, Main Commerce Building, 14th and Constitution Avenue, NW., Washington, D.C.

The Numerically Controlled Machine Tool Technical Advisory Committee was initially established on January 3, 1973. On December 20, 1974, the Acting Assistant Secretary for Administration approved the recharter and extension of the Committee for two additional years, pursuant to Section 5(c)(1) of the Export Administration Act of 1969, as amended, 50 U.S.C. App. Sec. 2404(c)(1) (Supp. III, 1973) and the Federal Advisory Committee Act. The New Technology Subcommittee of the Numerically Controlled Machine Tool Technical Advisory Committee was established on July 15, 1975, with the approval of the Director, Office of Export Administration, pursuant to the charter of the Committee.

The Committee advises the Office of Export Administration, Bureau of East-West Trade, with respect to questions involving technical matters, world-wide availability and actual utilization of production and technology, and licensing procedures which may affect the level of export controls applicable to numerically controlled machine tools, including technical data related thereto, and including those whose export is subject to multilateral (COCOM) controls. The New Technology Subcommittee was formed to determine the impact of advanced electronics on the design of numerically controlled systems.

The agenda for the meeting is:

(1) Opening remarks by the Subcommittee Chairman.

(2) Presentation of papers or comments by the public.

(3) Discussion of future work programs of the Subcommittee:

(a) Identification of areas of new technology related to the purpose of the Committee, including DNC, CAM, microprocessors, software, robots and programmable controls.

(b) Possible identification of resource persons in each area of interest.

The meeting will be open for public observation and a limited number of seats will be available to the public. To the extent time permits members of the public may present oral statements to the Subcommittee. Written statements may be submitted at any time before or after the meeting.

Copies of the minutes of the meeting will be available upon written request addressed to the Freedom of Information Officer, Room 3100, Domestic and International Business Administration, U.S. Department of Commerce, Washington, D.C. 20230.

For further information, contact Mr. Charles C. Swanson, Director, Operations Division, Office of Export Administration, Domestic and International Business Administration, Room 1620, U.S. Department of Commerce, Washington, D.C. 20230, telephone: A/C 202/967-4196.

Dated August 28, 1975.

RAUER H. MEYER,
Director, Office of Export Administration, Bureau of East-West Trade, U.S. Department of Commerce.

[FR Doc.75-23278 Filed 9-2-75;8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[Docket No. 75F-0206]

NALCO CHEMICAL CO.

Filing of Petition for Food Additive

Pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409 (b)(5), 72 Stat. 1786 (21 U.S.C. 348 (b)(5))), notice is given that a petition (FAP 5H3110) has been filed by Nalco Chemical Co., 2901 Butterfield Rd., Oak Brook, IL 60521, proposing that § 121.1225 *Adjuvants for pesticide use dilutions* (21 CFR 121.1225) be amended to provide for safe use of a sodium acrylate and acrylamide copolymer as a drift control agent to be added by a grower or applicator to fungicide formulations before applying to growing crops.

The environmental impact analysis report and other relevant material have been reviewed, and it has been determined that the proposed use of the additive will not have a significant environmental impact. Copies of the environmental impact analysis report may be seen in the office of the Assistant Commissioner for Public Affairs, Rm. 15B-42 or the office of the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852, during working hours, Monday through Friday.

Dated: August 26, 1975.

HOWARD R. ROBERTS,
Acting Director, Bureau of Drugs.

[FR Doc.75-23238 Filed 9-2-75;8:45 am]

[Docket No. 75F-0207]

MONSANTO CO.

Filing of Petition for Food Additive

Pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409 (b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 5B3059) has been filed by Keller and Heckman, 1150 17th St., NW., Washington, D.C., on behalf of Monsanto Co., proposing that paragraph (b)(3)(xx) of § 121.2514 *Resinous and polymeric coatings* (21 CFR 121.2514) be amended to provide for safe use of a copolymer of 2-ethylhexyl acrylate and ethyl acrylate as a component of resinous and polymeric coatings intended to contact food.

The environmental impact analysis report and other relevant material have been reviewed, and it has been determined that the proposed use of the additive will not have a significant environmental impact. Copies of the environmental impact analysis report may be seen in the office of the Assistant Commissioner for Public Affairs, Rm. 15B-42 or the office of the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852, during working hours, Monday through Friday.

Dated: August 26, 1975.

HOWARD R. ROBERTS,
Acting Director, Bureau of Foods.

[FR Doc.75-23239 Filed 9-2-75;8:45 am]

Office of Education

TRAINING GRANTS; BUREAU OF EDUCATION OF THE HANDICAPPED

Priorities and Notice of Closing Date for Receipt of Applications

Notice is hereby given that pursuant to the authority contained in sections 631, 632, and 634 of Part D of the Education of the Handicapped Act (20 U.S.C. 1431, 1432, and 1434), the U.S. Commissioner of Education, with the approval of the Secretary of Health, Education, and Welfare, has established the final closing date of October 22, 1975 for receipt of applications for new and continuation training grants under Part D of the Act.

Regulations governing grants for teacher training authorized under Part D of the Act were published in the FEDERAL REGISTER as Part 121f of Title 45 of the Code of Federal Regulations (45 CFR Part 121f) on February 20, 1975 (40 FR 7419–7422). Awards are also subject to the Office of Education General Provisions Regulations, 45 CFR Part 100a.

Applications must be received by the U.S. Office of Education Application Control Center on or before October 22, 1975.

A. *Applications sent by mail.* An application sent by mail should be addressed as follows: U.S. Office of Education, Application Control Center, 400 Maryland Avenue, SW., Washington, D.C. 20202, Attention: 13.451. An application sent by mail will be considered to be received on time by the Application Control Center if:

(1) The application was sent by registered or certified mail not later than October 17, 1975 as evidenced by the U.S. Postal Service postmark on the wrapper or envelope, or on the original receipt from the U.S. Postal Service; or

(2) The application is received on or before the closing date by either the Department of Health, Education, and Welfare, or the U.S. Office of Education mailrooms in Washington, D.C. (In establishing the date of receipt, the Commissioner will rely on the time date stamp of such mailrooms or other documentary evidence of receipt maintained by the Department of Health, Education, and Welfare, or the U.S. Office of Education).

B. *Hand delivered applications.* An application to be hand delivered must be taken to the U.S. Office of Education Application Control Center, Room 5673, Regional Office Building Three, 7th and D Streets, SW., Washington, D.C. Hand delivered applications will be accepted daily between the hours of 8 a.m. and 4 p.m., Washington, D.C. time, except Saturdays, Sundays, or Federal holidays. Applications will not be accepted after 4 p.m. on the closing date.

C. *Purpose.* In order to ensure an adequate supply of educational personnel competent to deal with the special problems of the handicapped, this program provides financial assistance through grants to institutions of higher education, State educational agencies, and other appropriate nonprofit agencies as defined in Part D of the Education of the Handicapped Act for the training of teachers, supervisors, administrators, researchers, teacher educators, speech pathologists, and other special services personnel, such as specialists in physical education and recreation and paraprofessionals.

D. *Eligible applicants.* Eligible applicants under this part of the Act include institutions of higher education, State educational agencies and other nonprofit agencies.

E. *Program priorities.* In addition to the criteria set forth in section 121f.20 (45 CFR 121f.20), several program priorities will be stressed in the award of new and continuation grants. Applications must contain descriptions of personnel preparation programs relevant to these priorities, as well as those which are unique to the State or local geographical area. The program priorities, not in rank order, follow with estimated funds for new and continuation at both pre-service and in-service levels of training. Examples are given after the stated priority.

(1) Early childhood education—$5,220,000 estimated. Preparation of personnel to function with preschool handicapped children and infants.

(2) Severely handicapped—$8,690,000 estimated. Preparation of personnel to serve the severely and multi-handicapped; preparation of personnel to serve handicapped children where large needs still exist, e.g., seriously emotionally disturbed and autistic; programs which prepare personnel for national and regional needs, e.g., low incidence areas such as the visually handicapped and deaf.

(3) Paraprofessional—$1,170,000 estimated. Preparation of personnel who will assist in the classroom in the education of handicapped children.

(4) Physical Education—$895,000 estimated. Preparation of personnel who will provide physical education for handicapped children.

(5) Recreation—$800,000 estimated. Preparation of personnel who will provide therapeutic recreation service for handicapped children.

(6) Interdisciplinary—$580,000 estimated. Preparation on an interdisciplinary basis of personnel who will work with handicapped children.

(7) General Special Education—$10,785,000 estimated. Preparation of personnel who will provide educational services to handicapped children.

(8) Vocational/career education—$1,310,000 estimated. Programs which stress the preparation of personnel to function in career or vocational education programs for the handicapped.

(9) Regular Education—$6,550,000 estimated. Programs which train at a preservice and/or in-service level regular education teachers as well as physical education and recreation specialists, with supportive services from special educators to work with children who display variations in learning or behavioral styles.

(10) Developmental Assistance—$400,000 estimated. Programs which provide post-doctoral training in the education of the handicapped.

(11) Model Implementation (Special Project)—$3,350,000 estimated. Programs which develop new models of instruction or train personnel for a new type of role.

F. *Program information and forms.* Information and application forms may be obtained from the Division of Personnel Preparation, Bureau of Education for the Handicapped, U.S. Office of Education, Washington, D.C. 20202.

G. The priorities relating to amounts of money and major funding categories listed in paragraph E were established in the budget and in testimony before the Congress. Since they would be not subject to change as a result of public comment, the Commissioner of Education has determined that proposed rulemaking procedures are unnecessary and should be waived under 5 U.S.C. 553(b).

Effective date. Pursuant to section 431 (d) of the General Education Provisions Act, as amended (20 U.S.C. 1232(d)), the priorities set forth in this notice have been transmitted to the Congress concurrently with the publication of this document in the FEDERAL REGISTER. That section provides that matters subject thereto shall become effective on the forty-fifth day following the date of such transmission, subject to the provisions therein concerning Congressional action and adjournment.

(20 U.S.C. 1431, 1432, 1434)

(Catalog of Federal Domestic Assistance Number 13.451 — Handicapped — Teacher Training)

Dated: July 29, 1975.

T. H. BELL,
U.S. Commissioner of Education.

Approved: August 27, 1975.

DAVID MATHEWS,
Secretary of Health, Education, and Welfare.

[FR Doc.75-23292 Filed 9-2-75;8:45 am]

Office of the Secretary

[Contract No. HEW-100-76-0029]

ANALYSIS OF INCENTIVE REIMBURSEMENT SYSTEM FOR HEALTH CARE/LONG TERM CARE SERVICES PROVIDED TO THE ELDERLY AND LONG-TERM DISABLED

Contract Award

Pursuant to Section 606 of the Community Services Act of 1974, (Pub. L. 93-644) 42 U.S.C. 2946, this agency announces the award of Contract No. HEW-100-76-0029 to Applied Management Sciences, 962 Wayne Avenue, Suite 701, Silver Spring, Maryland 20910 for a research project entitled, "Analysis of Incentive Reimbursement System for Health Care/Long Term Care Services Provided to the Elderly and Long-Term Disabled." The purpose of this project is to evaluate the assets and liabilities of an incentive reimbursement system developed under Contract No. HEW-OS-74-176 for financing health and other long-term care services provided to the elderly and long-term disabled. The estimated cost of this contract is $89,846 and the intended completion date is July 31, 1976.

Dated: August 28, 1975.

WILLIAM A. MORRILL,
Assistant Secretary for Planning and Evaluation.

[FR Doc.75-23288 Filed 9-2-75;8:45 am]

OFFICE OF THE REGIONAL DIRECTOR, REGION VI

Statement of Organization, Functions, and Delegations of Authority

Part 1 of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health, Education, and Welfare, Office of the Secretary (40 FR 4665–70 1/31/75) is amended to add under Section 1E86.20 Functions, the functions of the Office of the Assistant Regional Director for Program Coordination and the Office of the Assistant Regional Director for Intergovernmental Operations. The amended statement reads as follows:

H. *Assistant Regional Director for Program Coordination.*

1. Serves as principal advisor to the Regional Director and supervises a staff unit to ensure the coordination of HEW programs. Serves as principal advisor to the Regional Director in identifying and directing activities to meet the needs and requirements for the planning and evaluation of HEW and related Federal, State, local and private human resources programs within the Region.

2. Develops cooperative relationships among the principal HEW Regional components in order to promote the coordination of resources to accomplish regional program priorities.

3. Is responsible for resolving cross-programmatic issues and stimulating interaction among and across categorical program lines in order to improve the effectiveness and efficiency of human resource activities; plans and carries out studies of regional program operations for the purpose of advising the Regional Director and other regional officials of ways to encourage the meshing of Federal, State and local resources. Identifies needs, opportunities, and mechanisms for interagency coordination, planning and evaluation activities, in order to better accomplish Regional Office goals and objectives.

4. Establishes and maintains an issues identification and resolution process, in coordination with other Regional staff, and with this process:

a. Coordinates identification and analysis of HEW-related issues needing clarification and facilitates resolution of such issues; and

b. Identifies on a geographic basis needs and problems in the Region with a special emphasis on target and special concern groups.

5. Establishes with the Assistant Regional Director of Intergovernmental Operations (ARD/IGO) an intergovernmental review and comment process in order to:

a. Disseminate proposed National policies, legislation, and regulations within the Region;

b. Analyze these proposals for Regional implications, especially in light of Regional observation of needs.

6. Establishes and maintains an evaluation planning and management process which:

a. Provides an interface with central office evaluation planning process;

b. For HEW programs managed by the Regional Office, identifies information needs for Regional decision-making and prepares a Regional Office plan for developing, implementing and utilizing evaluation results;

c. Identifies programs directly operated by the Regional Director, information needed to describe programs progress and then develops instrument and techniques for measuring progress in reaching program goals; and

d. Ensures for all DHEW programs dissemination of evaluation results within the Region.

7. Designs and implements methods for improving evaluation and monitoring capabilities of Regional Agencies.

8. Develops and monitors implementation of a Regional capacity-building plan. Coordinates plan with ARD/IGO and Regional Agencies. Identifies and assesses the constraints which impede current and/or potential participants from preparing effective program designs. Develops strategies for eliminating constraints and improving capacities. Plans for and monitors the provisions of technical or financial assistance to general purpose governments in the development of integrated service and management systems.

9. Establishes in coordination with the Assistant Regional Director, Administration and Management, and ARD/IGO, procedural and substantive criteria for the management review of those grants and contracts covered by the RDRS system, all developmental assistance programs, and all programs serving cross-agency target groups. Reviews grants and contracts proposals for general adherence to program goals and management soundness and exercises Regional sign-off authority as appropriate.

10. Participates in interagency or interdepartmental studies with responsibility for fact-finding, analysis, and making recommendations to top level policy making officials about National program planning.

11. Provides leadership and expertise in the design, establishment, maintenance, and effective use of management information and the systems related thereto.

12. Organizes, directs and coordinates regional activities related to the Operational Planning System. In this regard, establishes and maintains a regional planning process designed to achieve mission-related objectives within the framework of Departmental goals and regional priorities. Through this process:

a. Identifies and analyzes regional needs, incorporating these into Regional Issue papers which are statements of regional planning priorities and/or regional recommendations for headquarters policies;

b. Establishes regional objectives and plans which address identified needs;

c. Participates in HEW Master Planning Calendar activities, the forward planning process and development of preliminary program budgets in conjunction with Regional agencies.

I. *Assistant Regional Director for Intergovernmental Operations.* 1. Serves as a principal advisor to the Regional Director and supervises a staff unit charged with the accomplishment of the Department's intergovernmental coordination and management assistance mission in the Region.

2. Serves as the Regional Director's representative in establishing and maintaining systematic contacts with the offices of Governors, State Legislators, Congressmen, county executives and Mayors. Recommends methods for achieving goals and objectives, exercising priorities and implementing policies pertaining to State and local general purpose governments.

3. Establishes and maintains a process for the identification of intergovernmental issues; refers these issues to the Regional Director, the Assistant Regional Director for Program Coordination (ARD/PC), and/or the Regional Agency Heads (as appropriate) for proper resolution; and coordinates the dissemination of information on DHEW policies, legislation and budget to State and local general purpose governments and representatives of public interest groups.

4. In cooperation with the ARD/PC and/or Regional Agency Heads, coordinates and monitors procedures for securing timely State and local general purpose government review and comment upon appropriate DHEW policies, legislation and regulations; keeps the Regional Director informed about current developments concerning significant new human resource legislation and policies at the State and local levels.

5. Identifies and brings to the attention of the ARD/PC issues and problems which may be amendable to DHEW evaluation; facilitates in coordination with the ARD/PC the dissemination of significant evaluation findings to State and local governments.

6. Ensures that the Regional Office role in implementation of departmental policies through such systems as the Operational Planning System (OPS) is fully understood by State and local general purpose governments. In cooperation with the ARD/PC and/or Regional Agency Heads develops a process for disseminating information on operational objectives to State and local governments and special concern groups. Serves as a focal point for the exchange of information with other Federal departments when interagency efforts are required to implement policies and legislation.

7. Coordinates the planning and delivery of management assistance to State and local general purpose governments in the accomplishment of common program objectives.

8. In coordination with the ARD/PC Regional Agencies, implements an Intergovernmental Capacity Building Program, including methods for eliminating constraints which impede current and/or potential participants from developing

effective delivery systems; provides management assistance to general purpose governments in the development of integrated planning, services and management systems.

9. Participates on interagency and intradepartmental committees concerned with fact-finding, analysis and making recommendations to policy level officials concerning intergovernmental issues.

10. Provides leadership for carrying out the Regional Office manpower coordination role under the Comprehensive Employment and Training Act (CETA). Assures that the regional work plan is implemented properly through the Regional Manpower Coordinator and the Manpower Working Group. Identifies interrelationships between manpower coordination activities and other Departmental initiatives including capacity building, services integration, and the proposed Allied Services Act.

11. Ensures regional office compliance with the National Environmental Policy Act, National Historic Preservation Act, National Archeological Preservation Act, related laws, executive orders, regulations and guidelines. Recommends regional office policy and develops procedures to ensure a coordinated and interdisciplinary approach to assist programs in the conduct of environmental analysis and preparation of documents for activities subject to the above-mentioned requirements in accordance with Departmental procedures. Identifies and advises the Regional Director as to a recommended course of action with respect to emerging environmental issues of concern to the Department and coordinates environmental reviews by regional program staff in response to other Federal agency requests for input. Apprises general purpose government, Federal Regional Councils, clearinghouses and other concerned organizations with respect to HEW NEPA requirements and proposed actions impacting on the community. Serves as the principal regional contact point with the Department's Chief Environmental Officer and notifies him of key issues and emerging problems on which the Secretary should be advised. Participates in and coordinates regional input to environmentally related interagency studies and task forces.

12. Establishes and maintains procedures for compliance with the Intergovernmental Cooperation Act (ICA), including the processing of waivers to the single state agency requirement; securing review and comment on proposed DHEW assisted projects and State plans through Clearinghouses established in accordance with OMB Circular A-95; and providing timely budgetary and fiscal information to State and local officials in accordance with Treasury Circular 1082.

13. In coordination with the ARD for Financial Management and Regional Agency Heads processes multi-program requests for federal assistance under the Joint Funding and Simplification Act (JFSA); provides training to Regional Office personnel; and establishes procedures for coordination of requirements with NEPA, ICA and related statutes.

14. Ensures that consumer protection agencies at the State and local level as well as lower income consumers served by the Department are provided with timely information relating to DHEW policies, programs and procedures.

15. In cooperation with the Regional Engineer and Regional Agency Heads establishes and monitors procedures for the conservation of energy among State and local governments receiving DHEW financial assistance.

Dated: August 25, 1975.

JOHN OTTINA,
Assistant Secretary for Administration and Management.

[FR Doc.75-23290 Filed 9-2-75;8:45 am]

SECRETARY'S ADVISORY COMMITTEE ON POPULATION AFFAIRS

Meeting

The Advisory Committee on Population Affairs, established to advise the Secretary regarding all significant aspects of family planning and population research activities coming under the purview of the Department of Health, Education, and Welfare is scheduled to hold a meeting on October 23, 1975. The meeting will be held in Room 5169 of the Department's North Building located at 330 Independence Ave., SW., Washington, D.C. The meeting is scheduled to convene at 9:30 a.m. and adjourn at 5 p.m.

The Committee will discuss the sterilization of individuals in federally subsidized programs and family planning legislation. The meeting is open for public observation.

Dated: August 18, 1975.

LOUIS M. HELLMAN,
Chairman and Executive Secretary.

[FR Doc.75-23289 Filed 9-2-75;8:45 am]

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of Interstate Land Sales Registration

[Docket No. N-75-420]

BONANZA RANCHOS SUBDIVISION

Hearing

In the matter of Bonanza Ranchos Subdivision, OILSR No. 0-2544-09-762, Docket No. 75-29-IS, pursuant to 15 U.S.C. 1706(d) and 24 CFR 1720.160(d).

Notice is hereby given that: 1. Bonanza Ranch Estates, Inc., Eduardo C. Cadea, Comptroller, its officers and agents, hereinafter referred to as "Respondent," being subject to the provisions of the Interstate Land Sales Full Disclosure Act (Pub. Law 90-448) (15 U.S.C. 1701 et seq.), received a Notice of Proceedings and Opportunity for Hearing issued June 26, 1975, which was sent to the developer pursuant to 15 U.S.C. 1706(d), 24 CFR 1710.45(b)(1) and 1720.125 informing the developer of information obtained by the Office of Interstate Land Sales Registration alleging that the Statement of Record and Property Report for Bonanza Ranchos Subdivision, located in Dade County, Florida, contain untrue statements of material fact or omit to state material facts required to be stated therein or necessary to make the statements therein not misleading.

2. The Respondent filed an Answer received August 5, 1975, in response to the Notice of Proceedings and Opportunity for Hearing.

3. In said Answer the Respondent requested a hearing on the allegations contained in the Notice of Proceedings and Opportunity for Hearing.

4. Therefore, pursuant to the provisions of 15 U.S.C. 1706(d) and 24 CFR 1720.160(d), it is hereby ordered that a public hearing for the purpose of taking evidence on the questions set forth in the Notice of Proceedings and Opportunity for Hearing will be held before Judge James W. Mast, in Room 7146, Department of HUD, 451 7th Street, SW., Washington, D.C., on September 19, 1975, at 10:00 a.m.

The following time and procedure is applicable to such hearing: All affidavits and a list of all witnesses are requested to be filed with the Hearing Clerk, HUD Building, Room 10150, Washington, D.C., 20410 on or before September 5, 1975.

6. The Respondent is hereby notified that failure to appear at the above scheduled hearing shall be deemed a default and the proceedings shall be determined against Respondent, the allegations of which shall be deemed to be true, and an ORDER Suspending the Statement of Record, herein identified, shall be issued pursuant to 24 CFR 1710.45(b)(1).

This Notice shall be served upon the Respondent forthwith pursuant to 24 CFR 1720.440.

By the Secretary.

Dated: August 26, 1975.

JAMES W. MAST,
Administrative Law Judge.

[FR Doc.75-23255 Filed 9-2-75;8:45 am]

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. 75-18; Notice 2]

HIGHWAY SAFETY ACT SANCTIONS REVIEW BOARD; UTAH HEARING

Appointment of Board Members

On July 28, 1975, the Federal Highway Administrator and the National Highway Traffic Safety Administrator acting jointly issued a notice (40 FR 32154, July 31, 1975) initiating proceedings to determine whether to invoke the sanctions specified in 23 U.S.C. § 402 against the State of Utah. The basis for the initiation of the proceedings was Utah's failure to enact a helmet use law for motorcycle drivers and passengers. The notice also announced that the sanctions hear-

ing would be held at the Department of Transportation Headquarters Building, Room 2230, 400 Seventh Street, S.W., Washington, D.C. 20590 at 10:00 a.m. on September 4, 1975.

Accordingly, pursuant to § 1206.7 of Title 23, Code of Federal Regulations, a review board of three officials of the Department of Transportation has been appointed to conduct the hearing in accordance with the rules of procedure set forth in Part 1206 of Title 23, Code of Federal Regulations, for the purpose of receiving evidence and views from the State of Utah and interested persons concerning the proposal to invoke sanctions. The membership of the board is as follows:

Office of the Secretary Member and Presiding Officer: Herbert H. Kaiser, Jr., Deputy Assistant Secretary for Environment, Safety, and Consumer Affairs.

Federal Highway Administration Member: William G. Emrich, Director, Office of Environment and Design, Region V, Homewood, Illinois.

National Highway Traffic Safety Administration Member: Frank Ephraim, Director of the Office of Program Evaluation.

Issued on August 28, 1975.

HERBERT H. KAISER, Jr.,
Presiding Officer,
Sanctions Hearing Board.

[FR Doc.75-23362 Filed 8-29-75;11:42 am]

CIVIL AERONAUTICS BOARD

AIRLINE OPERATIONAL CONTROL SOCIETY

Meeting

Notice is hereby given that a presentation will be made by the Airline Operational Control Society on October 2, 1975, at 10 a.m. (local time), in Room 1027, Universal Building, 1825 Connecticut Avenue, NW., Washington, D.C., entitled, "The Aircraft Dispatcher."

Dated at Washington, D.C., August 27, 1975.

[SEAL] EDWIN Z. HOLLAND,
Secretary.

[FR Doc.75-23285 Filed 9-2-75;8:45 am]

[Order 75-8-139; Docket 27052]

HUGHES AIRWEST CORP.

Order To Show Cause

Adopted by the Civil Aeronautics Board at its office in Washington, D.C. on the 28th day of August, 1975.

Application of Hughes Airwest Corp. for admendment of certification for route 76 (Modification of Los Angeles-San Francisco Long-Haul Restriction).

On September 27, 1974, Hughes Airwest petitioned the Board to issue an order directing interested persons to show cause why the Board should not approve its concurrently filed application to modify subparagraph (i) of the proviso of condition (4) of Airwest's certificate for route 76. The modification would relax the current requirement that San Francisco-Los Angeles nonstop flights using the Los Angeles International Airport serve Eureka-Arcata or a point north thereof.[1] Under Airwest's proposed modification, such San Francisco-Los Angeles nonstop flights would be restricted only by a requirement that they also serve Chico, California or a point north thereof or serve a point south of Los Angeles, other than Santa Ana-Laguna Beach, Indio-Palm Springs or San Diego, California.[2]

In support of its petition, Airwest alleges that the present restriction is unnecessary and wastes fuel and other resources and that it causes inconvenience to the traveling public by reducing Airwest's operational flexibility.[3] Airwest also alleges that the relaxation of restrictions which it proposes would not adversely affect any other carrier. Airwest sets these allegations against the background of our policy of realigning local service carrier routes to provide opportunities for maximum scheduling flexibility and equipment utilization and concludes that an expeditious acceptance of its proposed certificate amendment by show cause procedures is appropriate.

Answers in opposition to Airwest's petition were filed by Western Air Lines and United Air Lines. Both Western and United allege that approval of Airwest's proposed certificate amendment would result in increased Airwest frequencies—and diversion from other carriers—in the San Francisco-Los Angeles market. United emphasizes as well the negative impact of the proposed amendment on service to the Pacific Northwest. Western alleges that the real purpose of Airwest's petition is to strengthen its Los Angeles/San Francisco-Mexico market position, and that it would be contrary to "Ashbacker Radio Corp. v. F.C.C.," 326 U.S. 327 (1945), to grant the petition in the face of Western's own pending application (now in Docket 25776) to serve these same Mexican markets. United and Western conclude that, given the substantial issues of law and fact which their objections raise, Airwest's application ought not be handled by show cause procedures. Airwest filed a reply to the answers of Western and United.[4]

Upon consideration of the pleadings and of all the relevant facts, we have decided to issue an order to show cause proposing to amend Airwest's certificate as requested. We tentatively find and conclude that the public convenience and necessity require the amendment of Airwest's certificate for route 76 so as to modify subparagraph (i) of condition (4) in the manner set out above.

In support of our findings, we tentatively find and conclude that the restriction in question unnecessarily restricts Airwest's operating flexibility and wastes fuel. Its modification is consistent with the Board's often reiterated general policy of eliminating or modifying such certificate restrictions, the retention of which have been placed in issue, absent an affirmative showing that their continuance is required. See, e.g., Order 75-7-15, July 2, 1975; Order 74-7-63, July 16, 1974; Order 69-6-87, June 17, 1969. Neither Western nor United has come forward with such a sufficient affirmative showing in their answers to Airwest's petition.

Specifically, in regard to the general contentions of possible diversion made by the objecting carriers, it appears doubtful that Airwest, a minor participant in the heavily served Los Angeles-San Francisco market, would divert a significant amount of traffic from either United or Western due to a restriction modification which will not change Airwest's inability to operate turn-around service between the cities in question.[5] However, Airwest has not provided the Board with any indication of what service changes, if any, it proposes to make in the event that its requested amendment is granted, and we thus lack necessary information upon which to make conclusive findings on the question of diversion. Therefore, we will direct Airwest to provide such information within fourteen days of the date of adoption of this order.

Interested persons will be given twenty-one (21) days following the filing of Airwest of the proposed service schedules, as detailed in ordering paragraph 1 below, to show cause why the tentative findings and conclusions set forth herein should not be made final.[6]

Accordingly, *it is ordered*, That:

[1] Subparagraph (i) of existing condition (4) of Hughes Airwest's current certificate reads:

"*Provided:* That the holder may schedule nonstop service (i) between San Francisco and Los Angeles-Ontario, Calif. (when served through the Los Angeles International Airport), on flights which also serve Eureka-Arcata, Calif., or a point north thereof: *Provided, further:* That if said flights serve Eugene or Medford, Oreg., they shall also serve Portland or a point north thereof."

[2] Hughes Airwest requests that subparagraph (i) be modified to read as follows (modifications underscored):

"Between San Francisco and Los Angeles-Ontario, Calif. (when served through the Los Angeles International Airport), (1) on flights which also serve Chico, Calif., or a point north thereof: Provided, further: That if said flights serve Eugene or Medford, Oreg., they shall also serve Portland or a point north thereof, or (2) on flights which also serve a point south of Los Angeles other than Santa Ana-Laguna Beach, Indio-Palm Springs or San Diego, Calif."

[3] Airwest contends that the economic significance of the restriction has never been adjudicated since it was accepted as a pretrial restriction in the Pacific Northwest-California Service Investigation, Docket 18884.

[4] Airwest accompanies that reply with a motion to file an unauthorized pleading, which motion will be granted.

[5] Western's contention that a grant of the modifications requested by Airwest would violate Western's Ashbacker rights in regard to its application for new U.S.-Mexico rights is without merit. Western has totally failed to demonstrate that element which is at the heart of Ashbacker: the preclusion as a legal or economic matter of its application for U.S.-Mexico authority.

[6] We specifically invite comments on the question of diversion in light of Airwest's proposed schedules of service.

1. Within fourteen (14) days from the date of adoption of this order, Hughes Airwest is directed to file with the Board and serve upon all of the parties listed in paragraph 6 herein current and proposed schedules in the markets at issue in Docket 27052 under (a) the assumption that its request for certificate modification in Docket 27052 is granted and (b) under the assumption that it is not granted;

2. All interested persons are directed to show cause why the Board should not issue an order making final the tentative findings and conclusions stated herein and amending subparagraph (i) of condition (4) of the certificate of public convenience and necessity of Hughes Airwest for route 76 as follows:

"*Provided:* That the holder may schedule nonstop service between San Francisco and Los Angeles-Ontario, Calif. (when served through the Los Angeles International Airport), (1) on flights which also serve Chico, Calif., or a point north thereof, *Provided, further:* That if said flights serve Eugene or Medford, Oreg., they shall also serve Portland or a point north thereof, or (2) on flights which also serve a point south of Los Angeles other than Santa Ana-Laguna Beach, Indio-Palm Springs or San Diego, Calif.";

3. Any interested person having objection to the issuance of an order making final any of the proposed findings or conclusions set forth herein shall, within twenty-one (21) days after the filing by Hughes Airwest of the service schedules provided for in paragraph (1) above, file with the Board and serve upon all persons listed in paragraph (6) herein a statement of objections together with a summary of testimony, statistical data, and other evidence expected to be relied upon to support the stated objections;

4. If timely and properly supported objections are filed, full consideration will be accorded the matters and issues raised by the objections before further action is taken by the Board;

5. In the event no objections are filed, all further procedural steps will be deemed to have been waived and the Board may proceed to enter an order in accordance with the tentative findings and conclusions set forth herein;

6. A copy of this order shall be served upon United Air Lines, Western Air Lines, Trans World Airlines, the States of Oregon, California and Arizona, and the mayors of Los Angeles, San Francisco, Chico, Arcata, Eureka, El Centro and Yuma, Calif., Tucson, Arizona and Eugene and Medford, Oregon; and

7. The motion of Hughes Airwest for leave to file an unauthorized pleading, be and it hereby is granted.

This order shall be published in the FEDERAL REGISTER.

By the Civil Aeronautics Board.

[SEAL] EDWIN Z. HOLLAND,
Secretary.

[FR Doc.75-23287 Filed 9-2-75;8:45 am]

[Docket 28095]

LUFTTRANSPORT-UNTERNEHMEN GMBH & CO. KG. (LTU)

Prehearing Conference

Notice is hereby given that a prehearing conference in this proceeding is assigned to be held on September 24, 1975, at 10 a.m. (local time) in Room 1031N, Universal North Building, 1875 Connecticut Avenue, NW., Washington, D.C., before Administrative Law Judge Frank M. Whiting.

Dated at Washington, D.C., August 27, 1975.

[SEAL] ROBERT L. PARK,
Chief Administrative Law Judge.

[FR Doc.75-23286 Filed 9-2-75;8:45 am]

[Docket 27073]

TEXAS INTERNATIONAL AIRLINES, INC. AND BRANIFF AIRWAYS, INC.

Enforcement Proceeding; Hearing

Notice is hereby given, pursuant to the provisions of the Federal Aviation Act of 1958, as amended, that hearing in the above-entitled matter is assigned to be held on October 6, 1975, at 10 a.m. (local time) in Room 503, Universal Building, 1825 Connecticut Avenue, N.W., Washington, D.C., before Administrative Law Judge Dee C. Blythe.

Dated at Washington, D.C., August 27, 1975.

[SEAL] ROBERT L. PARK,
Chief Administrative Law Judge.

[FR Doc.75-23346 Filed 9-2-75;8:45 am]

ENVIRONMENTAL PROTECTION AGENCY

[FRL 422-2; OPP-33000/311]

RECEIPT OF APPLICATIONS FOR PESTICIDE REGISTRATION

Data To Be Considered in Support of Applications

On November 19, 1973, the Environmental Protection Agency (EPA) published in the FEDERAL REGISTER (38 FR 31862) its interim policy with respect to the administration of Section 3(c)(1)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended. This policy provides that EPA will, upon receipt of every application for registration, publish in the FEDERAL REGISTER a notice containing the information shown below. The labeling furnished by the applicant will be available for examination at the Environmental Protection Agency, Room EB-31, East Tower, 401 M Street SW., Washington, D.C. 20460.

On or before November 3, 1975, any person who (a) is or has been an applicant, (b) believes that data he developed and submitted to EPA on or after October 21, 1972, is being used to support an application described in this notice, (c) desires to assert a claim for compensation under section 3(c)(1)(D) for such use of his data, and (d) wishes to preserve his right to have the Administrator determine the amount of reasonable compensation to which he is entitled for such use of the data, must notify the Administrator and the applicant named in the notice in the FEDERAL REGISTER of his claim by certified mail. Notification to the Administrator should be addressed to the Information Coordination Section, Technical Services Division (WH-569), Office of Pesticide Programs, 401 M Street SW., Washington, D.C. 20460. Every such claimant must include, at a minimum, the information listed in the interim policy of November 19, 1973.

Applications submitted under 2(a) or 2(b) of the interim policy will be processed to completion in accordance with existing procedures. Applications submitted under 2(c) of the interim policy cannot be made final until the 60 day period has expired. If no claims are received within the 60 day period, the 2(c) application will be processed according to normal procedure. However, if claims are received within the 60 day period, the applicants against whom the claims are asserted will be advised of the alternatives available under the Act. No claims will be accepted for possible EPA adjudication which are received after November 3, 1975.

Dated: August 25, 1975.

JOHN B. RITCH, Jr.,
Director,
Registration Division.

APPLICATIONS RECEIVED (OPP-33000/311)

EPA File Symbol 241-EUT. American Cyanamid Co., Agricultural Div., PO Box 400, Princeton NJ 08540. PAY-OFF 3E TOBACCO SUCKER CONTROL AGENT. Active Ingredients: Penoxalin ([N-(1-ethylpropyl - 3,4 - dimethyl-2,6-dinitrobenzenamine]) 34.4%; xylene 5.8%. Method of Support: Application proceeds under 2(b) of interim policy. PM25

EPA File Symbol 35934-E. Chemply, Inc., PO Box 18049, Pittsburgh PA 15236. SODIUM HYPOCHLORITE 15%. Active Ingredients: Sodium hypochlorite 10.5%. Method of Support: Application proceeds under 2(c) of interim policy. PM34

EPA Reg. No. 464-402. Dow Chem. Co., PO Box 1706, Midland MI 48640. DOWPON M GRASS KILLER. Active Ingredients: Sodium salt of dalapon 72.5%; magnesium salt of dalapon 12.0%. Method of Support: Application proceeds under 2(c) of interim policy. PM25

EPA Reg. No. 352-354. E. I. du Pont de Nemours & Co., Inc., 7056 Dupont Bldg., Wilmington DE 19898. BENLATE BENOMYL FUNGICIDE PLUS. Active Ingredients: Benomyl [methyl 1-(butylcarbamoyl) 2-benzimidazolecarbamate] 50%. Method of Support: Application proceeds under 2(b) of interim policy. Republished: Added uses. PM22

EPA Reg. No. 352-375. E. I. du Pont de Nemours & Co., Inc., Biochemicals Department, 7056 Dupont Bldg., Wilmington DE 19898. LEXONE METRIBUZIN WEED KILLER. Active Ingredients: 4-amino-6-1,1-dimethylethyl) - 3-(methylthio - 1,2,4-triazin-5(4H)-one 50%. Method of Support: Application proceeds under 2(b) of interim policy. Republished: Added use. PM25

EPA File Symbol 35923-O. Kel-Glo Corp., 54 NE 73rd St., Miami FL 33138. 406 TRI-TIN ANTI-FOULING PAINT. Active Ingredients: Bis(tributyltin) adipate 21.26%. Method of Support: Application proceeds under 2(c) of interim policy. PM24

[FR Doc.75-23072 Filed 9-2-75;8:45 am]

[FRL 424-5; PP5G1627/T11]

PARAQUAT

Establishment of Temporary Tolerance

Chevron Chemical

Chevron Chemical Co., 940 Hensley St., Richmond CA 94804, submitted a pesticide petition (PP 5G1627) to the Environmental Protection Agency (EPA). This petition requested that a temporary tolerance be established for residues of the desiccant, defoliant, and herbicide paraquat (1,1'-dimethyl-4,4'-bipyridinium) derived from application of either the dichloride or the bis(methyl sulfate) salt calculated in both instances as the cation in or on dry beans at 0.5 part per million.

This temporary tolerance would permit the marketing of the above commodities treated in accordance with an experimental use permit which is being issued concurrently under the Federal Insecticide, Fungicide, and Rodenticide Act.

The data submitted in the petition and other relevant material have been evaluated. It has been determined that the tolerance is adequate to cover residues resulting from the proposed experimental use and that such tolerance will protect the public health. Therefore, the temporary tolerance is established as requested for the pesticide for distribution under the Chevron Chemical Co. name with the following provisions:

1. The total amount of the active ingredient to be used must not exceed the quantity authorized by the experimental use permit.

2. Chevron Chemical Co. must immediately notify the EPA of any findings from the experimental use that have a bearing on safety. The company must also keep records of product, distribution, and performance and on request make the records available to any authorized officer or employee of the EPA or the Food and Drug Administration.

This temporary tolerance expires on August 28, 1976. Residues remaining in or on dry beans after expiration of this tolerance will not be considered actionable if the pesticide is legally applied during the term and in accordance with provisions of the experimental use permit/temporary tolerance. This temporary tolerance may be revoked if the experimental use permit is revoked or if any scientific data or experience with this pesticide indicate such revocation is necessary to protect the public health.

Section 408(j) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 346a(j)].

Dated: August 28, 1975.

EDWIN L. JOHNSON,
Deputy Assistant Administrator for Pesticide Programs.

[FR Doc.75-23347 Filed 9-2-75;8:45 am]

[FRL 424-8]

EFFLUENT STANDARDS AND WATER QUALITY INFORMATION ADVISORY COMMITTEE

Meeting

The Effluent Standards and Water Quality Information Advisory Committee was established to assist in the development of information bases to establish feasible technical and economic applications of Best Available Technology (BAT) under P.L. 92-500 for U.S. Industry.

As a result of previously conducted public planning meetings, two industry areas were selected for initial industry/ES&WQIAC task force development. The industry areas are (1) Organics, Plastics and Synthetics and, (2) Paperboard from wastepaper.

A series of monthly workshops/meetings have been planned on these industry areas corresponding to the milestones established for the task forces: Completion of Data Collection; Completion of Analysis; Completion of Draft Report; and, Final Action on Best Available Technology (BAT) Report.

The third workshop/meeting will be conducted at Washington, D.C. on Sept. 25 and 26, 1975. The workshop/meeting will begin at 9:00 AM, Thursday, Sept. 25, Room 821, Crystal Mall, Bldg. #2, 1921 Jefferson Davis Highway, Arlington, Virginia.

Thursday, Sept. 25 will be devoted to a review of and disposition of reports on three additional study efforts of ES&WQIAC. The agenda for Thursday includes a review and action on disposition of reports on (1) Development of a Report on the Status and Use of the Matrix Method (2) Analysis of Litigation on Implementation of P.L. 92-500 and (3) Analysis of Toxic Substances Legislation.

The workshop/meeting on Friday, Sept. 26 will begin at 9:00 AM in Room 1112 (Conference Room). The agenda includes: Review of Draft BAT Reports on Organics, Synthetics, Plastics and Paperboard from Waste Paper; Consensus on Revisions to Reports; Development of a Detailed Plan for Completion of Final Reports; and New Business.

The meeting will be open to the public and under the overall direction of the Committee Chairman. Since space is limited, call or write to Dr. Martha Sager, Chairman, or Mr. Martin Brossman, Executive Director, ES&WQIAC, EPA, Crystal Mall, Bldg. #2, Washington, D.C. 20460 Tel: A.C. 703 557-7390.

MARTHA SAGER,
Chairman, ES&WQIAC.

[FR Doc.75-23354 Filed 9-2-75;8:45 am]

[FRL 424-6; OPP-50025]

THOMPSON-HAYWARD CHEMICAL CO.

Issuance of Experimental Use Permit

Pursuant to section 5 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (86 Stat. 973; 7 U.S.C. 136), an experimental use permit has been issued to Thompson-Hayward Chemical Company, Kansas City, Kansas 66110. Such permit is in accordance with, and subject to, the provisions of 40 CFR Part 172; Part 172 was published in the FEDERAL REGISTER on April 30, 1975 (40 FR 18780), and defines EPA procedures with respect to the use of pesticides for experimental purposes.

This experimental use permit (No. 148-EUP-19) allows the use of 580.75 pounds of 1-(4-chlorophenyl) - 3-(2,6 - difluorobenzyol) -urea on mosquitoes in temporary flooded areas. A total of 4,645 acres is involved; the program is authorized only in the States of California, Colorado, Delaware, Florida, Georgia, Illinois, Minnesota, Mississippi, Montana, Nebraska, New Hampshire New York, Ohio, Oregon, Texas, Utah, Washington, and Wyoming. The experimental use permit is effective from July 31, 1975, to July 31, 1976.

Interested parties wishing to review the experimental use permit are referred to Room E-315, Registration Division (WH-567), Office of Pesticide Programs, EPA, 401 M St., S.W., Washington, D.C. 20460. It is suggested that such interested persons call 202/755-4851 before visiting the EPA Headquarters Office, so that the appropriate permit may be made conveniently available for review purposes. These files will be available for inspection from 8:30 a.m. to 4:00 p.m. Monday through Friday.

Dated August 28, 1975.

EDWIN L. JOHNSON,
Deputy Assistant Administrator for Pesticide Programs.

[FR Doc.75-23353 Filed 9-2-75;8:45 am]

FEDERAL COMMUNICATIONS COMMISSION

[Report No. 768]

COMMON CARRIER SERVICES INFORMATION[1]

Domestic Public Radio Services Applications Accepted for Filing[2]

AUGUST 25, 1975.

Pursuant to §§ 1.227(b)(3) and 21.30 (b) of the Commission's rules, an application, in order to be considered with any domestic public radio services application appearing on the attached list, must be substantially complete and tendered for filing by whichever date is earlier: (a) The close of business one business day preceding the day on which the Commission takes action on the previously filed application; or (b) within 60 days after the date of the public notice listing the first prior filed application (with which subsequent applications are

[1] All applications listed in the appendix are subject to further consideration and review and may be returned and/or dismissed if not found to be in accordance with the Commission's Rules, regulations and other requirements.

[2] The above alternative cut-off rules apply to those applications listed in the appendix as having been accepted in Domestic Public Land Mobile Radio, Rural Radio, Point-to-Point Microwave Radio and Local Television Transmission Services (Part 21 of the Rules).

in conflict) as having been accepted for filing. An application which is subsequently amended by a major change will be considered to be a newly filed application. It is to be noted that the cut-off dates are set forth in the alternative—applications will be entitled to consideration with those listed in the appendix if filed by the end of the 60 day period, only if the Commission has not acted upon the application by that time pursuant to the first alternative earlier date. The mutual exclusivity rights of a new application are governed by the earliest action with respect to any one of the earlier filed conflicting applications.

The attention of any party in interest desiring to file pleadings pursuant to section 309 of the Communications Act of 1934, as amended, concerning any domestic public radio services application accepted for filing, is directed to §§ 21.27 of the Commission's rules for provisions governing the time for filing and other requirements relating to such pleadings.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] VINCENT J. MULLINS,
Secretary.

APPLICATIONS ACCEPTED FOR FILING

DOMESTIC PUBLIC LAND MOBILE RADIO SERVICE

20219–CD–P–76, Decatur Telephone Company, Inc. (New), C.P. for a new 1-way station to operate on 158.10 MHz to be located 1 mile west of Decatur, Mississippi, 4000' W. Hwy. 15, and 800' N. of Conehatta Rd., Decatur, Mississippi.

20220–CD–P–76, Decatur Telephone Company, Inc. (New), C.P. for a new 2-way station to operate on 157.750 MHz to be located 1 mile west of Decatur, Mississippi, 400' W. Hwy. 15 and 800' N. of Conehatta Rd., Decatur, Mississippi.

20221–CD–P–(3)–76, Airsignal International, Inc. (New), C.P. for a new station to operate on 454.075 MHz (Base) at Pilot Hill, Laramie, Wyoming; and 459.175 MHz (Control) at 3rd and Grand Avenue, Laramie, Wyoming; and 454.175 MHz (Repeater) at Pilot Hill, Laramie, Wyoming.

20222–CD–P–(2)–76, Airsignal International, Inc. (New), C.P. for a new 1-way station to operate on 152.24 MHz (Base) at Pilot Hill, Laramie, Wyoming; and 459.250 MHz (Control) at 3rd and Grand Avenue, Laramie, Wyoming.

20223–CD–P–76, Airsignal International, Inc. (New), C.P. for a new 1-way station to operate on 152.24 MHz to be located at 1025 E. 15th Street, Cheyenne, Wyoming.

20224–CD–P–76, Airsignal International, Inc. (New), C.P. for a new 2-way station to operate on 454.025 MHz to be located at 1025 E. 15th Street, Cheyenne, Wyoming.

20225–CD–P–(4)–76, Airsignal of California, Inc. (New), C.P. for a new 1-way station to operate on 152.24 MHz (Base) and 158.70 MHz (Base) at Sulphur Springs Mtn., 1.6 mile NE. of Vallejo, California, to be described as Loc. #1; also at Grizzley Peak, Oakland Hills, California, to be described as Loc. #2.

20226–CD–P–(2)–76, Airsignal of California, Inc. (New), C.P. for a new 1-way station to operate on 35.22 MHz (Base) at Grizzly Peak, Oakland Hills, California, to be described as Loc. #1; also at Sulphur Springs Mtn., 1.6 mile NE. of Vallejo, California, to be described as Loc. #2.

20227–CD–P/L–76, Mississippi Telephone Corporation (KLB753), C.P. and License to reinstate facilities operating on 152.66 MHz (Base) located at Intersection of Hwy. 63 and 594, 5 miles SE. Leakesville, Mississippi.

20228–CD–P–76, The Monon Telephone Co., Inc. (New), C.P. for a new 1-way station to operate on 158.10 MHz to be located at 315 North Market Street, Monon, Indiana.

20229–CD–P–76, Mobile Phone of Texas, Inc. (New), C P. for a new 2-way station to operate on 152.03 MHz (Base) to be located at 1400 17th Street, Snyder, Texas.

20230–CD–P–76, Radio Communications, Inc. (New), C.P. for a new 1-way station to operate on 43.22 MHz (Base) to be located 5.8 miles NW. of Frederick, Maryland.

20231–CD–P–76, Radio Communications, Inc. (New), C.P. for a new 2-way station to operate on 152.18 MHz (Base) to be located 5.8 miles NW. of Frederick, Maryland.

20233–CD–P–76, General Telephone Company a new 2-way station (with some one-way of Upstate New York, Inc. (New), C.P. for a new 2-way station (with some one-way operations) to operate on 152.66 MHz (Base) to be located 1.5 miles E. of Gloversville, N.Y., on Blanchard Road, Johnstown, N.Y.

20234–CD–P–76, Empire Mobilcomm Systems, Inc. (New), C.P. for a new 1-way station to operate on 152.24 MHz (Base) to be located 0.7 mile NW. on Awbrey Butte, Bend, Oregon.

20235–CD–P–76, Citizens Utilities Company of Pennsylvania (New), C.P. for a new 2-way station to operate on 152.54 MHz (Base) to be located 2000' W. of Rt. 66, one mile NW. of New Bethlehem, Pennsylvania.

20236–CD–P–76, Airsignal International, Inc. (KAF245), C.P. for new developmental facilities at existing station to operate on 97.96 MHz to be located at 125 E. 31st Street, Kansas City, Missouri.

20237–CD–P–(2)–76, Airsignal International, Inc. (KFL895), C.P. for add'l. facilities to operate on 2118.8 MHz (Control) at new Location #2: Fruitville Rd. and Christie Avenue, Sarasota, Florida; also for add'l. facilities to operate on 2163.8 MHz (Repeater) at existing Loc. #1: 4212 30th St. West, Bradenton, Florida.

20238–CD–P–76, RCC of Virginia, Inc. (KLP 629), C.P.: for additional facilities to operate on 158.70 MHz (Base, 1-way) at new Location #2: 23 Sesame Street, Richmond, Virginia.

20239–CD–P–(3)–76, Public Service Associates, Inc. (KWT894), C.P. for additional facilities to operate on 454.050, 454.250, and 454.300 MHz (Base) at existing site located on Baldy Hill, ⅞ mile NW. of Felts Field, Spokane Municipal Airport, Spokane, Wash.

20240–CD–P–76, Mobile Radio Communications, Inc. (KSV904), C.P. for additional facilities to operate on 158.70 MHz (Base, 1-way) at New Loc. #6: NW. Corner of Old Cemetery on Miller Street, Liberty, Missouri.

20241–CD–P–(2)–76, Texoma Mobilfone, Inc. (KLF523), C.P. to change antenna system and relocate facilities operating on 152.12 MHz (Base) at antenna site located 1 mile south of Highway 82, 2 miles east of Gainesville, Texas; also for additional facilities to operate on 152.03 MHz (Base) at same location.

20242–CD–P–(2)–76, Lubbock Radio Paging Service, Inc. (KKE970), C.P. to change antenna system and relocate facilities operating on 454.050 MHz and 454.125 MHz (Base) located at Metro Tower, Broadway and Avenue L, Lubbock, Texas.

20243–CD–P–76, Stockton Mobilphone, Inc. (KRM984), C.P. to change antenna system and relocate facilities operating on 152.24 MHz (Base, 1-way) at antenna site located at 5235 East Carpenter Road (approximately 600 feet N. of Rd.) Stockton, California.

20244–CD–P–76, Denver and Ephrata Telephone and Telegraph Company (KGI782), C.P. to change antenna system and relocate facilities operating on 43.58 MHz (Base, 1-way at antenna site located at Williamson Park, Lancaster, Pa., described as Loc. #2.

20245–CD–P–76, Texoma Mobilfone, Inc. (KLB502), C.P. for additional facilities to operate on 152.09 MHz at existing site located at Highway 75, 5 miles N. of Sherman, Texas.

20246–CD–P–76, Business Communications, Inc., d/b/a New Orleans Mobilfone (KKA 400), C.P. for additional facilities to operate on 454.225 MHz (Base) at existing site located at 700 Poydras Street, New Orleans, Louisiana.

20247–CD–P–(2)–76, Airsignal International, Inc. (KIQ511), C.P. for additional facilities to operate on 2178.4 MHz (Repeater) at existing Loc. #1: 0.85 mile N. of Venice Blvd., 1280' E. of Byway Road, Venice, Florida; also for additional facilities to operate on 2128.4 MHz (Control) at New Loc. #2: Fruitville Road and Christie Avenue, Sarasota, Florida.

20248–CD–P–(2)–76, Autofone, Inc. (New), C.P. for a new 2-way station to operate on 152.06 MHz (Base) at Loc. #1: On Hwy. 56, 0.55 mile N. of Swainsboro, Georgia; also to operate on 454.150 MHz (Base) at Loc. #2: On Hwy. 56, 3.2 miles S. of Swainsboro, Georgia.

20249–CD–P–76, Omni Communications, Inc. (KCC786), C.P. to relocate facilities operating on 152.06 MHz (Base) at Loc. #2: Prudential Building, Prudential Center, Boston, Massachusetts.

20250–CD–P–76, The Mountain States Telephone and Telegraph Company (KAF633), C.P. for additional facilities to operate on 152.72 MHz located 10 miles W. of Grand Junction, Colorado; also to replace transmitter operating on 152.75 MHz at same location.

21251–CD–P–76, Pacific Northwest Bell Tel. Co. (KOF331), C.P. to change antenna system and frequency at Loc. #1: 4 miles ESE. of Florence, Oregon, to operate on 152.60 MHz (Base).

20252–CD–P/L–76, Southwestern Bell Tel. Co. (KKT566), C.P. and License to change antenna system operating on 152.57 MHz (Base) located 2.3 miles E. of Stratford, on Okla. St. Hwy. 19, North side of road, Stratford, Oklahoma.

20253–CD–P–76, The Pacific Tel. & Tel. Co. (KUD229), C.P. for additional facilities to operate on 459.825 MHz (Auxiliary Test) at 3848 7th Avenue, San Diego, California (Air-Ground).

Correction

21267–CD–P–75, (KEA260), Mobile Radio Message Service, Inc. Correct statement in Public Notice No. 745 dated March 17, 1975, to show the addition of a standby transmitting facility. All other particulars remain as reported.

RURAL RADIO SERVICE

60049–CR–P/L–76, The Mountain States Tel. & Tel. Co. (New), C.P. and License for a new Rural Subscriber-Fixed station to operate on 157.86 MHz located at Rancho Moana, 15½ miles NW. of Prescott, Arizona.

60050–CR–P/L–76, Lafourche Telephone Company (New), C.P. and License for a new Rural Subscriber-Fixed station to operate on 157.80 and 157.92 MHz located 7 miles east of cut off, Lafourche, Louisiana.

60051–CR–P–76, South Central Bell Tel. Co. (New), C.P. for a new Rural Subscriber-Fixed station to operate on 157.86 MHz located approximately 4.2 miles East of Port Sulphur, Louisiana.

60052–CR–P/L–76, Center Island Beach Club, Inc. (WGI74), C.P. and License for additional facilities operating on 157.83, 157.86, 157.89, 157.92, 157.95, 157.98, 158.01, 158.04, 158.07 MHz located at 23 Chinook Way, Center Island, Washington; also to reinstate existing facilities operating on 157.77 and 157.80 MHz at same location.

POINT-TO-POINT MICROWAVE RADIO SERVICE

2779–CF–ML–75, RCA Alaska Communications, Inc. (WGP62), Bird Creek, Alaska. Lat. 60°57'52" N. Long. 149°26'19" W. Mod. of License to change polarity from Horizontal to Vertical on frequency 2125.4 MHz toward Bird Point, Alaska, on azimuth 128°54'.

2378–CF–P–76, All America Cables and Radio, Inc. (WWZ34), Cerro Marquesa, 1.6 Miles NNW. of Aquas Buenas, Puerto Rico. Lat. 18°16'51" N., Long. 66°06'38" W. C.P. to change antenna system and add frequencies 3870.0H MHz toward San Juan, Puerto Rico, on azimuth 90°28', and 10715.0H MHz toward Cerro Las Pinas, Puerto Rico, on azimuth 167°00'.

379–CF–P–76, Same (WWZ36), Cerro Las Pinas, 5.9 Miles SW. of Caguas, Puerto Rico. Lat. 18°09'16" N., Long. 66°04'51" W. C.P. to change antenna system and add frequencies 11645.0H MHz toward Cerro Marquesa, Puerto Rico, on azimuth 347°01', and 11365.0V MHz toward Monte Llano, Puerto Rico, on azimuth 296°41'.

380–CF–P–76, Same (WWZ33), 901 Ponce de Leon Avenue, San Juan, Puerto Rico. Lat. 18°27'45" N., Long. 66°04'52" W. C.P. to add frequency 3919.0H MHz toward Cerro Marquesa, Puerto Rico, on azimuth 189°28'.

381–CF–P–76, Same (WWZ35), Monte Llano, State Rd. #1, Barrio Monte Llano, Puerto Rico. Lat. 18°08'01" N., Long. 66°07'53" W. C.P. to change antenna system and add frequency 11035V MHz toward Cerro Las Pinas, Puerto Rico, on azimuth 66°54'.

398–CF–P–76, New York Telephone Company (New), Fort Hill, 1.1 Miles SSE. of Savannah, New York. Lat. 43°03'10" N., Long. 76°45'11" W. C.P. for a new station on frequencies 11605H, 11445V MHz toward Van Buren, New York, on azimuth 79°34', and 11485H, 11132V MHz toward Auburn, New York, on azimuth 131°54'.

399–CF–P–76, Same (KEF74), 36 South Street, Auburn, New York. Lat. 42°56'45" N., Long. 76°33'57" W. C.P.to change antenna system and location, change frequencies 6135, 6375 MHz toward Van Buren to 11035H, 10875V MHz toward a new station at Fort Hill, New York, on azimuth 312°01'; replace transmitters and change power.

400–CF–P–76, Same (KEF75), Van Buren, 2 Miles NW. of Warners, New York. Lat. 43° 06'19" N., Long. 76°21'31" W. C.P. to change antenna system and frequencies 6055V, 6295V MHz toward Syracuse, New York, to 11035H, 10875V MHz on azimuth 110°02'; change 6015V, 6255V MHz toward Auburn to 11155H, 10995V MHz toward a new station at Fort Hill, New York, on azimuth 259°51'; replace transmitters and change power.

401–CF–P–76, Same (KEF76), 413 East Fayette Street, Syracuse, New York. Lat. 43°02'55" N., Long. 76°08'51" W. C.P. to change frequencies 6175, 6415 MHz to 11325V, 11485H MHz toward Van Buren, New York, on azimuth 290°11'; replace transmitters and change power.

446–CF–P–76, South Central Bell Telephone Company (KJH23), 521 West Chestnut Street, Louisville, Kentucky. Lat. 38°14'58" N., Long. 85°45'39" W. C.P. to change antenna system and add frequencies 3810V, 3890V, 4050V MHz toward Fisherville, Kentucky, on azimuth 105°33'.

447–CF–P–76, Same (WJM46), 1.0 Mile SE. of Fisherville, Kentucky. Lat. 38°10'46" N., Long. 85°26'39" W. C.P. to change antenna system and add frequencies 3770V, 3850V, 3930V MHz toward Louisville, Kentucky, on azimuth 285°45', and 3850V, 3930V, 4090V MHz toward Mt. Eden, Kentucky, on azimuth 116°52'.

448–CF–P–76, Same (WJM47), 0.7 Mile East of Mt. Eden, Kentucky. Lat. 38°03'25" N., Long. 85°08'22" W. C.P. to change antenna system and add frequencies 3730V, 3810V, 3890V MHz toward Fisherville, Kentucky, on azimuth 297°04', 3810V MHz toward East Frankfort, Kentucky, on azimuth 60°42', and 3890V MHz toward Mackville, Kentucky, on azimuth 169°20'.

449–CF–P–76, Same (KYC48), East Frankfort, 0.5 Mile South of Frankfort, Kentucky. Lat. 38°11'04" N., Long. 84°51'03" W. C.P. to change antenna system and add frequencies 4170V MHz toward Mt. Eden, Kentucky, on azimuth 240°53', and 3850H MHz toward Junction West, Kentucky, on azimuth 145°02'.

450–CF–P–76, Same (WJM48), 0.7 Mile North of Mackville, Kentucky. Lat. 37°44'48" N., Long. 85°03'57" W. C.P. to add frequencies 3930V MHz toward Mt. Eden, Kentucky, on azimuth 349°23', and 3930H MHz toward Danville, Kentucky, on azimuth 113°47'.

445–CF–P–76, Same (KJK51), 216 South Fourth Street, Danville, Kentucky, Lat. 37°38'38" N., Long. 84°46'25" W. C.P. to add frequencies 3890H MHz toward Mackville, Kentucky, on azimuth 293°58', and 3730V MHz toward Richmond, Kentucky, on azimuth 77°31'.

456–CF–P–76, Same (KJD27), 1.8 Miles SW. of Richmond, Kentucky. Lat. 37°43'28" N., Long. 84°16'37" W. C.P. to add frequencies 4170V MHz toward Danville, Kentucky, on corrected azimuth 257°48', and 3770V MHz toward Winchester, Kentucky, on azimuth 20°25'.

457–CF–P–76, Same (KYS48), 232 West Lexington Avenue, Winchester, Kentucky. Lat. 37°59'35" N., Long. 84°11'02" W. C.P. to add frequency 4130V MHz toward Richmond, Kentucky, on azimuth 200°30'.

458–CF–P–76, Puerto Rico Telephone Company (WWR76), Power and "A" Streets, Ponce, Puerto Rico. Lat. 18°00'23" N., Long. 66°36'51" W. C.P. to add frequency 6115.7H MHz toward Santa Isabel, Puerto Rico, on azimuth 100°46'.

459–CF–P–76, Same (WWY31), Baldorioty Street, Santa Isabel, Puerto Rico. Lat. 17°58'06" N., Long. 66°24'21" W. C.P. to add frequency 6367.7H MHz toward Ponce, Puerto Rico, on azimuth 280°50'.

403–CF–P–76, Microwave Communications, Inc. (WAX64), 875 North Michigan Ave., Chicago (Cook) Illinois. Lat. 41°53'56" N., Long. 87°37'26" W. C.P. to change antenna system, replace transmitter and to add 6197.2H and 6404.8V towards Downers Grove, Illinois, on azimuth 245°49'.

404–CF–P–76, Same (WAX65), 501 63rd Street, Downers Grove (Du Page) Illinois. Lat. 41°46'22" N., Long 87°59'50" W. C.P. to change antenna system, replace transmitter, and to add 5945.2H and 6063.8H towards Chicago, Illinois, on azimuth 65°34'; 5989.7V and 6108.3V towards Minooka, Illinois, on azimuth 215°02'.

405–CF–P–76, Same (WAX66), 1.45 Miles NNW. of Minooka, (Kendall) Illinois. Lat. 41°28'41" N., Long. 88°16'17" W. C.P. to replace transmitter and to add 5939.7H and 6390.0H towards Downers Grove, Illinois, on azimuth 34°51'; 6301.0V and 6330.7H towards Ransom, Illinois, on azimuth 219° 15'.

406–CF–P–76, Same (WAX67), 1.9 Miles South of Ransom (LaSalle) Illinois. Lat. 41°07'22" N., Long. 88°39'17" W. C.P. to replace tranmitter and to add 5989.7H and 6049.0H towards Minooka, Illinois, on azimuth 38°59'; 6019.3H and 6137.9H towards Gridley, Illinois, on azimuth 205°35'.

407–CF–P–76, Same (WAX68), 0.7 Mile North of Gridley (Livingston) Illinois. Lat. 40° 45'52" N., Long. 88°52'49" W. C.P. to replace transmitter, change antenna system, and to add 6271.4V and 6390.0V towards Ransom, Illinois, on azimuth 25°27'; 6256.5V and 6375.2V towards Bloomington, Illinois, on azimuth 202°08'.

408–CF–P–76, Same (WAX69), 0.66 mile West of Bloomington (McLean) Illinois. Lat. 40° 28'34" N., Long. 89°02'02" W. C.P. to change antenna system, replace transmitter, and to add 6004.5V and 6123.1V towards Gridley, Illinois, on azimuth 22°02'; 5974.8H, 6034.2H, and 6093.5H towards Waynesville, Illinois, on azimuth 192°04'.

409–CF–P–76, Same (WGH97), 2.75 Miles SSE. of Waynesville, (DeWitt) Illinois. Lat. 40° 12'00" N., Long. 89°06'33" W. C.P. to replace transmitter and to add 6226.9H, 6286.2H, and 6345.5H towards Bloomington, Illinois, on azimuth 12°01' and 5960.0H, 6078.6H, and 6137.9H towards Elkhart, Illinois, on azimuth 229°35'.

302–CF–P–76, Southern Bell Telephone & Telegraph Company (KIU54), Chipley, Florida. Lat. 30°46'47" N., Long. 85°32'38" W. C.P. to add 4050V MHz toward Double Branch Pond (KIU61), Florida.

303–CF–P–76, Southern Bell Telephone & Telegraph Company (KIU64), Double Branch Pond, Florida. Lat. 30°34'56" N., Long. 85°38'41" W. C.P. (a) to change frequency to 3770V MHz toward Chipley, Florida, on azimuth 24°22' and (b) to add 3770V MHz toward Merial Lake, Florida, on azimuth 187°36'.

304–CF–P–76, Same (KIV58), Merial Lake, 6.5 Miles NW. of Southport, Florida. Lat. 30° 22'42" N., Long. 85°40'34" W. C.P. to add 3770V MHz toward Panama City (KIV59), Florida, on azimuth 176°15'.

308–CF–P–76, Service Electric Company (KGI61), Pimple Hill, 8.0 Miles SE. of Blakeslee, Pennsylvania. Lat. 41°01'35" N., Long. 75°30'20" W. C.P. to change from vertical to horizontal the polarity of 5989.7H MHz, 6049.0H MHz, 6108.3H MHz, and 6167.6H MHz toward Hazleton, Pennsylvania, on azimuth 261°01'.

316–CF–P–76, Western Maryland Communications, Inc. (KQX32), Cacapon Mountain, 2.0 Miles West of Ridge, West Virginia. Lat. 39°27'03" N., Long' 78°20'48" W. C.P. to replace transmitters on frequencies 6034.2H MHz, 6152.8H MHz, 6286.2H MHz, and 6404.8H MHz and to increase power to 2.0 watts on path toward Irons Mountain (KGO30), Maryland, on azimuth 305°49'.

317–CF–P–76, Same (KGO30), Irons Mountain, 3.2 Miles East of Cumberland, Maryland. Lat. 39°37'35" N., Long. 78°42'33" W. C.P. (a) to replace transmitters on frequencies 5974.8H MHz, 6093.5H MHz, 6197.2H MHz., and 6315.9H MHz and to increase power to 2.0 watts on same frequencies toward respective points of communication at Cumberland and Frostburg, Maryland, and Keyser, West Virginia; and (b) to increase power to 2.0 watts on 6256.5H MHz toward Keyser, West Virginia.

372-CF-P-76, Southwest Texas Transmission Company (KKK27), Beeler Farm, 14.0 Miles North of Fredericksburg, Texas. Lat. 30°26' 26" N., Long 98°43'58" W. C.P. (a) to delete Mason, Texas, as point of communication; (b) to replace transmitters on frequencies 6055H MHz, 6115H MHz, and 6175H MHz on existing paths toward Marble Falls and Llano, Texas, on azimuths 71°15' and 07°53', respectively; and (c) to add same frequencies toward new point of communication at Kingsland, Texas, on azimuth 53°29'.

392-CF-P-76, General Telephone Company of Ohio (KQO23), 2.39 Miles SSW. of Logan, Ohio. Lat. 39°30'22" N., Long. 82°24'56" W. C.P. to add 5960.0H MHz toward Athens, Ohio, on azimuth 127°30'. (Note: Public Notice not required for second application. File No. 396-CF-P-76.)

416-CF-P-76, Eastern Microwave, Inc. (KFN 21), New York (Gulf and Western Bldg.), New York. Lat. 40°46'09" N., Long. 73°58' 55" W. C.P. to add 10975V MHz toward West Milford (WQQ53), New Jersey, on azimuth 310°44'.

417-CF-P-76, Eastern Microwave, Inc. (WQQ53), West Milford, New Jersey. Lat. 41°02'26" N., Long. 74°23'57" W. C.P. to add 11305H MHz toward Highland Lakes (KYZ74), New Jersey, on azimuth 328°06'.

4041-CF-P/ML-75, Illinois Bell Telephone Company (WAN84), Fixed-Developmental. Temporary fixed locations within State of Illinois and Lake and Porter Counties in State of Indiana: Construction permit/license (a) to expand area of operation to foregoing; (b) to correct output power of existing transmitters to .01 watt; and (c) to use any FCC Type accepted transmitter(s).

445-CF-P-76, Microban Corporation of America (New), Pittsburgh, Pennsylvania. Lat. 40°26'30" N., Long. 80°00'02" W. C.P. for a new station on 11505.0V MHz toward 1715 Grandview Ave., Pittsburgh, Pennsylvania, on azimuth 268°20'.

502-CF-R-76, Indiana Bell Telephone Company (KYS50), Fixed Developmental. Any temporary fixed locations within the territory of the grantee. Application for Renewal of Radio License (195-CF-P-75) for the period ending August 1, 1980.

410-CF-P-76, Microwave Communications, Inc. (WAX70), 4.2 Miles ESE. of Elkhart, (Logan) Illinois. Lat. 40°00'25" N., Long. 89°24'15" W. C.P. to change antenna system, replace transmitter, and to add 6212.0H, 6330.7H, and 6390.0H towards Waynesville, Illinois, on azimuth 49°13; 6271.4H and 6390.0H towards Rochester, Illinois, on azimuth 201°02'.

411-CF-P-76, Same (WAX71), 228 East Main Street, Rochester (Sangamon) Illinois. Lat. 39°44'53" N., Long. 89°31'58" W. C.P. to replace transmitter and to add 6019.3H and 6049.0V towards Elkhart, Illinois, on azimuth 20°52'; 6019.3V and 6049.0H towards Girard, Illinois, on azimuth 214°28'.

412-CF-P-76, Same (WAX72), 0.8 Mile North of Girard, (Macoupin) Illinois. Lat. 39° 27'49" N., Long. 89°47'04" W. C.P. to replace transmitter and to add 6212.0V and 6330.7V toward Rochester, Illinois, on azimuth 34°18'; 6271.4V and 6301.0H towards Brighton, Illinois, on azimuth 207°15'.

413-CF-P-75, Same (WAX73), 3.5 Miles East of Brighton, (Macoupin) Illinois. Lat. 39°02'43" N., Long. 90°03'38" W. C.P. to replace transmitter and to add 6019.3V and 6049.0H towards Girard, Illinois, on azimuth 27°05'; 6019.3H and 6078.6H towards St. Louis, Missouri, on azimuth 193°55'.

414-CF-P-75, Same (WAX74), 720 Olive Street, St. Louis, Missouri. Lat. 38°37'42" N., Long. 90°11'32" W. C.P. to replace transmitter, change antenna systems, and to add 6271.4H and 6330.7H towards Brighton, Illinois, on azimuth 13°50'.

Corrections

New England Telephone and Telegraph Company (KZI61), 35-CF-P-76. Correct: Latitude to read 43°31'54" N. All other particulars remain as reported in Public Notice No 763 dated July 21 1975

LOCAL TELEVISION TRANSMISSION

9702-CT-R-76, Diamond State Telephone Company (KB9816), Within territory of Grantee: Application for Renewal of Radio Station License (3069-C1-ML-74) Mobile TV-Pickup, for the period August 1, 1975, to August 1, 1980.

9703-CT-R-76, Bell Telephone Company of Pennsylvania (KA2101). Within territory of Grantee: Application for Renewal of Radio Station License (2663-C1-ML-74), Mobile T--Pickup, for the period August 1, 1975, to August 1, 1980.

[FR Doc.75-23137 Filed 9-2-75;8:45 am]

FEDERAL ENERGY ADMINISTRATION

CONSUMER AFFAIRS/SPECIAL IMPACT ADVISORY COMMITTEE Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (Public Law 92-463, 86 Stat. 770), notice is hereby given that the Consumer Affairs/Special Impact Advisory Committee will meet Thursday, September 18, 1975, at 9 a.m., Room 7132, 12th & Pennsylvania Avenue, NW., Washington, D.C.

The Committee was established to provide the Federal Energy Administration with diversified information possessed by a wide range of highly qualified individuals who have been extensively involved in planning, development, and implementation of programs to remedy the problems of the consumer, the poor, the elderly, and the handicapped persons in rural and urban America.

The agenda for the meeting is as follows:

1. Subcommittee Reports on:
   a. Utility Issues.
   b. Social Relief Programs.
   c. Mutual Environmental and Consumer Issues.
   d. Pricing, Including Natural Gas.
   e. Impact of Energy Policy on the cities.
   f. Consumer Participation.
2. Old Business.
3. New Business.

Subcommittees may meet informally in Washington, the preceding evening, at the discretion of the Subcommittee chairmen. For further details, contact Lois Weeks, Advisory Committee Management Officer at (202) 961-7022.

The meeting is open to the public. The Chairman of the Committee is empowered to conduct the meeting in a fashion that will, in his judgment, facilitate the orderly conduct of business. Any member of the public who wishes to file a written statement with the Committee will be permitted to do so, either before or after the meeting. Members of the public who wish to make oral statements should inform Lois Weeks, Advisory Committee Management Officer at (202) 961-7022, at last 5 days before the meeting and reasonable provision will be made for their appearance on the agenda.

Further information concerning this meeting may be obtained from the Advisory Committee Management Office.

Minutes of the meeting will be made available for public inspection at the Federal Energy Administration, Washington, D.C.

Issued at Washington, D.C. on August 28, 1975.

DAVID G. WILSON,
Acting General Counsel.

[FR Doc.75-23272 Filed 8-28-75;2:10 pm]

FEDERAL MARITIME COMMISSION

FARRELL LINES INC. ET AL. Agreement Filed

Notice is hereby given that the following agreement has been filed with the Commission for approval pursuant to section 15 of the Shipping Act, 1916, as amended (39 Stat. 733, 75 Stat. 763, 46 U.S.C. 814).

Interested parties may inspect and obtain a copy of the agreement at the Washington office of the Federal Maritime Commission, 1100 L Street, NW., Room 10126; or may inspect the agreement at the Field Offices located at New York, N.Y., New Orleans, Louisiana, San Francisco, California and Old San Juan, Puerto Rico. Comments on such agreements, including requests for hearing, may be submitted to the Secretary, Federal Maritime Commission, Washington, D.C., 20573, on or before September 23, 1975. Any person desiring a hearing on the proposed agreement shall provide a clear and concise statement of the matters upon which they desire to adduce evidence. An allegation of discrimination or unfairness shall be accompanied by a statement describing the discrimination or unfairness with particularity. If a violation of the Act or detriment to the commerce of the United States is alleged, the statement shall set forth with particularity the acts and circumstances said to constitute such violation or detriment to commerce.

A copy of any such statement should also be forwarded to the party filing the agreement (as indicated hereinafter) and the statement should indicate that this has been done.

Farrell Lines Incorporated; Columbus Line; Associated Container Transportation (Australia) Ltd. and Australia National Line.

Notice of Agreement Filed by:

John R. Mahoney, Esq., Casey, Lane & Mittendorf, 26 Broadway, New York, New York 10004.

Sanford C. Miller, Esq., Haight, Gardner, Poor & Havens, One State Street Plaza, New York, New York 10004.

and

Edward Aptaker, Esq., Morgan, Lewis & Bockius, 1140 Connecticut Avenue, N.W., Washington, D.C. 20036.

Agreement No. 10174, among Farrell Lines, Inc., Columbus Line, Associated Container Transportation (Australia) Ltd. and Australia National Line, common carriers by water operating cellular container services in the trade between Australia and U.S. Atlantic and Gulf

Coast ports, provides for the establishment of a cooperative working arrangement whereby the carriers agree to consult with each other for the purpose of arranging their sailings to provide a more effective and efficient service to the ports in the trade.

By Order of the Federal Maritime Commission.

Dated: August 28, 1975.

JOSEPH C. POLKING,
Assistant Secretary.

[FR Doc.75-23294 Filed 9-2-75;8:45 am]

PACIFIC-INDONESIAN CONFERENCE

Agreement Filed

Notice is hereby given that the following agreement has been filed with the Commission for approval pursuant to section 15 of the Shipping Act, 1916, as amended (39 Stat. 733, 75 Stat. 763, 46 U.S.C. 814).

Interested parties may inspect and obtain a copy of the agreement at the Washington office of the Federal Maritime Commission, 1100 L Street, NW., Room 10126; or may inspect the agreement at the Field Offices located at New York, N.Y., New Orleans, Louisiana, San Francisco, California and Old San Juan, Puerto Rico. Comments on such agreements, including requests for hearing, may be submitted to the Secretary, Federal Maritime Commission, Washington, D.C., 20573, on or before September 23, 1975. Any person desiring a hearing on the proposed agreement shall provide a clear and concise statement of the matters upon which they desire to adduce evidence. An allegation of discrimination or unfairness shall be accompanied by a statement describing the discrimination or unfairness with particularity. If a violation of the Act or detriment to the commerce of the United States is alleged, the statement shall set forth with particularity the acts and circumstances said to constitute such violation or detriment to commerce.

A copy of any such statement should also be forwarded to the party filing the agreement (as indicated hereinafter) and the statement should indicate that this has been done.

Notice of Agreement Filed by:

Mr. H. R. Rollins, Secretary, Pacific-Indonesian Conference, 635 Sacramento Street, San Francisco, California 94111.

Agreement 6060-17 is an "enabling clause" which would permit the Pacific-Indonesian Conference to "* * * enter into agreements with other conferences or rate-making groups, for the purpose of discussing and/or agreeing upon matters of mutual interest."

By Order of the Federal Maritime Commission.

Dated: August 28, 1975.

JOSEPH C. POLKING,
Assistant Secretary.

[FR Doc.75-23295 Filed 9-2-75;8:45 am]

PACIFIC-STRAITS CONFERENCE

Agreement Filed

Notice is hereby given that the following agreement has been filed with the Commission for approval pursuant to section 15 of the Shipping Act, 1916, as amended (39 Stat. 733, 75 Stat. 763, 46 U.S.C. 814).

Interested parties may inspect and obtain a copy of the agreement at the Washington office of the Federal Maritime Commission, 1100 L Street, N.W., Room 10126; or may inspect the agreement at the Field Offices located at New York, N.Y., New Orleans, Louisiana, San Francisco, California and Old San Juan, Puerto Rico. Comments on such agreements, including requests for hearing, may be submitted to the Secretary, Federal Maritime Commission, Washington, D.C., 20573, on or before September 23, 1975. Any person desiring a hearing on the proposed agreement shall provide a clear and concise statement of the matters upon which they desire to adduce evidence. An allegation of discrimination or unfairness shall be accompanied by a statement describing the discrimination or unfairness with particularity. If a violation of the Act or detriment to the commerce of the United States is alleged, the statement shall set forth with particularity the acts and circumstances said to constitute such violation or detriment to commerce.

A copy of any such statement should also be forwarded to the party filing the agreement (as indicated hereinafter) and the statement should indicate that this has been done.

Notice of Agreement Filed by:

Mr. H. R. Rollins, Secretary, Pacific-Straits Conference, 635 Sacramento Street, San Francisco, California 94111.

Agreement 5680-18 is an "enabling clause" which would permit the Pacific-Straits Conference to ". . . enter into agreements with other conferences or rate-making groups, for the purpose of discussing and/or agreeing upon matters of mutual interest."

By Order of the Federal Maritime Commission.

Dated: August 28, 1975.

JOSEPH C. POLKING,
Assistant Secretary.

[FR Doc.75-23296 Filed 9-2-75;8:45 am]

FEDERAL POWER COMMISSION

[Docket Nos. AR64-1, et al.; Docket Nos. RP67-8, RP69-27, RP70-19]

AREA RATE PROCEEDING, ET AL. (HUGOTON-ANADARKO) AND TRANSWESTERN PIPELINE CO.

Proposed Plan of Refund

AUGUST 26, 1975.

Take notice that Transwestern Pipeline Company on August 4, 1975, filed a proposed plan of refund of supplier refunds received pursuant to the Commission's Order issued March 17, 1975, in Docket Nos. AR64-1, et al., directing disbursement and flow-through of refunds, as well as the disposition of certain refund amounts being retained by Transwestern pending Commission action. Transwestern's proposal, to be implemented by operation of the PGA provision of its FPC Tariff, is a plan of flowing through to its customers, not only the Hugoton-Anadarko Area refunds, but amounts being held pending Commission action in other proceedings, as set forth on the schedule attached thereto.

Transwestern proposes the following:

(1) To flow-through to its jurisdictional customers all refunds being held, and the disposition of which is awaiting Commission action. Such flow-through shall be implemented by crediting the refunds to the Gas Cost Adjustment Account pursuant to Section 19.2 (b) (3) (e) and 19.6 of the General Terms and Conditions of its FPC Gas Tariff.

(2) Such refunds shall include the equitable entitlement amounts heretofore retained pending Commission action and to which Transwestern will relinquish all claims.

Such supplier refunds are as follows:

Docket No. AR64-1 et al. (Hugoton-Anadarko):	
Refunds and interest pending distribution	$1,268,537.24
Equitable entitlement	16,989.24
Subtotal	$1,285,526.48
Docket No. AR61-1 et al. (Permian):	
Oct. 6, 1972, refund report, refunds pending distribution	601,218.52
Equitable entitlement amounts retained from prior reports	76,186.86
Total refunds to be credited	1,962,931.86

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Power Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with Section 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before September 4, 1975. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of the filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-23223 Filed 9-2-75;8:45 am]

[Docket Nos. AR64-1, et al.]

AREA RATE PROCEEDING, ET AL. (HUGOTON-ANADARKO AREA)

Report of Refunds

AUGUST 26, 1975.

Take notice that on August 4, 1975, Cities Service Gas Company (Cities)

tendered for filing and acceptance its report of intended disposition of refunds received in compliance with the Commission's Order Directing Disbursement and Flow-Through of Refunds issued March 17, 1975, and with the Commission's Order Granting Motion for Clarification issued July 18, 1975, in Docket Nos. AR64–1, et al.

Cities states that the proposal pertains to producer-supplier refunds received and retained by Cities aggregating $6,989,269.67, principal and interest, all applicable to gas purchased by Cities from the Hugoton-Anadarko Area.

Cities states that this aggregate sum does not include refunds not yet received by Cities from four named respondent-producers pursuant to ordering paragraphs (A) and (B) of the aforementioned Order of March 17, 1975, in the instant docket, totalling $17,078.16 including interest to Septemeber 1, 1970. Cities proposes that upon receipt of such refunds, it will submit a report to the Commission and proposes that it be permitted to retain all such sums because they are de minimis, with only approximately $9,750 being subject to refund to jurisdictional customers. Cities states that it has made diligent efforts to obtain the disbursement of such refunds, but has not succeeded due to difficulties in locating producers, transfers of ownership, producer deaths, and a claim of producer exemption.

Cities states that it intends to flow through to its jurisdictional customers $3,048,939.53 of the aggregate amount and to retain $3,940,330.14 and that such intended disposition is consistent with its obligations to flow through refunds received from producer-suppliers to its jurisdictional customers as set forth in the Stipulation and agreement approved by the Commission's Order of December 22, 1961, in Docket No. RP62–1; the Stipulation and Agreement approved by the Commission's Order of June 28, 1965, in Docket Nos. RP64–9, et al.; the Stipulation and Agreement approved by the Commission's Order of January 30, 1969, in Docket No. RP68–16; and the Stipulation and Agreement approved by the Commission's Order of August 24, 1970, in Docket Nos. RP69–39 and RP70–22. Cities states that pursuant to each of the aforementioned Stipulation and Agreements it has the right to retain the allocated portion of all producer refunds received which are attributable to its non-jurisdictional business, being $2,420,947.97. Cities states that pursuant to the post-audit provisions set forth in Articles IV and V of the aforementioned Stipulation and Agreement in Docket Nos. RP64–9, et al., and in Article IV of the aforementioned Stipulation Agreement in Docket No. RP68–16, Cities has the right to retain $1,519,382.17. Cities states that the Commission clarified that these post-audit provisions will be honored by its Order Granting Motion for Clarification issued July 18, 1975.

Cities states that copies of the filing were served on all of Cities' jurisdictional customers and interested state regulatory commissions.

Any person desiring to be heard or to make any protest with reference to this filing should, on or before September 4, 1975, file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules and Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations Under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken, but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-23224 Filed 9-2-75;8:45 am]

[Docket No. ER 76-57]

ARIZONA PUBLIC SERVICE CO.

Supplement to Agreement

AUGUST 26, 1975.

Take notice that on August 8, 1975, Arizona Public Service Company (APS) tendered for filing Supplement No. 16 of an Agreement with Navajo Tribal Utility Authority (NTUA), FPC Rate Schedule No. 6, which provides for the delivery of part of NTUA's entitlement from APS' Four Corners Generating Station near Farmington, New Mexico to NTUA at the Navajo Reservation boundary just north of the APS' Leupp Junction Substation. APS states that the Supplement provides for no change of rate and is not a rate increase.

Copy of the filing was served upon the Arizona Corporation Commission.

APS requests that the waiver provisions of Section 35.11 of the Commission's regulations be waived and permit this Supplement to become effective as soon as practical.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Power Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before September 5, 1975. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-23225 Filed 9-2-75;8:45 am]

[Docket No. ER76-67]

KANSAS CITY POWER & LIGHT CO.

Filing of Service Schedule

AUGUST 26, 1975.

Take notice that on August 11, 1975, Kansas City Power & Light Company (KCPL) tendered for filing a Service Schedule under the Twin Cities-Iowa-Omaha-Kansas City 345 Kv Interconnection Coordinating Agreement. KCPL's FPC Rate Schedule No. 67, and KCPL requests that said Service Schedule be permitted to become effective thirty (30) days after filing. KCPL states that the Service Schedule provides for the Sale of Long Term Interruptible Capacity to Omaha Public Power District (OPPD).

KCPL states that long Term Interruptible Capacity is being provided to OPPD to permit OPPD to enter into a related transaction with Nebraska Public Power District (NPPD) which latter will require additional capacity for reliability on its system.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Power Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before September 4, 1975. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-23226 Filed 9-2-75;8:45 am]

[Docket Nos. E-9028, E-9058 and ER76-71]

MISSISSIPPI POWER AND LIGHT CO.

Proposed Agreement for Purchase of Power

AUGUST 26, 1975.

Take notice that on August 12, 1975, Mississippi Power and Light Company (MP&L), tendered for filing an Agreement for Purchase of Power between MP&L and the Yazoo Valley Electric Power Association at Midway, Mississippi in substitution for an unexecuted Agreement for Purchase of Power filed on September 20, 1974, and accepted for filing on January 7, 1975, in Docket No. E-9028 to become effective on the date of initiation of service. Service commenced under that agreement on January 30, 1975.

MP&L states that its Rate Schedule REA-13 (Revised) incorporated therein was heretofore filed with the Commission on January 10, 1975, in Docket No. E-9058 and is the currently effective tariff for service to its electric power association customers pending action of the Commission in Docket No. E-9058.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Power Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before September 4, 1975. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-23227 Filed 9-2-75;8:45 am]

[Docket No. ID-1647]

CLIFTON F. ROGERS

Supplemental Application

AUGUST 26, 1975.

Take notice that on July 18, 1975, Clifton F. Rogers (Applicant) filed a supplemental application with the Federal Power Commission. Pursuant to Section 305(b) of the Federal Power Act, Applicant seeks authority to hold the following positions:

Chairman of the Board, President & Director, Upper Peninsula Power Company, Public Utility.

President & Director, Upper Peninsula Generating Company, Public Utility.

Upper Peninsula Power Company, 616 Sheldon Avenue, Houghton, Michigan, is engaged in the electric utility business in the upper peninsula of Michigan. In addition to its own generating facilities, Upper Peninsula Power Company owns 19% of the outstanding Common (voting) stock of Upper Peninsula Generating Company with Cliffs Electric Service Company owning the other 81%.

Upper Peninsula Generating Company, 616 Sheldon Avenue, Houghton, Michigan, is engaged in the generation of electric energy for sale to its two owners, Cliffs Electric Service Company having the right to purchase 50% and Upper Peninsula Power Company 50% of the energy generated from Units 1 through 4 with Cliffs Electric Service Company having the right to purchase all energy from Units 5 and 6. All the facilities of Upper Peninsula Generating Company are located at Marquette, Michigan.

Any person desiring to be heard or to make any protests with reference to said application should on or before September 5, 1975, file with the Federal Power Commission, Washington, D.C. 20426, petitions to intervene or protests in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Persons wishing to become parties to a proceeding or to participate as a party in any hearing therein must file petitions to intervene in accordance with the Commission's Rules. The application is on file with the Commission and available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-23228 Filed 9-2-75;8:45 am]

[Docket No. ER76-68]

SOUTHERN INDIANA GAS & ELECTRIC CO.

Filing of Supplement to Electric Service Agreement

AUGUST 26, 1975.

Take notice that on August 11, 1975, Southern Indiana Gas and Electric Company (Company) tendered for filing an Agreement Letter, of July 10, 1975, captioned "Second Supplement to Electric Power Agreement", dated May 25, 1971 (Alcoa Generating Corporation Rate Schedule FPC No. 2 Modifying said Agreement and the Letter Agreement, dated April 30, 1973—First Supplement Southern Indiana Gas and Electric Company—Rate Schedule FPC No. 32). According to the Company, the Letter Agreement, herein referred to as the "Supplement", amends and supplements, but does not supersede the Electric Power Agreement, dated May 28, 1971 and the First Supplement thereto—Letter Agreement, dated April 30, 1973, between the parties.

According to the Company, the Second Supplement updates the Electric Power Agreement, dated May 28, 1971, and the first supplement thereto, both of which are referred to above, by providing that effective August 1, 1975, for short term power reserved by Alcoa Generating Corporation for a period of not less than a calendar week, the demand charge shall be $0.45 per kilowatt and $0.075 per kilowatt per day for each day beginning with the day for which power is reserved and ending with the following Saturday and for firm power of 40 MW the demand charge shall be $1.95 per KW per month (rate of $0.45 per KW per week) whether or not Alcoa Generating Corporation takes the power requested. These charges were determined by mutual agreement of the parties and are based upon levels customarily and currently being charged by utilities in the area where Southern Indiana Gas and Electric Company and Alcoa Generating Corporation are located, the Company states.

The Company requests the Commission waive the prior notice requirements and permit an effective date of August 1, 1975.

Any person desiring to be heard or to protest said application should file a petition to intervene or protest with the Federal Power Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure. All such petitions or protests should be filed on or before September 5, 1975. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this application are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-23229 Filed 9-2-75;8:45 am]

[Docket No. E-9496]

UNION ELECTRIC CO.

Filing of Revised Tariff Sheets

AUGUST 26, 1975.

Take notice that on August 11, 1975, Union Electric Company (UE) tendered for filing certain Revised Tariff Sheets in the captioned docket. Union states that such sheets reflect the exclusion of construction work in progress from its rate base pursuant to the Commission's order of July 11 in this proceeding. Union states that it filed revised schedules to Statements M and N similarly reflecting the exclusion of construction work in progress from rate base. Union states that copies of this filing were mailed to all parties of record.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Power Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before September 5, 1975. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-23230 Filed 9-2-75;8:45 am]

[Docket No. E-8960]

UTAH POWER & LIGHT CO.

Filing of Supplemental Data

AUGUST 26, 1975.

Take notice that on June 9, 1975, The Montana Power Company (Montana) tendered supplemental data intended to make complete the original filing of August 5, 1974, of Utah Power and Light Company (Utah). This data consists of Montana's Certificate of Concurrence to the supplemental information to its Interconnection Agreement with Utah, filed by Utah on August 5, 1974. This action is in response to the letter of April 11, 1975, issued to Montana by the Secretary of the Federal Power Commission.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Power Commission, 825 North Capitol

Street, NE., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before September 5, 1975. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-23231 Filed 9-2-75;8:45 am]

[Docket No. E-9478]

ALABAMA POWER CO., ET AL.

Extension of Time

AUGUST 26, 1975.

On July 31, 1975, Consumers Power Company filed a motion to extend the time for filing answers to the petition to intervene and for hearing filed by Georgia Power Project, et al., on June 30, 1975.

Upon consideration, notice is hereby given that the date for filing answers to the petition in the above matter is extended to and including September 8, 1975.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-23309 Filed 9-2-75;8:45 am]

[Docket No. RP75-90]

ALABAMA-TENNESSEE NATURAL GAS CO.

Further Extension of Time

AUGUST 25, 1975.

On August 22, 1975, Staff Counsel filed a motion to extend the procedural dates fixed by order issued April 24, 1975, as most recently modified by notice issued July 29, 1975, in the above-designated matter. Staff has contacted the interested parties in this proceeding and there is no opposition to the proposed dates.

Upon consideration, notice is hereby given that the procedural dates in the above matter are modified as follows:

Service of Staff Testimony, September 30, 1975.
Service of Intervenor Testimony, November 11, 1975.
Service of Company Rebuttal, November 25, 1975.
Hearing, December 16, 1975 (10:00 a.m. EST).

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-23319 Filed 9-2-75;8:45 am]

[Docket No. RI75-131]

CHEVRON OIL CO.

Proposed Change in Rate

AUGUST 26, 1975.

Respondent has filed a proposed change in rate and charge for the jurisdictional sale of natural gas, as set forth in Appendix A hereof.

The proposed changed rate and charge may be unjust, unreasonable, unduly discriminatory, or preferential, or otherwise unlawful.

The Commission finds: It is in the public interest and consistent with the Natural Gas Act that the Commission enter upon a hearing regarding the lawfulness of the proposed change, and that the supplement herein be suspended and its use be deferred as ordered below.

The Commission orders: (A) Under the Natural Gas Act, particularly Sections 4 and 15, the Regulations pertaining thereto [18 CFR, Chapter I], and the Commission's Rules of Practice and Procedure, a public hearing shall be held concerning the lawfulnes of the proposed change.

(B) Pending hearing and decision thereon, the rate supplement herein is suspended and its use deferred until date shown in the "Date Suspended Until" column. This supplement shall become effective, subject to refund, as of the expiration of the suspension period without any further action by the Respondent or by the Commission. Respondent shall comply with the refunding procedure required by the Natural Gas Act and Section 154.102 of the Regulations thereunder.

(C) Unless otherwise ordered by the Commission, neither the suspended supplement, nor the rate schedule sought to be altered, shall be changed until disposition of this proceeding or expiration of the suspension period, whichever is earlier.

By the Commission.

[SEAL] KENNETH F. PLUMB,
Secretary.

APPENDIX A

Docket No.	Respondent	Rate schedule No.	Supplement No.	Purchaser and producing area	Amount of annual increase	Date filing tendered	Effective date unless suspended	Date suspended until—	Cents per Mcf*		Rate in effect subject to refund in docket No.
									Rate in effect	Proposed increased rate	
RI75-131..	Chevron Oil Co.....	3	13	Mountain Fuel Supply Co. (Wyoming) (Rocky Mountain).	$3,014	7-28-75	.....	9-27-75	27.42	27.5792	RI75-131.

* Unless otherwise stated, the pressure base is 15.025 lb/in²a.
† Unless otherwise stated, the rate shown is the total rate, inclusive of any applicable British thermal unit adjustment and tax.

The proposed tax increase which exceeds the applicable area ceiling in Opinion No. 658 is suspended until September 27, 1975, which is the time when the suspension period for the underlying rate will expire.

[FR Doc.75-23332 Filed 9-2-75;8:45 am]

[Docket No. CP76-51]

COLUMBIA GAS TRANSMISSION CORP.

Application

AUGUST 25, 1975.

Take notice that on August 11, 1975, Columbia Gas Transmission Corporation (Applicant), 1700 MacCorkle Avenue, S.E., Charleston, West Virginia 25314, filed in Docket No. CP76-51 an application pursuant to Section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing sales of natural gas in interstate commerce for resale under revised service agreements with Baltimore Gas and Electric Company (Baltimore), The Cincinnati Gas Electric Company (Cincinnati), Columbia Gas of Ohio, Inc. (Ohio), Columbia Gas of Virginia, Inc. (Virginia), Roanoke Gas Company, (Roanoke), UGI Corporation (UGI), and Washington Gas Light Company and subsidiaries, Shenandoah Gas Company and Frederick Gas Company, Inc. (WGL), all as more fully set forth in the application on file with the Commission and open to public inspection.

Applicant requests authorization to sell natural gas under the following circumstances effected by revised service agreements with all signed April 30, 1975:

1. Reduction in Baltimore's winter contract quantity from 10,950,000 Mcf to 5,650,000 Mcf of gas under Rate Schedule WS in Zone 2.

2. Reduction Cincinnati's winter contract quantity from 1,500,000 Mcf to 1,250,000 Mcf of gas under Rate Schedule WS in Zone 4.

3. Reduction in Ohio's winter contract quantity from 1,403,600 Mcf to 1,210,000 Mcf of gas under Rate Schedule WS in Zone 6.

4. Reduction in Virginia's winter contract quantity from 1,397,500 Mcf to 1,075,000 Mcf of gas under Rate Schedule WS in Zone 2.

5. Reduction in Roanoke's contract demand from 25,000 Mcf to 23,750 Mcf of gas per day under Rate Schedule CDS in Zone 2.

6. Reduction in Roanoke's maximum daily quantity from 8,000 Mcf to 7,600 Mcf of gas and in winter contract quantity from 550,000 Mcf to 380,000 Mcf of gas under Rate Schedule WS in Zone 2.

7. Reduction in UGI's winter contract quantity from 3,650,000 Mcf to 2,906,300

Mcf of gas under Rate Schedule WS in Zone 6.

8. Reduction in WGL's winter contract quantity from 19,140,000 Mcf to 15,630,000 Mcf of gas under Rate Schedule WS in Zone 2.

Applicant states that Baltimore, Cincinnati, Ohio, Virginia, Roanoke, UGI and WGL have advised Applicant that they desire to decrease their winter contract quantities and that Roanoke has advised Applicant that it desires also to reduce its contract demand and maximum daily quantity. It is stated that the proposed revised service agreements reflect the requested reductions. Applicant requests that the Commission authorize sales under the proposed service agreements with an effective date of November 1, 1975, for service with the revisions under Rate Schedule WS and December 1, 1975, for service with revisions under Rate Schedule CDS.

Applicant states that the proposed revisions would not result in the reallocation of natural gas supply among Applicant's customers, the shift of supply from the winter months to the summer months, or a more inferior use of the gas. It is further stated that the proposed revisions would not affect Applicant's curtailment program.

The application indicates that the customers desire a reduction in the winter contract quantities to reduce the demand cost of gas which Applicant is unable to deliver. Additionally, the application indicates that Roanoke has a gas supply in excess of its needs under its current circumstances of service.

Any person desiring to be heard or to make any protest with reference to said application should on or before September 16, 1975, file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Power Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-23320 Filed 9-2-75;8:45 am]

[Docket Nos. RP75-105 and RP75-106]

COLUMBIA GULF TRANSMISSION CORP. AND COLUMBIA GAS TRANSMISSION CORP.

Order Granting Late Petition To Intervene

AUGUST 26, 1975.

On July 28, 1975, the National Fuel Gas Supply Corporation (National Fuel) filed a petition to intervene out of time in this docket. Notice of the filing of the above-referenced dockets was issued on June 4, 1975, with protests or petitions to intervene due on or before June 20, 1975. Several petitions to intervene were received and subsequently granted by order dated July 14, 1975. National Fuel now comes stating that it inadvertently failed to file a timely petition for intervention, that its interest will not adequately be represented by any other party to this proceeding, and that allowance of its intervention will cause no delay.

The Commission finds: Participation by National Fuel in this proceeding may be in the public interest and good cause exists for permitting such intervention.

The Commission orders: (A) The above mentioned petitioner is hereby permitted to intervene in this proceeding, subject to the Rules and Regulations of the Commission; *Provided, however,* that the participation of such intervenor shall be limited to matters affecting the rights and interests specifically set forth in its petition to intervene; and *Provided, further,* that the admission of such intervenor shall not be construed as recognition that it might be aggrieved because of any order or orders issued by the Commission in this proceeding.

(B) The intervention granted herein shall not be the basis for delaying or deferring any procedural schedules heretofore established for the orderly and expeditious disposition of this proceeding.

(C) The Secretary shall cause prompt publication of this order in the FEDERAL REGISTER.

By the Commission.

[SEAL] KENNETH F. PLUMB,
Secretary.

[FR Doc.75-23310 Filed 9-2-75;8:45 am]

[Docket Nos. RP73-107, RP74-90, RP75-91 (Pipeline Production)]

CONSOLIDATED GAS SUPPLY CORP.

Order Granting Motion for Severance and Expeditious Treatment of Appalachian Pipeline Production Issue, Consolidating Proceedings, and Establishing Procedural Dates

AUGUST 25, 1975.

On July 23, 1975, Consolidated Gas Supply Corporation (Consolidated) filed a motion requesting that the Commission issue an order severing and expediting decision of the question of whether the costs of its production of natural gas in the Appalachian area from leases acquired after October 8, 1969, or from wells drilled after January 1, 1973, shall be included in its overall cost of service for ratemaking purposes or whether such costs should be excluded from the total cost of service and the national or area rate, as appropriate, substituted for volumes produced from such leases or wells.

Consolidated states that it has continued to advocate cost-of-service treatment for all production in the Appalachian area in its rate filings in Docket Nos. RP73-107, RP74-90 and RP75-91, in accordance with Consolidated's history of inclusion of all of its own production activities' cost in that region as part of its cost-of-service. However, Consolidated in its motion notes that in Docket No. RP74-90, the Staff advocates excluding from its cost-of-service Consolidated's cost of producing natural gas from leases acquired after October 8, 1969, or from wells drilled after January 1, 1973, and rather, pricing those volumes of gas produced from such wells and leases at the national or area rate, as appropriate. Consolidated states it anticipates the issue arising as well in Docket Nos. RP73-107 and RP75-91.

In view of the impact of the treatment of Appalachian pipeline production on Consolidated and on the customers it serves, the Company believes the prompt resolution of this issue is essential. Consolidated indicates it will be compelled to restrict its drilling program to those projects where production can be obtained profitably within the national or area rates should the Commission not permit cost-of-service treatment and further, such restricted drilling will inevitably reduce the supply available to Consolidated from the Appalachian region.

On July 29, 1975, Rochester Gas and Electric Corporation (Rochester) filed its Response in support of Consolidated's Motion to sever and expedite decision on the treatment of the Appalachian pipeline production issue. Rochester declares it is wholly dependent upon Consolidated for its own gas supply and concurs with Consolidated's assertion that the resolution of the question of proper ratemaking treatment of Consolidated's Appalachian area production expenses will have a direct and probably decisive impact upon Consolidated's drilling activity in that region. Rochester adds it is in the public interest to avoid unnecessary delay in the resolution of this issue when the production of natural gas is critically important.

On August 7, 1975, the Commission Staff filed its Answer to Consolidated's Motion, also indicating its support for severance of the Appalachian pipeline production issue from the other issues in the proceedings. Staff, however, requests that because Consolidated's Motion affects the disposition of the issue in Docket No. RP75-91, a proceeding in which Staff has yet to serve its testi-

mony, the Commission establish procedural dates for the service of Staff's testimony and any intervenor's testimony on the issue of pipeline production as it relates to Docket No. RP75–91.

By Order dated July 14, 1975,[1] in another pipeline rate filing, we severed the issue of whether cost of service treatment should be afforded for the company's production from leases in the Appalachian area acquired after October 8, 1969. Similar treatment is appropriate in the immediate dockets and we shall so provide in this order. We note, however, that in Opinion No. 731[2] we expressed our concern with respect to the standards that must be met to satisfy the "special circumstances" criterion for such cost of service treatment as set forth in Opinion No. 568[3] and Opinion No. 568–A[4]. In finding that the circumstances must be truly extraordinary, we concluded that the pipeline seeking the higher cost of service treatment must carry the same burdens of proof and persuasion that an independent producer must meet in order to gain an exception from the area rate applicable to its sale. Thus, more than a showing of unit costs higher than the area rate, or intimations that the company will have to discontinue its exploration program without the requested relief, is required. In light of Opinion No. 731, all parties submitting evidence on this issue should specifically address the *extraordinary* nature of the circumstances surrounding Consolidated's production from leases acquired after October 8, 1969, in the Appalachian area.

Our review of Consolidated's Motion to sever and expedite the decision on the treatment of pipeline production costs in Docket Nos. RP73–107 and RP74–90 and in Docket No. RP75–91 indicates it is reasonable and appropriate in the public interest to avoid any unnecessary delay in the resolution of this issue, and we believe good cause exists to grant Consolidated's Motion as hereinafter provided. Therefore, we shall sever the Appalachian pipeline production issue in Docket Nos. RP73–107 and RP74–90 and in Docket No. RP75–91 and consolidate the proceedings on that issue for the purpose of hearing and decision.

We note that by Notice issued July 29, 1975, by the Secretary, Consolidated's Rebuttal Testimony in Docket Nos. RP 74–90 and RP73–107 is due to be served on or before September 11, 1975; therefore, we shall assign procedural dates for the service of testimony on the Appalachian pipeline production issue in Docket No. RP75–91 only.

The Commission finds: Good cause exists to grant Consolidated's motion to sever and expedite decision of the question of whether the costs of Consolidated's production of natural gas in the Appalachian area from leases acquired after October 8, 1969, or from wells drilled after Januuary 1, 1973, shall be included in its overall cost of service for ratemaking purposes or whether such costs should be excluded from the total cost of service and the national or area rates, as appropriate, substituted for volumes produced from such leases or wells and to establish procedural dates for hearing on that issue as hereinafter ordered and conditioned.

The Commission orders: (A) Consolidated's Motion, filed July 23, 1975, in Docket Nos. RP73–107, RP74–90 and RP 75–91, for severance and expeditious treatment of the Appalachian pipeline production issue is hereby granted, as hereinafter ordered and conditioned.

(B) The trial of the Appalachian pipeline production issue in Docket Nos. RP 73–107 and RP74–90 and in Docket No. RP75–91 is hereby consolidated, for purposes of hearing and decision thereon.

(C) These consolidated proceedings shall hereinafter be docketed as Docket Nos. RP73–107, RP74–90 and RP75–91 (Pipeline Production).

(D) Pursuant to authority of the Natural Gas Act, particularly Sections 4 and 5 thereof, and the Commission's Rules and Regulations, a public hearing for the purposes of cross-examination of the evidence on the Appalachian pipeline production issue shall be held on December 16, 1975, at 10:00 A.M. in a hearing room of the Federal Power Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426.

(E) On or before November 3, 1975, the Commission Staff shall serve its prepared testimony and exhibits in Docket No. RP75–91 on the Appalachian pipeline production issue. Any intervenor evidence on the Appalachian pipeline production issue in Docket No. RP75–91 shall be filed on or before November 17, 1975. Any rebuttal by Consolidated on the same issue in Docket No. RP75–91 shall be served on or before December 2, 1975.

(F) A Presiding Administrative Law Judge to be designated by the Chief Administrative Law Judge for that purpose, (See Delegation of Authority, 18 CFR 3.5(d)), shall preside at the hearing in this proceeding, shall prescribe relevant procedural matters not herein provided, and shall control this proceeding in accordance with the policies expressed in the Commission's Rules of Practice and Procedure.

(G) The Secretary shall cause prompt publication of this order in the Federal Register.

By the Commission.

[SEAL] KENNETH F. PLUMB, *Secretary.*

[FR Doc.75-23321 Filed 9-2-75;8:45 am]

[Docket No. E-9294]

DETROIT EDISON CO.

Further Extension of Procedural Dates

AUGUST 25, 1975.

On August 8, 1975, Staff Counsel filed a motion to extend the procedural dates fixed by order issued March 27, 1975, as most recently modified by notice issued June 23, 1975, in the above-designated matter.

Upon consideration, notice is hereby given that the procedural dates in the above matter are modified as follows:

Service of Staff Testimony, October 23, 1975.
Service of Intervenor Testimony, November 10, 1975.
Service of Company Rebuttal, November 25, 1975.
Hearing, December 15, 1975 (10:00 a.m. EST).

KENNETH F. PLUMB, *Secretary.*

[FR Doc.75-23322 Filed 9-2-75;8:45 am]

[Docket No. RP73-104, et al.]

EL PASO NATURAL GAS CO.

Extending and Establishing Further Procedural Dates

August 21, 1975.

On August 13, 1975, Staff Counsel filed a motion to extend procedural dates set by order issued February 8, 1974, as most recently modified by notice issued July 2, 1975, and to establish further procedural dates in the above-designated matter.

Notice is hereby given that the procedural dates in the above matter are modified as follows:

Service of Staff's Evidence and the California Public Utility Commission's Evidence on Depreciation, October 31, 1975.
Service of Intervenor Evidence, November 14, 1975.
Service of Company's Additional Rebuttal, December 2, 1975.
Hearing, December 9, 1975 (10 a.m. e.s.t.).

By direction of the Commission.

KENNETH F. PLUMB, *Secretary.*

[FR Doc.75-23307 Filed 9-2-75;8:45 am]

[Docket No. CP76-53]

EL PASO NATURAL GAS CO.

Application

August 26, 1975.

Take notice that on August 12, 1975, El Paso Natural Gas Company (Applicant), P.O. Box 1492, El Paso, Texas 79978, filed in Docket No. CP76–53 an application pursuant to Section 7(c) of the Natural Gas Act, as implemented by Section 157.7(c) of the Regulations thereunder (18 CFR 157.7(c)), for a certificate of public convenience and necessity authorizing the construction commencing October 25, 1975, and operation of facilities for miscellaneous rearrangements, all as more fully set forth in the application on file with the Commission and open to public inspection.

The stated purpose of this budget-type application is to enable Applicant to act with reasonable dispatch in making unspecified minor rearrangements of gas sales and transportation facilities. It is stated that the proposed rearrangements would not result in any change in service rendered or the volumes of natural gas authorized to be sold or delivered by Applicant. Applicant states that

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[1] *Columbia Gulf Transmission Corporation, Columbia Gas Transmission Corporation*, Docket Nos. RP75–105, RP75–106.
[2] Issued May 15, 1975.
[3] 42 FPC 738 (1969).
[4] 42 FPC 1089 (1969).

the maximum number of facilities that it would construct, rearrange and operate under the proposed authorization woud be 5 measuring and regulating stations with standard appurtenances, including tap and valve assemblies, which would be removed or installed at various locations on Applicant's interstate system at an estimated cost of approximately $100,000, and various sizes of lateral, loop or other pipelines ranging in length from a maximum of 5,000 feet of 4½-inch pipeline to 2,000 feet of 16-inch pipeline, which would be installed at various points along Applicant's interstate system at an estimated aggregate cost of approximately $200,000. Applicant states that the estimated aggregate cost of all of the proposed facilities would not exceed $300,000.

Applicant states that the construction and operation of the proposed facilities for miscellaneous rearrangements would be made in connection with the sale and delivery of authorized volumes of natural gas to an existing distributor customers.

Any person desiring to be heard or to make any protest with reference to said application should on or before September 17, 1975, file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Power Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-23311 Filed 9-2-75;8:45 am]

[Docket No. E-7561]

HOLYOKE WATER POWER CO., ET AL.

Amended Extension of Time

AUGUST 22, 1975.

In the matter of Holyoke Water Power Company, Western Massachusetts Electric Company, New England Power Company.

On August 20, 1975, notice was issued in the above-designated matter extending the date for Massachusetts, Vermont, Connecticut and New Hampshire to file direct testimony to August 27, 1975. This notice of August 20, 1975, is hereby amended to apply the extension of the date to file direct testimony in the above matters to all parties.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-23308 Filed 9-2-75;8:45 am]

[Docket No. RP76-3]

INLAND GAS COMPANY, INC.

Tariff Filing

AUGUST 25, 1975.

Take notice that on July 31, 1975, The Inland Gas Company, Inc. (Inland), filed in Docket No. RP76-3 pursuant to Section 4 of the Natural Gas Act its FPC Gas Tariff, Original Volume No. 1, setting forth curtailment procedures for deliveries of natural gas for direct sale, all as more fully set forth in the proposed tariff on file with the Commission and open to public inspection.

By motion accompanying the proposed tariff Inland states that said tariff would have an issue date of July 30, 1975, and would become effective on January 1, 1976, pending determination of permanent curtailment procedures. Inland alleges that such proposed procedures are necessitated by the curtailment of natural gas supplies by Tennessee Gas Pipeline Company, a Division of Tenneco Inc. (Tennessee). Inland states that its contract demand service agreement with Tennessee, its major supplier, provides for delivery of 51,000 Mcf of natural gas per day, but that commencing December 16, 1974, contractual deliveries to Inland were curtailed by Tennessee by approximately 60 percent, to approximately 20,000 Mcf of natural gas per day. Inland states that it also has 7,000 Mcf of gas per day available from locally produced and purchased gas.

Inland states that approximately 98 percent of its total annual sales of gas are to 17 of its industrial customers and that the remainder of the gas is sold throughout its system to small rural domestic and commercial customers. Inland states further that two of its larger industrial customers account for approximately 87 percent of its annual total sales. Inland's motion further states that it makes no sales subject to the jurisdiction of the Commission.

Inland states that due to the situation created by the curtailments by Tennessee, it has imposed on its 9 larger industrial customers with daily contract demands in excess of 300 Mcf of gas a proportional curtailment. Inland further states that because one of its major customers is not utilizing its full entitlement of gas, there is presently no curtailment in effect. The motion states that it expects that no curtailment will be imposed in either August or September, but that a curtailment not in excess of 15 percent will be imposed in October and that a curtailment of approximately 30 percent of entitlements is expected in November and December. Inland states that these interim curtailment procedures have been agreed to by the larger industrial customers through December 31, 1975.

Inland alleges that the proposed curtailment procedures would fully protect its rural domestic and commercial customers by imposing proportionate curtailments on its larger industrial customers with entitlements in excess of 300 Mcf of gas per day. It is stated that a curtailment plan in strict accordance with the priorities of service set forth in Section 2.78 of the Commission's General Policy and Interpretations (18 CFR 2.78) would severely adversely impact one of Inland's major customers and might cause a number of its smaller industrial customers to cease operations. Inland states that its proposed curtailment plan is not in strict accordance with the end-use priorities that are prescribed in Section 2.78 but that its proposed plan would mitigate or obviate the need for extraordinary relief, which would require Inland to flow-through such requests into Tennessee's curtailment proceeding and would require a formal litigated proceeding. Inland alleges that its proposal would spread the burden of curtailment on its nine larger industrial customers and that the proposed curtailment procedures are in accord with Commission Order 467-B and consistent with the curtailment policy contained therein particularly under the conditions existing in its situation.

The proposed tariff provides for overrun penalties of $10.00 per Mcf and distribution of the penalties among those customers which were unable to receive gas as a result of the overruns.

Any person desiring to be heard or to make any protest with reference to said tariff filing should on or before September 15, 1975, file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing

to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-23323 Filed 9-2-75;8:45 am]

[Docket No. ER76-70]

INTERSTATE POWER CO.

Proposed Changes in Rates and Charges

AUGUST 26, 1975.

Take notice that on August 13, 1975, Interstate Power Company (Interstate) tendered for filing proposed changes to its FPC Rate Schedule No. 88 for an increase in its transmission service charges to one of its customers, the Cooperative Power Association (CPA). Interstate states that the proposed increase would result in increased revenues of $418,720, or an increase of 63.3% based on test year 1974, and that the reason for the proposed changes is to offset a decline in overall rate of return due to increased costs of operation.

Interstate proposes an effective date of September 15, 1975, and states that notice of this filing has been given to CPA.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Power Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before September 8, 1975. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-23312 Filed 9-2-75;8:45 am]

[Docket No. ER76-78]

MID-CONTINENT AREA POWER POOL AGREEMENT

Filing of Amendment to Agreement

AUGUST 26, 1975.

Take notice that on August 18, 1975, Northern States Power Company (Minnesota) (Northern States), as filing agent for the Mid-Continent Area Power Pool (MAPP) Agreement, tendered for filing a proposed amendment to the MAPP Agreement. Northern States states that the proposed amendment revises certain provisions of the agreement relating to voting on amendments.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Power Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before September 12, 1975. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-23313 Filed 9-2-75;8:45 am]

[Docket No. RP76-4]

NATIONAL FUEL GAS SUPPLY CORP.

Proposed Changes in FPC Gas Tariff

AUGUST 25, 1975.

Take notice that National Fuel Gas Supply Corporation, on August 15, 1975, tendered for filing proposed changes in its FPC Gas Tariff, Original Volume No. 1. The proposed changes would increase revenues from jurisdictional sales and service by $12,484,000 based on the 12 month period ending December 31, 1975, as adjusted.

National states that the increased rates are required to recoup increased costs incurred in operating and maintaining its system, including, but not limited to, increased cost of capital, increased depreciation due to increases in depreciation rates, and increased wages, taxes and other operation and maintenance expenses. The rates proposed reflect an overall rate of return of 10.2%. The filing also reflects a continuing decline in National's gas supply with a consequent reduction in annual sales volumes. Further, National states that the proposed rates do not include the appropriate surcharge as provided by its purchased gas adjustment clause. At such time as the increased rates are to become effective National will make the appropriate filing to reflect the applicable surcharge adjustment in effect at that time.

National states that it has included in this filing costs applicable to facilities to be acquired from The Sylvania Corporation pursuant to the proposed merger of Sylvania and National which is the subject of Docket No. CP75-344. National further states that if a certificate of public convenience and necessity in Docket No. CP75-344 is not issued prior to the expiration of the suspension period in this proceeding, it will file revised tariff sheets reflecting the elimination of costs applicable to Sylvania.

National states that copies of this filing were served upon the company's jurisdictional customers and the regulatory commissions of the States of New York, Ohio and Pennsylvania.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Power Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before September 9, 1975. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-23324 Filed 9-2-75;8:45 am]

[Docket No. ER76-73]

NIAGARA MOHAWK POWER CORP.

Tariff Filing

AUGUST 25, 1975.

Take notice that Niagara Mohawk Power Corporation, on August 14, 1975, tendered for filing as a rate schedule, a transmission agreement between Niagara Mohawk Power Corporation and Orange and Rockland Utilities, Inc., dated February 14, 1975.

The service to be rendered by Niagara Mohawk Power Corporation (Niagara) provides for the transmission of power and energy between (a) Niagara's transmission connection to the Power Authority of the State of New York (PASNY) Fitzpatrick-Edic No. 1, 345 Kv transmission line and (b) Niagara's transmission connection with Niagara's Leeds 345 Kv Substation.

According to Niagara, transmission capacity to be made available to Orange and Rockland Utilities, Inc. (Rockland) will be that which is scheduled as unsupported firm power for Rockland by PASNY in accordance with the James A. Fitzpatrick Nuclear Power Plant (Fitzpatrick) contracts and agreements in effect between PASNY and Rockland.

Niagara states copies of this filing were served upon the following:

Orange and Rockland Utilities, Inc., 75 West Route 59, Spring Valley, NY 10977.

Niagara requests the agreement become effective as of July 28, 1975.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Power Commission, 825 North Capital Street NE., Washington, D.C. 20426, in accordance with Section 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before September 8, 1975. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-23325 Filed 9-2-75;8:45 am]

[Docket No. CP76-52]

NORTHERN NATURAL GAS CO.

Application

AUGUST 26, 1975.

Take notice that on August 11, 1975, Northern Natural Gas Company (Applicant), 2223 Dodge Street, Omaha, Nebraska 68102, filed in Docket No. CP76-52 an application pursuant to Section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the transportation of vaporized liquefied natural gas (LNG) for its Peoples Natural Gas Division (Peoples) and the construction and operation of certain interconnection facilities, all as more fully set forth in the application on file with the Commission and open to public inspection.

Applicant states that Peoples is planning to construct a 1.5 million Mcf equivalent LNG plant with a 50,000 Mcf per day send out approximately 4 miles south of Applicant's Ventura Compressor Station in Hancock County, Iowa. It is stated that the facility would be used for peak shaving during the heating season. Applicant further states that Peoples has requested that Applicant provide the facilities required for delivery of the natural gas volumes to the plant for the liquefaction and storage and for redelivery of vaporized LNG volumes to Applicant for transportation for Peoples.

Applicant states that by an agreement between itself and Peoples dated July 2, 1975, it has agreed to deliver upon the request of Peoples, during the period of March 27 through October 26 of each year (summer season) up to 15,000 Mcf of summer maximum daily volume to Peoples' Ventura LNG facility for liquefaction and storage. It is further stated that on days not within the summer season, Peoples may request, and subject to the approval of Applicant, have gas delivered to its Ventura LNG Plant under the same terms and conditions as gas delivered during the summer season.

Applicant states that under the agreement, Peoples would designate volumes to be delivered by Applicant to the Ventura LNG Plant during the next 24 hour period. Such deliveries on any given day would not be in excess of those that could otherwise be delivered to Peoples within its total authorized entitlement for such day, by individual billing group.

Applicant states that the volumes of natural gas diverted to the Ventura LNG Plant are to be considered remote deliveries to the billing group from which the gas was diverted and would be considered to be the first volume delivered to each billing group. The commodity charge per Mcf would be that which would have been charged for the billing group from which the gas was diverted, pursuant to the appropriate CD-1 rate schedule then in effect.

Applicant states that it would accept and transport by displacement to the designated billing groups vaporized LNG at a daily rate of up to 50,000 Mcf of winter maximum daily volume during the period of October 27 through March 26 (winter season). It is stated that on each day of the winter season, Peoples would designate the volume of vaporized LNG it would inject into Applicant's system, by volume and billing group; and such volumes would not exceed the winter maximum daily volume for the billing group. Winter season volumes delivered on any day would be considered the first volumes delivered to the billing group on that day.

It is stated that Peoples would pay Applicant a demand charge which would be determined by applying the summer or winter seasonal demand rate set forth below to the appropriate maximum daily volumes. Peoples would also pay a commodity charge which would be determined by applying the appropriate summer or winter commodity rate set forth below to the summer or winter season transport volumes as determined under the terms of the Agreement.

I. Commodity charge per Mcf:

A. Summer (April-October):

Rates to Ventura from Group:

	Cents per Mcf
A	3.47
B	0.56
C	0.69
D	----
EP	----

B. Winter (November-March) Rates from Ventura to Group:

	Cents per Mcf
A	0.36
B	3.46
C	0.60
D	2.91
EF	2.15

II. Seasonal Demand charge/Mcf:

A. Summer—$3.582×summer maximum daily volume.

B. Winter—$4.524×WMDV winter maximum daily volume.

II. The penalty charge for unauthorized summer volumes delivered to Ventura from any billing group is $2.00 per Mcf.

Applicant states that it would require piping, valves and a meter station in Hancock County, Iowa, to implement the proposed service. The estimated cost of the proposed facilities is stated to be $210,000, and it is further stated that Peoples would reimburse Applicant for the total actual cost.

It is stated that all volumes of gas transported under the proposed service would be resold by Peoples only to small volume firm customers.

Any person desiring to be heard or to make any protest with reference to said application should on or before September 18, 1975, file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Power Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-23314 Filed 9-2-75;8:45 am]

[Docket No. CP76-47]

NORTHERN NATURAL GAS CO.

Application

AUGUST 25, 1975.

Take notice that on August 8, 1975, Northern Natural Gas Company (Applicant), 2223 Dodge Street, Omaha, Nebraska 68102, filed in Docket No. CP76-47 an application pursuant to Section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the construction and operation of a 1,080 horsepower compressor unit and appurtenant facilities in Winkler County, Texas, all as more fully set forth in the application on file with the Commission and open to public inspection.

Applicant states that part of its production volumes from Lea County, New Mexico, are produced into Applicant's 16-inch pipeline between Hobbs, New Mexico, Station and Treating Plant, and the Kermit, Texas, Compressor Station. Applicant states further that the Kermit Station consists of one 9,300 horsepower turbine compressor unit which discharges into Applicant's Kermit-to-Beaver line. Applicant alleges that with the existing 9,300 h.p. compressor unit operating fully loaded certain of Applicant's downstream facilities are not being fully utilized in terms of available horsepower.

Applicant requests authorization to construct and operate a 1,080 h.p. compressor unit at its Kermit Station in addition to the existing facilities. Applicant states that under current operating conditions, with the Kermit Station fully loaded, the Seminole Texaco Compressor Station (Seminole Station) is utilizing only 77 percent of available horsepower

and Brownfield, Texas Compressor Station (Brownfield Station) is utilizing only 49 percent of available horsepower.

Applicant states that by installing the proposed compressor facilities under the following conditions existing facilities would operate more efficiently, a saving in compressor fuel would be realized, and system flexibility would be augmented:

(1) With the line to Plains Measuring Station operating at normal volume levels from Hobbs Station, the remaining volumes would move south into the suction of the proposed 1,080 HP turbine compressor. Under this condition the existing unit would be bypassed; the new unit would be utilizing 97 percent of available horsepower; Seminole Station would utilize 100 percent of its available horsepower and Brownfield Station 99 percent). Requirements for compressor fuel at these three stations are estimated to be 5230 Mcf per day.

(2) Operation of the additional compressor facilities proposed herein along with the existing compressor at Kermit Station would also allow Northern to increase the flows south to Kermit and in the Kermit to Beaver line by 16,200 MCF per day during peaking periods or when volumes flows to Plains Measuring Station are depressed. This would allow applicants to more nearly optimize production in Lea County. Under these conditions both the proposed 1,080 HP turbine compressor and the existing 9,300 HP unit would be fully utilized. Requirements for compressor fuel through Brownfield Station would be approximately 6030 Mcf per day.

It is stated that by comparisons under present operating conditions when the existing 9,300 HP turbine compressor unit is fully loaded, compressor fuel requirements through Brownfield Station are approximately 6040 Mcf per day. However, under the first stated condition efficient use of downstream compressor facilities would be attained and daily compressor fuel requirements would be reduced by approximately 810 Mcf; and, under the second stated condition additional flexibility in the Permian West Leg would be obtained while daily compressor fuel requirements would be reduced.

The estimated cost of the proposed facilities is approximately $522,000 and with respect to the financing of the proposed facilities Applicant incorporates by reference its balance sheet and income statement as contained in its FPC Form No. 2 Report on file with the Commission.

Any person desiring to be heard or to make any protest with reference to said application should on or before September 17, 1975, file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceedling or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Power Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearinig.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-23326 Filed 9-2-75;8:45 am]

[Docket No. RP74-102 (Volumetric Limitations)]

NORTHERN NATURAL GAS CO.

Extension of Procedural Dates

AUGUST 25, 1975.

On August 22, 1975, Northern Natural Gas Company filed a motion to extend procedural dates set by order issued July 7, 1975, in the above-designated matter. On August 20, 1975, an order was issued clarifying the testimony required by the order of August 7, 1975.

Upon consideration, notice is hereby given that the procedural dates in the above matter are modified as follows:

Service of Direct Testimony by Northern Natural Gas Company, September 26, 1975.
Hearing, October 15, 1975 (10 a.m. e.d.t.).

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-23327 Filed 9-2-75;8:45 am]

[Docket No. RI75-74]

DWIGHT S. RAMSAY

Withdrawal

AUGUST 26, 1975.

On August 7, 1975, Dwight S. Ramsay filed a request to withdraw the petition for special relief filed on December 9, 1974, in the above-designated matter.

Notice is hereby given that pursuant to § 1.11(d) of the Commission's Rules of Practice and Procedure, the withdrawal of the above petition shall become effective on September 8, 1975.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-23314 Filed 9-2-75;8:45 am]

[Docket No. CI75-744]

RHONDA OPERATING CO.

Withdrawal

AUGUST 26, 1975.

On August 18, 1975, Rhonda Operating Company filed a request for withdrawal of its application for certificate of public convenience and necessity, filed June 5, 1975, in the above-designated docket.

Notice is hereby given that pursuant to Section 1.11(d) of the Commission's Rules and Regulations, the withdrawal of the above applications shall become effective on September 15, 1975.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-23316 Filed 9-2-75;8:45 am]

[Docket No. E8953]

SUPERIOR WATER, LIGHT AND POWER CO.

Extension of Date of Hearing

AUGUST 25, 1975.

On August 18, 1975, Staff Counsel filed a motion to extend the date of hearing as fixed by order issued August 30, 1974, as most recently modified by notice issued July 25, 1975, in the above-designated matter.

Upon consideration, notice is hereby given that the date of hearing in the above matter is extended from August 26, 1975 to September 29, 1975.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-23329 Filed 9-2-75;8:45 am]

[Docket No. CP76-55]

TRANSCONTINENTAL GAS PIPE LINE CORP.

Application

AUGUST 26, 1975.

Take notice that on August 14, 1975, Transcontinental Gas Pipe Line Corporation (Applicant), P.O. Box 1396, Houston, Texas 77001, filed in Docket No. CP76-55 an application pursuant to Section 7(c) of the Natural Gas Act, as implemented by Section 157.7(b) of the Regulations thereunder (18 CFR 157.7 (b)), for a certificate of public convenience and necessity authorizing the construction during a twelve-month period commencing August 12, 1975, and the operation of certain natural gas purchase facilities, all as more fully set forth in the application on file with the Commission and open to public inspection.

Applicant states that the purpose of this budget-type application is to augment its ability to act with reasonable dispatch in contracting for and connecting to its pipeline system supplies of natural gas which may become available to it from various producing areas generally coextensive with its pipeline system or the systems of other pipeline companies which may be authorized to transport gas for or exchange gas with Applicant and in continuing the purchase and receipt of gas supplies which are already

connected to its system. The subject facilities would also be used to connect natural gas authorized to be sold to other pipeline companies.

The total cost of the proposed facilities would not be in excess of $12,000,000. The total cost of an onshore project would not be in excess of $1,500,000 and the total cost of an offshore project would not be in excess of $2,500,000.

Any person desiring to be heard or to make any protest with reference to said application should on or before September 19, 1975, file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Power Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-23317 Filed 9-2-75;8:45 am]

[Docket No. CP76-49]

TRANSCONTINENTAL GAS PIPE LINE CORP.

Application

AUGUST 25, 1975.

Take notice that on August 8, 1975, Transcontinental Gas Pipe Line Corporation (Applicant), P.O. Box 1396, Houston, Texas 77001, filed in Docket No. CP76-49 an application pursuant to Section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the rendition of a temporary storage service to its customers, all as more fully set forth in the application on file with the Commission and open to public inspection.

Applicant states that it has arranged with Mid Louisiana Gas Company (Mid Louisiana) to obtain approximately 2 million Mcf of storage capacity, plus an additional 500,000 Mcf of storage capacity if available in Mid Louisiana's Hester Storage Field, St. James Parish, Louisiana, pursuant to an agreement between Applicant and Mid Louisiana dated July 30, 1975. The proposed storage service would be available to Applicant for the period of August 1, 1975, through July 31, 1976, with injections of gas into storage primarily in the period of August 1, 1975, through October 31, 1975, and withdrawals primarily during the period of April 1, 1976, through July 31, 1976. Applicant states that the injections and withdrawals would be accomplished at the existing point of interconnection between Applicant and Mid Louisiana downstream of Applicant's Compressor Station No. 63 in St. James Parish, or at any other mutually acceptable point where exchange between them is authorized, subject to certain daily volumetric limitations contained in the agreement of July 30, 1975.

Applicant states that the temporary storage service would be rendered to its customers at a rate of 29.0 cents per Mcf of gas at 15.025 psia delivered to and received from Mid Louisiana, the same rate which Applicant would pay Mid Louisiana for the service. Applicant further states that no new sale of gas is proposed and that the volumes stored for Applicant's customers would be nominated out of their entitlements under Rate Schedules CD or OG.

Applicant states that the customers desiring the proposed service are as follows:

Applicant states that the customers desiring the proposed service are as follows:

Customer:	*Storage volume (Mcf at 14.7 lb/in²a)*
The Brooklyn Union Gas Co.	782,611
Consolidated Edison Co. of New York, Inc.	684,822
Long Island Lighting Co.	195,580
North Carolina Natural Gas Corp	88,128
Piedmont Natural Gas Co. Inc.	127,068
Public Service Co. of North Carolina, Inc.	117,406
UGI Corp.	9,369
United Cities Gas Co.—Georgia Division	19,617
United Cities Gas Co.—North and South Carolina Division	19,617
Total	2,044,218

Applicant states that no additional facilities are required for the proposed service. Applicant states that its Washington Storage Field is presently under development through the use of temporary compression and that during the summer of 1976, after the installation of permanent compression, substantially greater injection volumes will be required than are being injected this summer. It is said that the temporary husbanding program proposed in the instant application would permit customers effectively to carry over volumes from this summer to next thereby increasing their ability to inject volumes into the Washington Storage Field next summer and thus improving their ability to serve high priority markets commencing in the 1976-77 winter season.

Any person desiring to be heard or to make any protest with reference to said application should on or before September 15, 1975, file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Power Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-23330 Filed 9-2-75;8:45 am]

[Docket Nos. RP71-29, et al.]

UNITED GAS PIPE LINE CO.

Proposed Settlement

AUGUST 25, 1975.

Take notice that on August 14, 1975, the Administrative Law Judge in the proceeding in Docket Nos. RP71-29, et al., certified a proposed settlement to the Commission for action. The said proceeding is being conducted for the purpose of developing a plan to curtail the service rendered by United Gas Pipe Line Company (United) to its customers. The proposed settlement was submitted by United and it constitutes a scheme of allocation of United's services during the period of November 1, 1975 through October 31, 1976. The scheme of allocation is a departure from United's service obligations under the currently effective interim agreement, which departure is necessitated by a foreseeable decrease in the supply of natural gas that will be available to United during the period mentioned.

PROCEEDINGS

The proposed settlement resulted from proceedings held pursuant to a Federal Power Commission order issued on March 7, 1975 under Docket No. RP71-29. The March 7 order denied a motion for immediate modification of the existing curtailment plan and directed that further hearings in these proceedings be conducted in two phases. Phase I was to be convened immediately for the purpose of determining, in advance of the 1975-76 winter heating season, whether United's currently-effective interim curtailment program should either (1) remain in effect pending formulation of a permanent plan, or (2) be modified by the Commission pursuant to Section 5(a) of the Natural Gas Act. The March 7 order also provided for a later Phase II hearing for the purpose of formulating a permanent curtailment plan for implementation on United's system. By an "Order on Rehearing" issued May 2, 1975, the Commission ordered that a Phase III be added to the proceedings to consider matters pertaining to Section 12.3 of United's proposed tariff dealing with United's contractual liability filed on March 3, 1975 in Docket No. RP75-71.[1]

The Phase I hearing was convened on May 20, 1975 and recessed upon application of the combined parties for settlement conferences. Informed on May 30, 1975 that unanimous agreement upon a settlement in connection with an interim curtailment plan appeared unlikely but that further negotiations conducted simultaneously with the taking of testimony in connection therewith might eventually prove fruitful, the hearing on Phase I, as previously directed by the Presiding Administrative Law Judge, commenced on June 2, 1975 and continued with short interim recesses through June 24, 1975. A further settlement conference was convened on June 30, 1975 and on July 1, 1975 the Presiding Administrative Law Judge was advised by counsel for United that the majority of the parties had reached agreement on modifications to the three-category program as a settlement of the issues in Phase I.

Further hearing in connection with Phase I was thereupon suspended and the Presiding Administrative Law Judge, on request of the parties, directed that a hearing be convened on July 22, 1975 at which time testimony would be presented in support of, and in opposition to, United's proposed settlement, together with proposed variations thereto and any alternate proposals which any of the dissenting parties might wish to present. The hearing on the proposed settlement and variations thereto proceeded as scheduled and was concluded on August 4, 1975.[2]

The settlement proposal and the transcript of the hearing in connection with Phase I were certified to the Commission by the Administrative Law Judge on August 14, 1975 pursuant to Section 1.18(e) of the Rules of Practice and Procedure. The Judge's certification stated that "United's settlement proposal, concurred in by a substantial majority of the parties, constitutes the 'ameliorating' plan for the coming winter heating season."

HIGHLIGHT OF SETTLEMENT PLAN

Under the proposed settlement plan, the currently-effective interim three-category curtailment program would continue in effect subject to the following modifications:

(1) The curtailment allocations of United's customers shall be determined using the new end-use data which has been collected pursuant to the directives of the Commission in Opinion Nos. 647 and 647-A. Appendix A of the proposed plan contains an impact study showing estimated curtailments and deliveries under the proposed plan.

(2) The 3,000 Mcf per day Category III cut-off will be continued for the protection of industrial customers. However, any curtailments below that level shall be effectuated on a pro rata basis in three successive steps, to 1,500, 300, and 0 Mcf per day.

(3) Industrial feedstock requirements of United's city gate customers shall be reclassified from Category III to Category II. Only two city gate customers have reported such requirements.

(4) United's pro rata share of the industrial feedstock requirements reported by its seven pipeline customers shall also be reclassified from Category III to Category II except that no such deliveries shall be made when United must curtail below the 300 Mcf Category III step mentioned in paragraph 2 above.

(5) Industrial process gas requirements shall be protected to the extent of 3,000 Mcf per day which shall not be curtailed until all other Category III requirements have been curtailed to the 300 Mcf step mentioned in paragraph 2 above.

(6) Industrial customers may petition the Commission for a reclassification of their process gas requirements from Category III to Category II. Such a petition must specify why the process gas in question cannot be (a) converted to solid or liquid fuels or (b) satisfied through the use of supplemental gas supplies. The Commission may act on such petitions either with or without a formal hearing. The process gas requirements of five named direct industrial customers will be so reclassified based on testimony already provided in the Phase I hearing.

(7) City gate customers of United served through multiple delivery points shall be given a single base requirement for each of the two seasons reflected in Appendix A of the proposal. Provided, however (a) that the establishment of such single base requirements shall not affect existing transportation agreements between United and such customers or the Maximum Daily Delivery Obligation provisions contained in their individual service agreements with United, and (b) that said city gate customers shall be required, on a daily basis, to limit their industrial sales based on gas supplies from United to their aggregate industrial allocations.

The proposed settlement is premised on the belief that United will not have to curtail below the 1,500 Mcf Category III step. However, extremely cold weather could necessitate curtailment to or below the 300 Mcf Category III step. If curtailment below the 300 Mcf step cannot be avoided by means of storage withdrawals, the plan directs United to use its best efforts to obtain from its pipeline customers, on a voluntary basis subject to prompt repayment, the volumes of gas required to avoid such curtailment.

If the settlement is approved, United would be required to file within ten days revised tariff sheets to implement its proposal, copies of which constitute Appendix B to the settlement proposal. United would also be required to file by April 1, 1976 revised tariff sheets and an impact study setting forth United's proposed curtailment program for the winter 1976-77 and summer 1977 seasons. This would facilitate efforts toward a subsequent settlement in the event that Phase II of the proceeding is not completed prior to the 1976-77 winter season.

FILING OF COMMENTS

Any person, including the parties to this proceeding, desiring to file comments either in support of or in opposition to the proposed settlement should file such comments on or before September 9, 1975. Copies of such comments will be available in the Office of Public Information of the Federal Power Commission. Replies to the initial comments may be filed and will be accepted on or before September 23, 1975.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-23331 Filed 9-2-75;8:45 am]

[Docket No. E-9147 (Phase I)]

VIRGINIA ELECTRIC AND POWER CO.

Further Extension of Procedural Dates

AUGUST 26, 1975.

On August 14, 1975, Virginia Electric and Power Company filed a motion to extend the procedural dates fixed by order issued January 22, 1975, as most recently modified by notice issued July 9, 1975, in the above-designated matter. The motion states that the parties have been notified and have no objection.

Upon consideration, notice is hereby given that the procedural dates for all parties in the above matter are modified as follows:

PHASE I

Service of Intervenor Testimony, October 2, 1975.

[1] Docket No. RP75-71 was consolidated with RP71-29 by Commission order dated April 2, 1975.

[2] An alternate settlement proposal presented by Allied Chemical Corporation, et al., through the prepared testimony of Mr. R. A. Ransom based on the issue of "new and enlarged service" was stricken from the record by the Presiding Administrative Law Judge on motion by United inasmuch as the issue of "new and enlarged service" had previously been stated by the Commission to be more appropriate for consideration in Phase II.

Service of Company Rebuttal, October 16, 1975.
Hearing, December 16, 1975 (10 a.m. e.s.t.).

By direction of the Commission.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-23318 Filed 9-2-75;8:45 am]

FEDERAL RESERVE SYSTEM

COMMERCIAL STATE AGENCY, INC.

Order Approving Formation of a Bank Holding Company and Retention of Insurance Agency Activities

Commercial State Agency, Inc., Hokah, Minnesota ("Applicant"), has applied for the System's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company through acquisition of 81% or more of the voting shares of Commercial State Bank of Hokah, Hokah, Minnesota ("Bank"). The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Applicant has also applied, pursuant to section 4(c)(8) of the Act (12 U.S.C. 1842(c)(8)) and section 225.4(b)(2) of the Board's Regulation Y, for permission to retain its general insurance agency activities. Applicant engages in the activities of a general insurance agency on Bank premises in Hokah, Minnesota, which has a population of less than 5,000 people. Such activities have been determined by the Board in section 225.4(a)(9)(iii) of Regulation Y as permissible for bank holding companies, subject to Board approval of individual proposals in accordance with the procedures of section 225.4(b).

Notice of the application affording opportunity for interested persons to submit comments and views has been given in accordance with sections 3 and 4 of the Act (40 FR, p. 30868). The time for filing comments and views has expired, and none have been received.

Applicant, a Minnesota corporation, was organized in April 1974 for the purpose of becoming a bank holding company. Prior to April 1974 and since about 1955, Applicant had been operated as a general insurance agency proprietorship. Since numerous alternative sources of insurance services exist within the relevant market and retention of general insurance agency activities would not result in any concentration of resources, unfair competition, or conflicts of interest, competitive considerations are consistent with approval of the proposal to retain these insurance services.[1]

Bank with deposits of $4.0 million controls approximately 0.1 percent of commercial bank deposits in the state.[2] The Principal of Applicant and Bank are the same and the proposal seeks merely to change the ownership of Bank from individual holdings to a corporate form. Therefore, the proposal presents no adverse competitive effects.

Considerations relating to the financial and managerial resources and future prospects are generally satisfactory and consistent with approval, especially in view of Applicant's commitment to increase the equity capital accounts of the subsidiary bank. Considerations relating to the convenience and needs of the community involved, although consistent with approval, are not a major factor since the proposal is essentially a corporate reorganization. It is the judgment of the Federal Reserve Bank of Minneapolis that consummation of the proposed acquisition would be in the public interest and that the application should be approved.

Accordingly, pursuant to the provisions of 12 CFR 265.2(f)(22) and (32) of the Board's Rules Regarding Delegation of Authority, and on the basis of the record summarized above, the Federal Reserve Bank of Minneapolis hereby approves the application. The acquisition of Bank shall not be made (a) before the thirtieth calendar day following the effective date of this Order or (b) later than three months after the effective date of this Order or (b) later than three months after the effective date of this Order, unless such period is extended for good cause by the Board, or by the Federal Reserve Bank of Minneapolis, pursuant to delegated authority. The determination as to Applicant's insurance activities is subject to the conditions set forth in section 225.4(c) of Regulation Y and to the Board's authority to require reports by, and make examinations of, holding companies and their subsidiaries and to require modification or termination of the activities of bank holding company or any of its subsidiaries as the Board finds necessary to assure compliance with the provisions and purposes of the Act and the Board's regulations and orders issued thereunder, or to prevent evasion thereof.

By order of the Federal Reserve Bank of Minneapolis, acting under delegated authority for the Board of Governors of the Federal Reserve System, effective August 22, 1975.

[SEAL] CLEMENT A. VAN NICE,
First Vice President.

[FR Doc.75-23207 Filed 9-2-75;8:45 am]

GALLATIN BANCSHARES, INC.

Formation of Bank Holding Company

Gallatin Bancshares, Inc., Gallatin, Tennessee, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company through acquisition of 80 per cent of the voting shares of Bank of Gallatin, Gallatin, Tennessee. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the office of the Board of Governors or at the Federal Reserve Bank of Atlanta. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than October 1, 1975.

Board of Governors of the Federal Reserve System, August 27, 1975.

[SEAL] GRIFFITH L. GARWOOD,
Assistant Secretary of the Board.

[FR Doc.75-23208 Filed 9-2-75;8:45 am]

GENERAL ACCOUNTING OFFICE

REGULATORY REPORTS REVIEW

Receipt of Report Proposals

The following requests for clearance of reports intended for use in collecting information from the public were received by the Regulatory Reports Review Staff, GAO, on August 21, 1975. See 44 U.S.C. 3512 (c) & (d). The purpose of publishing this list in the FEDERAL REGISTER is to inform the public of such receipt.

The list includes the title of each request received; the name of the agency sponsoring the proposed collection of information; the agency form number, if applicable; and the frequency with which the information is proposed to be collected.

Written comments on the proposed ICC forms are invited from all interested persons, organizations, public interest groups, and affected businesses. Because of the limited amount of time GAO has to review the proposed forms, comments (in triplicate) must be received on or before September 22, 1975, and should be addressed to Mr. Carl F. Bogar, Assistant Director, Office of Special Programs, United States General Accounting Office, Room 5216, 425 I Street, NW., Washington, D.C. 20548.

Further information may be obtained from Patsy J. Stuart of the Regulatory Reports Review Staff, 202-376-5425.

INTERSTATE COMMERCE COMMISSION

Request for extension no change approval of cost study forms:

ACC-35—Form 2 of Highway Form A.

ACC-35A—Listing of Multiple Truckload Shipments.

ACC-37 & ACC-97—Form 4 of Highway Form A Pickup and Delivery Manifest and Trip Listing Sheet.

ACC-38 & ACC-98—Form 7 of Highway Form A Intercity Trip Report and Trip Listing.

ACC-39—Form 10 of Highway Form A Platform Handling on All Intercity Traffic.

ACC-40—Form 11—Analysis of Peddle Trip Operations.

These forms are used to obtain the data necessary to determine motor carrier costs throughout all territories of the United States for a particular year. Approximately 250 "Instruction 27" carriers are studied each year. Data developed through regional cost studies are used by

[1] Applicant engages in the sale of various types of general insurance and offers credit life and credit accident and health insurance to credit customers of Bank. All income generated from the sale of credit life and credit accident and health insurance to Bank's credit customers will accrue directly to the Bank beginning January 1, 1976.

[2] All banking data are as of December 1974.

the carriers, by the Commission, and by others in determining and evaluating motor carrier operating costs for ratemaking and related purposes. The average per response time required to complete the above forms is a total of 23 hours.

CARL F. BOGAR,
Assistant Director,
Regulatory Reports Review.

[FR Doc.75-23271 Filed 9-2-75;8:45 am]

NUCLEAR REGULATORY COMMISSION

[Docket No. 50-10]

COMMONWEALTH EDISON CO.

Proposed Issuance of Amendment to Facility Operating License

The Nuclear Regulatory Commission (the Commission) is considering the issuance of an amendment to Facility Operating License No. DPR-2 issued to the Commonwealth Edison Company (the licensee) for operation of the Dresden Nuclear Power Station Unit 1 (the facility), a boiling water reactor located in Grundy County, Illinois, and currently authorized for operation at power levels up to 700 MWt.

In accordance with the licensee's application for a license amendment dated July 31, 1975, the amendment would incorporate operating limits in the Technical Specifications based upon an evaluation of ECCS performance calculated in accordance with an acceptable evaluation model that conforms to the requirements of the Commission's Acceptance Criteria for Emergency Core Cooling Systems for Light Water Nuclear Power Reactors set forth in 10 CFR Section 50.46.

Prior to issuance of the proposed license amendment, the Commission will have made the findings required by the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations.

By October 3, 1975, the licensee may file a request for a hearing and any person whose interest may be affected by this proceeding may file a request for a hearing in the form of a petition for leave to intervene with respect to the issuance of the amendment to the subject facility operating license. Petitions for leave to intervene must be filed under oath or affirmation in accordance with the provisions of Section 2.714 of 10 CFR Part 2 of the Commission's regulations. A petition for leave to intervene must set forth the interest of the petitioner in the proceeding, how that interest may be affected by the results of the proceeding, and the petitioner's contentions with respect to the proposed licensing action. Such petitions must be filed in accordance with the provisions of this FEDERAL REGISTER Notice and Section 2.714, and must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Section, by the above date. A copy of the petition and/or request for a hearing should be sent to the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 and to John W. Rowe, Esquire of Isham, Lincoln & Beale, One First National Plaza, Chicago, Illinois 60670, the attorney for the licensee.

A petition for leave to intervene must be accompanied by a supporting affidavit which identifies the specific aspect or aspects of the proceeding as to which intervention is desired and specifies with particularity the facts on which the petitioner relies as to both his interest and his contentions with regard to each aspect on which intervention is requested. Petitions stating contentions relating only to matters outside the Commission's jurisdiction will be denied.

All petitions will be acted upon by the Commission or licensing board designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel. Timely petitions will be considered to determine whether a hearing should be noticed or another appropriate order issued regarding the disposition of the petitions.

In the event that a hearing is held and a person is permitted to intervene, he becomes a party to the proceeding and has a right to participate fully in the conduct of the hearing. For example, he may present evidence and examine and cross-examine witnesses.

For further details with respect to this action, see the application for amendment dated July 31, 1975, which is available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C. 20555. The license amendment and the Safety Evaluation, when issued, may be inspected at the above location, and a copy may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Reactor Licensing.

Dated at Bethesda, Maryland, this 25th day of August 1975.

For the Nuclear Regulatory Commission.

DENNIS L. ZIEMANN,
Chief, Operating Reactors Branch No. 2, Division of Reactor Licensing.

[FR Doc.75-23261 Filed 9-2-75;8:45 am]

[Docket No. 50-369 and 50-370]

DUKE POWER CO. (WILLIAM B. McGUIRE NUCLEAR STATION, UNITS 1 AND 2)

Notice of Issuance of Amendments to Construction Permits

Notice is hereby given that pursuant to an Order dated April 23, 1975 by the Atomic Safety and Licensing Board, the U.S. Nuclear Regulatory Commission has issued Amendment No. 1 to Construction Permit No. CPPR-83 and Amendment No. 1 to Construction Permit No. CPPR-84, which were isued to Duke Power Company for construction of William B. McGuire Nuclear Station, Units 1 and 2, located in Mecklenburg County, North Carolina.

The Board's Order authorizes the addition of antitrust conditions to the construction permits. At the time Construction Permits Nos. CPPR-83 and CPPR-84 were issued, the antitrust proceeding was in progress.

The Executive Director for Operations has found that the provisions of the amendments comply with the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations published in 10 CFR Chapter I and has concluded that the issuance of the amendments will not be inimical to the common defense and security or to the health and safety of the public, and does not involve a significant hazards consideration.

A copy of the Order, dated April 23, 1975, the construction permits, the amendments, and other related documents are available for public inspection at the Commission's Public Document Room, 1717 H Street, N.W., Washington, D.C. and at the Public Library of Charlotte and Mecklenburg County, 310 North Tryon Street, Charlotte, North Carolina. Single copies of the amendments may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Reactor Licensing.

Dated at Bethesda, Maryland, this 22nd day of August 1975.

For the Nuclear Regulatory Commission.

A. W. DROMERICK,
Acting Chief, Light Water Reactors, Project Branch 1-1, Division of Reactor Licensing.

[FR Doc.75-23262 Filed 9-2-75;8:45 am]

[Docket No. 50-538]

MEMPHIS STATE UNIVERSITY

Receipt of Application for Construction Permit and Facility Operating License

Notice is hereby given that the Nuclear Regulatory Commission (the Commission) has received an application from Memphis State University dated April 11, 1975, filed pursuant to Section 104c of the Atomic Energy Act, as amended, for the necessary licenses to construct and operate an AGN-201 (Serial No. 108) nuclear reactor. The reactor is to be constructed on Memphis State's South Campus located in Shelby County, Tennessee, and is proposed for operation at a power level of 100 milliwatts for educational training and research.

A copy of the application is available for public inspection at the Commission's Public Document Room, 1717 H Street N.W., Washington, D.C.

Dated at Bethesda, Maryland, this 25th day of August 1975.

For the Nuclear Regulatory Commission.

DENNIS L. ZIEMANN,
Chief, Operating Reactors Branch No. 2, Division of Reactor Licensing.

[FR Doc.75-23263 Filed 9-2-75;8:45 am]

[Docket No. 50-245]

NORTHEAST NUCLEAR ENERGY CO., ET AL.

Issuance of Amendment to Facility Operating License

In the matter of Northeast Nuclear Energy Co., the Hartford Electric Light Co., Western Massachusetts Electric Co., Connecticut Light and Power Co.

Notice is hereby given that the U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 11 to Facility Operating License No. DPR-21 issued to Northeast Nuclear Energy Company, which revised Technical Specifications for operation of the Millstone Nuclear Power Station, Unit 1, located in Waterford, Connecticut. The amendment is effective as of its date of issuance.

The amendment modifies the Technical Specifications to clarify the maximum permissible reactor coolant temperature change rate.

The application for the amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment. Prior public notice of this amendment is not required since the amendment does not involve a significant hazards consideration.

For further details with respect to this action, see (1) the application for amendment dated July 21, 1975, (2) Amendment No. 11 to License No. DPR-21, with Change No. 24, and (3) the Commission's related Safety Evaluation. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street, N.W., Washington, D.C. and at the Waterford Public Library, Rope Ferry Road, Route 156, Waterford, Connecticut 06385.

A copy of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Reactor Licensing.

Dated at Bethesda, Maryland, this 25th day of August 1975.

For the Nuclear Regulatory Commission.

WALTER A. PAULSON,
Acting Chief Operating Reactors Branch No. 3, Division of Reactor Licensing.

[FR Doc.75-23264 Filed 9-2-75;8:45 am]

[Docket No. 50-245]

NORTHEAST NUCLEAR ENERGY CO., ET AL.

Issuance of Amendment to Facility Operating License

In the matter of Northeast Nuclear Energy Co., the Hartford Electric Light Co., Western Massachusetts Electric Co., Connecticut Light and Power Co.

Notice is hereby given that the U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 10 to Facility Operating License No. DPR-21 issued to Northeast Nuclear Energy Company, Connecticut Light and Power Company, The Hartford Electric Light Company, and Western Massachusetts Electric Company ("the licensees"). Facility Operating License No. DPR-21 authorizes the operation of the Millstone Nuclear Power Station, Unit No. 1, located in Waterford, Connecticut. The amendment is effective as of its date of issuance.

The amendment requires operability and surveillance of hydraulic snubbers required to protect the primary coolant system and all other safety related systems and components in accordance with the licensee's request dated December 23, 1974.

The application for the amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

For further details with respect to this action, see (1) the application for amendment dated December 23, 1974, (2) Amendment No. 10 to License No. DPR-21, with Change No. 23 and (3) the Commission's related Safety Evaluation. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street, N.W., Washington, D.C. and at the Waterford Public Library, Rope Ferry Road, Route 156, Waterford, Connecticut 06385.

A copy of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Reactor Licensing.

Dated at Bethesda, Maryland, this 25th day of August 1975.

For the Nuclear Regulatory Commission.

WALTER A. PAULSON,
Acting Chief, Operating Reactors Branch No. 3, Division of Reactor Licensing.

[FR Doc.75-23265 Filed 9-2-75;8:45 am]

[Docket No. 50-263]

NORTHERN STATES POWER CO.

Proposed Issuance of Amendment to Facility Operating License

The Nuclear Regulatory Commission (the Commission) is considering the issuance of an amendment to Facility Operating License No. DPR-22 issued to the Northern States Power Company (the licensee) for operation of the Monticello Nuclear Generating Plant (the facility), a boiling water reactor, located in Wright County, Minnesota and currently authorized for operation at power levels up to 1670 MWt.

In accordance with the licensee's application for a license amendment dated August 4, 1975, and filing dated July 9, 1975, the amendment would modify operating limits in the Technical Specifications based upon an evaluation of ECCS performance calculated in accordance with an acceptable evaluation model that conforms to the requirements of the Commission's regulations in 10 CFR Section 50.46. The amendment would modify various limits established in accordance with the Commission's Interim Acceptance Criteria, and would, with respect to the Monticello Nuclear Generating Plant, terminate the further restrictions imposed by the Commission's December 27, 1974 Order for Modification of License, and would impose instead, limitations established in accordance with the Commission's Acceptance Criteria for Emergency Core Cooling Systems for Light Water Nuclear Power Reactors, 10 CFR Section 50.46. The amendment would also incorporate Technical Specification changes associated with operation of the facility with additional 8x8 fuel assemblies.

Prior to issuance of the proposed license amendment, the Commission will have made the findings required by the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations.

By October 3, 1975, the licensee may file a request for a hearing and any person whose interest may be affected by this proceeding may file a request for a hearing in the form of a petition for leave to intervene with respect to the issuance of the amendment to the subject facility operating license. Petitions for leave to intervene must be filed under oath or affirmation in accordance with the provisions of Section 2.714 of 10 CFR Part 2 of the Commission's regulations. A petition for leave to intervene must set forth the interest of the petitioner in the proceeding, how that interest may be affected by the results of the proceeding, and the petitioner's contentions with respect to the proposed licensing action. Such petitions must be filed in accordance with the provisions of this FEDERAL REGISTER Notice and Section 2.714, and must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Section, by the above date. A copy of the petition and/or request for a hearing should be sent to the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 and to Gerald Charnoff, Esquire of Shaw, Pittman, Potts and Trowbridge, 910 17th Street NW., Washington, D.C. 20006, the attorney for the licensee.

A petition for leave to intervene must be accompanied by a supporting affidavit which identifies the specific aspect or aspects of the proceeding as to which intervention is desired and specifies with particularity the facts on which the petitioner relies as to both his interest and his contentions with regard to each aspect on which intervention is requested.

Petitions stating contentions relating only to matters outside the Commission's jurisdiction will be denied.

All petitions will be acted upon by the Commission or licensing board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel. Timely petitions will be considered to determine whether a hearing should be noticed or another appropriate order issued regarding the disposition of the petitions.

In the event that a hearing is held and a person is permitted to intervene, he becomes a party to the proceeding and has a right to participate fully in the conduct of the hearing. For example, he may present evidence and examine and cross-examine witnesses.

For further details with respect to this action, see (1) the application for amendment dated August 4, 1975, and the filing dated July 9, 1975, and (2) the Commission's Order for Modification of License and the documents referred to in the Order dated December 27, 1974 published in the FEDERAL REGISTER on January 9, 1975 (40 FR 1769), which are available for public inspection at the Commission's Public Document Room, 1717 H Street NW., Washington, D.C., and at The Environmental Conservation Library, Minneapolis Public Library, 300 Nicollet Mall, Minneapolis, Minnesota 55401. The license amendment and the Safety Evaluation, when issued may be inspected at the above locations, and a copy may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Reactor Licensing.

Dated at Bethesda, Maryland, this 25th day of August 1975.

For the Nuclear Regulatory Commission.

DENNIS L. ZIEMANN,
Chief, Operating Reactors Branch No. 2, Division of Reactor Licensing.

[FR Doc.75-23266 Filed 9-2-75;8:45 am]

REGULATORY GUIDE

Issuance and Availability

The Nuclear Regulatory Commission has issued a new guide in its Regulatory Guide Series. This series has been developed to describe and make available to the public methods acceptable to the NRC staff of implementing specific parts of the Commission's regulations and, in some cases, to delineate techniques used by the staff in evaluating specific problems or postulated accidents and to provide guidance to applicants concerning certain of the information needed by the staff in its review of applications for permits and licenses.

Regulatory Guide 5.33, "Qualification, Calibration, and Error Estimation Methods for Nondestructive Assay," describes methods and procedures acceptable to the NRC staff for meeting certain of the Commission's requirements as they relate to the use of nondestructive assay. This guide endorses ANSI Standard N15.20–1975, "Guide to Calibrating Nondestructive Assay Systems."

Comments and suggestions in connection with (1) items for inclusion in guides currently being developed (listed below) or (2) improvements in all published guides are encouraged at any time. Public comments on Regulatory Guide 5.53 will, however, be particularly useful in evaluating the need for an early revision if received by October 31, 1975.

Comments should be sent to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Section.

Regulatory Guides are available for inspection at the Commission's Public Document Room, 1717 H Street NW., Washington, D.C. Requests for single copies of issued guides (which may be reproduced) or for placement on an automatic distribution list for single copies of future guides should be made in writing to the Director, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Telephone requests cannot be accommodated. Regulatory Guides are not copyrighted and Commission approval is not required to reproduce them.

Other Division 5 Regulatory Guides currently being developed include the following:

Mass Calibration Techniques for Nuclear Material Control.
Protection of Nuclear Power Plants Against Industrial Sabotage.
Measurement Control Program for Special Nuclear Material Control and Accounting.
Monitoring Transfers of Special Nuclear Material.
Considerations for Determining the Systematic Error of Special Nuclear Material Accounting Measurement.
Interior Intrusion Alarm Systems.
Preparation of Uranyl Nitrate Solution as a Working Standard.
Shipping and Receiving Control of Special Nuclear Materials.
Barrier Design and Placement.
Internal Security Audit Procedures.
Nondestructive Assay of Plutonium-Bearing Fuel Rods.
Training and Qualifying Personnel for Performing Measurement Associated with the Control and Accounting of Special Nuclear Material.
Auditing of Measurement Control Program.
Reconciliation of Statistically Significant Shipper-Receiver Differences.
Prior Measurement Verification.
Verification of Prior Measurements by NDA.
Nondestructive Assay of High-Enrichment Uranium Scrap by Active Neutron Interrogation.
Control and Accounting for Highly Enriched Uranium in Waste.
Considerations for Determining the Random Error of Special Nuclear Material Accounting Measurement.
Use of Closed Circuit TV for Area Surveillance.
Preparation of Working Calibration and Test Materials for Analytical Laboratory Measurement Control Programs—Part I: Plutonium Nitrate Solutions.
Preparation of Working Calibration and Test Materials for Analytical Laboratory Measurement Control Programs—Plutonium Oxide.

(5 U.S.C. 552(a)).

Dated at Rockville, Maryland, this 25th day of August 1975.

For the Nuclear Regulatory Commission.

ROBERT B. MINOGUE,
Director, Office of Standards Development.

[FR Doc.75-23269 Filed 9-2-75;8:45 am]

[Docket No. STN 50-545]

WESTINGHOUSE ELECTRIC CORP.

Receipt of Standard Safety Analysis Report

Westinghouse Electric Corporation, in response to Option No. 1 of the policy statement of the Nuclear Regulatory Commission (the Commission) entitled "Methods of Achieving Standardization of Nuclear Power Plants", issued March 5, 1973, and pursuant to Appendix 0 to 10 CFR, Part 50, has filed with the Commission an eight-volume document entitled "Westinghouse Reference Safety Analysis Report 3S", (RESAR–3S), which was docketed on July 31, 1975. The tendered application for RESAR–3S was received on June 30, 1975. Following a preliminary review for completeness, the application was found to be acceptable for docketing. Docket No. STN 50–545 has been assigned to RESAR–3S and should be referenced in any correspondence relating thereto.

RESAR–3S has been submitted in accordance with the "reference system" option wherein an entire facility design or major fractions of it can be identified as a standard design to be used in multiple applications. RESAR–3S describes and analyzes a four-loop pressurized water reactor nuclear steam supply system (NSSS) with auxiliary and safety systems. The reactor is designed for initial operation at a rated core thermal power level of 3411 megawatts.

On March 11, 1974, the Commission docketed for review an application filed by Westinghouse Electric Corporation for its Reference Safety Analysis Report, RESAR–41. The RESAR–3S NSSS is in many respects similar to the RESAR–41 NSSS, with the principal exceptions being the reactor core size and the emergency core cooling system design. In addition, the RESAR–41 application is for a core thermal power level of 3800 megawatts, whereas the RESAR–3S application is for a core thermal power level of 3411 megawatts.

When its review of RESAR–3S is complete, the Commission's staff will prepare and publish a Safety Evaluation Report documenting the results of the review. In addition, RESAR–3S will be referred to the Advisory Committee on Reactor Safeguards (ACRS) for its review and a report thereon. Copies of the Safety Evaluation Report and the ACRS report will be made available to the pub-

lic. A notice relating to the availability of these documents will be published in the FEDERAL REGISTER.

All interested persons who desire to submit written comments for consideration by the staff and ACRS during their review of RESAR-3S should send them to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Section by October 3, 1975.

A copy of the RESAR-3S Reference Safety Analysis Report is available for public inspection at the Commission's Public Document Room, 1717 H Street, Washington, D.C. 20555. When available, the Safety Evaluation Report and the ACRS report will be made available for inspection by the public at the Commission's Public Document Room.

Dated at Bethesda, Maryland, this 27th day of August 1975.

For the Nuclear Regulatory Commission.

D. B. VASSALLO,
Chief, Light Water Reactors, Project Branch 1-1, Division of Reactor Licensing.

[FR Doc.75-23368 Filed 9-2-75;8:45 am]

OFFICE OF MANAGEMENT AND BUDGET

CLEARANCE OF REPORTS

List of Requests

The following is a list of requests for clearance of reports intended for use in collecting information from the public received by the Office of Management and Budget on 08/28/75 (44 USC 3509). The purpose of publishing this list in the FEDERAL REGISTER is to inform the public.

The list includes the title of each request received; the name of the agency sponsoring the proposed collection of information; the agency form number(s), if applicable; the frequency with which the information is proposed to be collected; the name of the reviewer or reviewing division within OMB, and an indication of who will be the respondents to the proposed collection.

Requests for extension which appear to raise no significant issues are to be approved after brief notice through this release.

Further information about the items on this daily list may be obtained from the Clearance Office, Office of Management and Budget Washington, D.C. 20503, (202-395-4529), or from the reviewer listed.

NEW FORMS

NATIONAL SCIENCE FOUNDATION

Qualifications of reviewers of NSF Projects—Reviewers Information, NSF 428, or occasion, individuals, Lowry, R. L., 395-3772.

DEPARTMENT OF AGRICULTURE

Economic Research Service: Milk buying and merchandising programs of food chains in the southern region, single-time, retail food chains, Lowry, R. L., 395-3772.

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Secretary, Safety and Security Survey, Other (see SF-83), public housing residents in TPP projects, Community and Veterans Affairs Division, George Hall, 395-3532.

REVISIONS

VETERANS ADMINISTRATION

Monthly Certification of Flight Training, 22-6553C, monthly, veteran student and flight schools, Caywood, D. P., 395-3443.

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service: Study to assess the nutritional quality and microbiological safety of various school food delivery systems, single-time, school food service managers, Human Resources Division, Lowry, R. L., 395-3532.

EXTENSIONS

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Office of Education: Student Loan Application Supplement OE1260, other (see SF-83), student applicants, IHE's and lenders, Marsha Traynham, 395-4529.

PHILLIP D. LARSEN,
Budget and Management Officer.

[FR Doc.75-23414 Filed 9-2-75;8:45 am]

CLEARANCE OF REPORTS

List of Requests

The following is a list of requests for clearance of reports intended for use in collecting information from the public received by the Office of Management and Budget on August 27, 1975 (44 USC 3509). The purpose of publishing this list in the FEDERAL REGISTER is to inform the public.

The list includes the title of each request received; the name of the agency sponsoring the proposed collection of information; the agency form number(s), if applicable; the frequency with which the information is proposed to be collected; the name of the reviewer or reviewing division within OMB, and an indication of who will be the respondents to the proposed collection.

Requests for extension which appear to raise no significant issues are to be approved after brief notice through this release.

Further information about the items on this daily list may be obtained from the Clearance Office, Office of Management and Budget, Washington, D.C. 20503, (202-395-4529), or from the reviewer listed.

NEW FORMS

U.S. CIVIL SERVICE COMMISSION

Physical Science Technician Supplemental Qualification Statement, on occasion, job applicants, Caywood, D. P., 395-3443.

Supplemental Questions for Policemen (Hospital), SLPMS 322, on occasion, eligibiles, Caywood, D. P., 395-3443.

Geographic Availability Inquiry, SLPMS 316, on occasion, applicants for civil service employment, Caywood, D. P., 395-3443.

Availability Statement for FPO, Atlanta Region, MAAO-83, on occasion, applicants, Caywood, D. P., 395-3443.

Application for Worker-Trainee, DAX 6.3, on occasion, job applicants, Caywood, D. P., 395-3443.

Interest Questionnaire for Worker-Trainee, DAX 6.3(A)(D), on occasion, applicants, Caywood, D. P., 395-3443.

Education and Experience Questionnaire for Junior Federal Assistant, DH-606, on occasion, applicants for JFA examination, Caywood, D. P., 395-3443.

Work Location for Agricultural and Biological Science Positions (Atlanta Region), RAAO-9, on occasion, applicants, Caywood, D. P., 395-3443.

Geographic Availability (South Georgia), MAAO-38, on occasion, applicants, Caywood, D. P., 395-3443.

ENVIRONMENTAL PROTECTION AGENCY

Family of forms for the St. Louis human morbidity study, other (see SF-83), family units, Collins, L., 395-5867.

Oxidant air pollution and chromosomal aberration in USC students, single-time, University of Southern California sophomores, Dick Eisinger, 395-6140.

DEPARTMENT OF AGRICULTURE

Extension Service: Homemaker progression interview—expanded food and nutrition education program, single-time, participant in EFNEP, Natural Resources Division, Lowry, R. L., 395-6827.

Food and Nutrition Service:

Food Stamp Program Corrective Action Plan, FNS-321, semi-annually, State Agencies, Human Resources Division, Lowry, R. L., 395-3532.

Food Stamp Program—Semiannual Consolidated Report, Small Project Area Reviews, FNS-323, semi-annually, State agencies, Human Resources Division, Lowry, R. L., 395-3532.

DEPARTMENT OF COMMERCE

Bureau of East-West Trade: Report of Restrictive Trade Practice or Boycott Request That Discriminates Against U.S. Citizens or Firms, DIB-630P, on occasion, U.S. exporters, freight forwarders, shippers, Strasser, A., 395-5867.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Office of the Secretary:

Analyze Obstacles to Obtaining Home Health Care and Recommend Regional HEW Strategies, OS-49-75, single-time, staff of agencies in six counties, Human Resources Division, Dick Eisinger, 395-3532.

Wives Questionnaire—Michigan Longitudinal Study, OS-38-75, single-time, wives in Michigan longitudinal study, Sunderhauf, M. B., 395-6140.

DEPARTMENT OF JUSTICE

Departmental and Other LEEP Evaluation Questionnaire, LEEP-30, single-time, student recipient of LEEP funds, George Hall, 395-6140.

DEPARTMENT OF TRANSPORTATION

Departmental and other airtrans rider attitude survey, single-time, passengers on airtrans system, Dallas/Ft. Worth Airport, Strasser, A., 395-5867.

REVISIONS

DEPARTMENT OF COMMERCE

Bureau of East-West Trade: Report of Restrictive Trade Practice or Boycott Request, DIB-621P, quarterly, U.S. exporters, freight forwarders, shippers, Strasser, A., 395-5867.

DEPARTMENT OF HEALTH, EDUCATION AND WELFARE

Office of Education: Application for Faculty Research Abroad, OE 7628, on occasion, faculty members of institutions of postsecondary education, Lowry, R. L., 395-3772.

Office of the Secretary:

Health Insurance Study, Medical History, Form A, OS-48-75-C, on occasion, enrolled households in Seattle and subsequent sites, Caywood, D. P., 395-3443.

Health Insurance Study, OS-48-75A, on occasion, individuals, Caywood, D. P., 395-3443.

EXTENSIONS

AGENCY FOR INTERNATIONAL DEVELOPMENT

Report of Exports—Schedule C-200 (for Voluntary Aid Programs), 1550-5, semi-annually, registered voluntary agencies, Harry B. Sheftel.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service: Report of Strawberries Received for Freezing (in Plants During the Processing Season), FV-498-1, weekly, berry and asparagus processors, Harry B. Sheftel.

DEPARTMENT OF COMMERCE

Bureau of Census: Sales of Lubricating Oils and Greases 1973, MA 29C, other (see SF-83), Refiners, compounders, and selected marketers, Harry B. Sheftel.

Mining Machinery Form and Reference List, MA-35P, annually, mining machinery mfgrs., Harry B. Sheftel.

PHILLIP D. LARSEN,
Budget and Management Officer.

[FR Doc.75-23415 Filed 9-2-75;8:45 am]

SECURITIES AND EXCHANGE COMMISSION

[File No. 500-1]

CANADIAN JAVELIN LTD.

Suspension of Trading

AUGUST 26, 1975.

In the matter of trading in securities of Canadian Javelin, Ltd. File No. 500-1.

The common stock of Canadian Javelin, Ltd., being traded on the American Stock Exchange pursuant to provisions of the Securities Exchange Act of 1934 and all other securities of Canadian Javelin, Ltd., being traded otherwise than on a national securities exchange; and

It appearing to the Securities and Exchange Commission that the summary suspension of trading in such securities on such exchange and otherwise than on a national securities exchange is required in the public interest and for the protection of investors;

Therefore, pursuant to Section 12(k) of the Securities Exchange Act of 1934, trading in such securities on the above mentioned exchange and otherwise than on a national securities exchange is suspended, for the period from August 27, 1975 through September 5, 1975.

By the Commission.

[SEAL] GEORGE A. FITZSIMMONS,
Secretary.

[FR Doc.75-23257 Filed 9-2-75;8:45 am]

[812-3802]

SOUTHEASTERN CAPITAL CORP.

Filing of Application

AUGUST 26, 1975.

In the matter of Southeastern Capital Corp., 505 Northcreek, 3715 Northside Parkway, N.W., Atlanta, Georgia 30327.

Notice is hereby given that Southeastern Capital Corporation ("Applicant"), registered under the Investment Company Act of 1940 ("Act") as a closed-end, non-diversified, management investment company, filed an application on April 29, 1975, and amendments thereto on July 21 and 24, 1975, pursuant to Section 17(b) of the Act for an order of the Commission exempting from the provisions of Section 17(a) of the Act the proposed merger of Applicant into Phoenix, Inc. ("Phoenix" or the "Surviving Corporation"), and pursuant to Section 6(c) of the Act for an order of the Commission modifying a prior order of the Commission entered September 9, 1970 (Investment Company Act Release No. 6181) to provide that the conditions imposed upon Applicant by such order may be satisfied by the Surviving Corporation as successor by merger to Applicant. All interested persons are referred to the application on file with the Commission for a statement of the representations contained therein, which are summarized below.

As of March 31, 1975, Applicant, a Tennessee corporation listed on the American Stock Exchange had 706,073 shares of its common stock issued and outstanding and had, on a consolidated basis with its wholly-owned subsidiary, Southeastern Capital Small Business Investment Corporation ("SCSBIC"), total net assets of approximately $9,772,050. As of April 30, 1975, Phoenix, a Georgia corporation and a personal holding company, had 72,228 shares of its common stock issued and outstanding and total net assets of approximately $3,059,578. Phoenix holds beneficially 189,263 or 26.81% of the shares of Applicant which amount represents a controlling interest in Applicant's outstanding voting securities. Mr. C. Edward Hansell, Chairman of the Board of both Applicant and Phoenix, owns beneficially 18,952 shares of Phoenix representing 26.24%, of its outstanding voting securities.

Applicant and Phoenix have entered into an Agreement and Plan of Reorganization dated April 23, 1975 and amended July 14, 1975 (the "Agreement") providing for the merger of Applicant into Phoenix which is to be the surviving corporation. The Agreement further provides that, on and after the merger date, the name of the Surviving Corporation will be changed to "Southeastern Capital Corporation", the Surviving Corporation will adopt new Articles of Incorporation and By-Laws substantially similar to those of the Applicant in effect prior to the merger, and the officers and directors of Applicant will become the officers and directors of the Surviving Corporation. Upon consummation of the proposed merger, the Surviving Corporation will register as an investment company under the Act.

Upon the merger date, each issued and outstanding share of Applicant will be converted into one share of the Surviving Corporation and each issued and outstanding share of Phoenix will be converted into .6 of a share of the Surviving Corporation. Phoenix proposed to make a five for one stock split of its shares in order that sufficient shares will be available for the proposed merger. The Agreement has been unanimously approved by the respective Boards of Directors of Applicant and Phoenix. Consummation of the proposed merger is conditioned on (1) the approval by a majority in number of the shareholders of both Phoenix and Applicant as well as by the vote required under the laws of Tennessee and Georgia, (2) the receipt of a tax ruling from the Internal Revenue Service that the proposed merger will constitute a tax-free reorganization and that no gain or loss will be recognized by either Phoenix or Applicant or their shareholders as a result of the merger, (3) the effectiveness of an S-14 registration statement filed by Phoenix under the Securities Act of 1933, (4) the satisfaction of the listing requirements of the American Stock Exchange for the shares of the Surviving Corporation, and (5) the receipt of the order requested by this application. The Applicant and Phoenix intend to consummate the proposed merger on the first month-end following the satisfaction of all the conditions precedent.

Section 17(a). Applicant states that, through Phoenix's controlling interest in the shares of Applicant, each company is an "affiliated person" of the other under the definition of "affiliated person" set forth in Section 2(a)(3) of the Act.

Section 17(a) of the Act, in pertinent part, provides that it is unlawful for any affiliated person of a registered investment company knowingly to sell or to purchase from such registered investment company any security or other property except securities of which the investment company is the issuer. Pursuant to Section 17(b) of the Act, the Commission, upon application, may grant an exemption from such prohibition after finding that the terms of the proposed transaction, including the consideration to be paid or received, are fair and reasonable and do not involve overreaching on the part of any person concerned and that the proposed transaction is consistent with the policy of each registered investment company concerned and the general purposes of the Act.

Other than its controlling interest in Applicant the only other significant asset of Phoenix is a controlling position (38.6%) in the shares of The First National Bank of McDonough, McDonough, Georgia ("McDonough Bank").

Applicant states that the exchange ratio to be used in the proposed merger was determined by the parties through arms-length bargaining based upon the total net asset values of the shares of Phoenix and the Applicant. In June of 1974, Applicant commissioned two independent investment banking firms, Robinson-Humphrey Company, Inc. ("Robinson-Humphrey") and Reynolds Securities, Inc. ("Reynolds"), to analyze the parties to the proposed merger and determine an appropriate exchange rate. Robinson-Humphrey arrived at an exchange ratio of 3.0111 shares of Applicant for each share of Phoenix based on adjusted net asset values per share of $14.03 for Applicant and $42.24 for Phoenix; Reynolds arrived at an exchange ratio of 2.9862 shares of Applicant for each share of Phoenix based on adjusted net asset values of $13.78 for Applicant and $41.15 for Phoenix. In July of 1975, Applicant commissioned and received from Robinson-Humphrey and Reynolds new appraisals of the respective values of Applicant's shares and Phoenix's shares based on current financials. Robinson-Humphrey determined an exchange ratio of 3.1973 shares of Applicant for each share of Phoenix to be appropriate based upon adjusted net asset values per share of $13.84 for Applicant and $44.25 for Phoenix. Reynolds determined an exchange ratio of 2.9487 shares of Applicant for each share of Phoenix to be fair based upon adjusted net asset values per share of $13.84 for Applicant and $40.81 for Phoenix.

Applicant represents that after the first independent appraisal the respective Boards of Directors of Applicant and Phoenix arrived at an exchange ratio based on the Robinson-Humphrey and Reynolds appraisals of three shares of Applicant for each share of Phoenix. Following the second independent appraisal, the Board of Directors of Applicant and Phoenix unanimously resolved to reaffirm the 3 to 1 exchange ratio. The exchange ratio would be reduced to 1 share of Applicant for six tenths of a share of Phoenix in light of the proposed 5 for 1 stock split of Phoenix's shares.

It is submitted that the proposed merger is consistent with the policies of the Applicant since the Surviving Corporation will adopt the investment policies of Applicant on the merger date. Applicant seeks as its primary investment objective the long-term growth of capital with income secondary.

Applicant asserts that the shares of the McDonough Bank presently held by Phoenix represents an attractive opportunity for growth and are consistent with Applicant's investment policies. Applicant has had, and the Surviving Corporation will have, a policy against investing in companies for the purpose of exercising control. It is stated that, if the proposed merger is consummated, the Surviving Corporation does not intend to exercise control over the McDonough Bank and, in fact, would be under an irrevocable declaration under the Bank Holding Company Act entered into by Phoenix with the Federal Reserve Board to divest control, i.e., reduce ownership to less than 25%, of the McDonough Bank by January 1, 1981.

Applicant asserts that its shareholders will benefit from the proposed merger by the elimination of expenses incurred in maintaining a Tennessee domicile when Applicant's only place of business is in Georgia. It is represented that the proposed merger affords Applicant the opportunity to broaden its asset base by the acquisition of the McDonough Bank shares without incurring brokerage expenses. Applicant submits that its shareholders will benefit from the proposed merger by eliminating the possibility of a disruptive change of control that might arise if Phoenix transfers its controlling position in Applicant in a block. As a result of the proposed merger, this interest will be diffused among all the Phoenix shareholders. Applicant represents that the proposed transaction is fair and reasonable and does not involve overreaching by any party concerned in that the proposed transaction will be consummated on the basis of an exchange ratio determined by the Boards of Directors of Applicant and Phoenix with the aid of independent analysts and independently approved by both boards and by the shareholders of both parties, including approval by a majority in number of the shareholders of each company. Based on the foregoing, Applicant requests an order of exemption from Section 17(a) pursuant to Section 17(b) of the Act permitting the proposed merger of Applicant into Phoenix.

Section 6(c). Applicant was incorporated on August 29, 1958 for the purpose of operating as a small business investment company. On September 9, 1970, the Commission entered an order ("Order") (Investment Company Act Release No. 6181) granting Applicant various exemptions from the Act which permitted it to transfer its license under the Small Business Investment Act of 1958 and other assets to its wholly-owned subsidiary, SCSBIC. Such Order was subject to numerous conditions designed to insure that SCSBIC was at all times owned and operated by Applicant. Applicant has applied, pursuant to Section 6(c) of the Act, for an order of the Commission providing that the conditions imposed upon Applicant by such Order may be fulfilled by the Surviving Corporation as successor by merger to Applicant.

Section 6(c) of the Act provides, in part, that the Commission, by order upon application, may conditionally or unconditionally exempt any person, security, or transaction, or any class or classes of persons, securities, or transactions from any provision or provisions of the Act or of any rule or regulation thereunder, if and to the extent such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

Notice is further given that any interested person may, not later than September 22, 1975, at 5:30 p.m., submit to the Commission in writing a request for a hearing on the matter accompanied by a statement as to the nature of his interest, the reason for such request, and the issues, if any, of fact or law proposed to be controverted, or he may request that he be notified if the Commission shall order a hearing thereon. Any such communication should be addressed: Secretary, Securities and Exchange Commission, Washington, D.C. 20549. A copy of such request shall be served personally or by mail (air mail if the person being served is located more than 500 miles from the point of mailing) upon Applicant at the address stated above. Proof of such service (by affidavit, or in case of an attorney-at-law, by certificate) shall be filed contemporaneously with the request. As provided by Rule 0-5 of the Rules and Regulations promulgated under the Act, an order disposing of the application will be issued as of course following said date unless the Commission thereafter orders a hearing upon request or upon the Commission's own motion. Persons who request a hearing, or advice as to whether a hearing is ordered, will receive any notices and orders issued in this matter, including the date of the hearing (if ordered) and any postponements thereof.

For the Commission, by the Division of Investment Management Regulation, pursuant to delegated authority.

GEORGE A. FITZSIMMONS,
Secretary.

[FR Doc.75-23258 Filed 9-2-75;8:45 am]

[Rel. No. 34—11621; File No. SR-PSE-75-1]

PACIFIC STOCK EXCHANGE INC.

Proposed Rule Change

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), as amended by Pub. L. No. 94-29, 16 (June 4, 1975), notice is hereby given that on August 25, 1975, the above-mentioned self-regulatory organization filed with the Securities and Exchange Commission a proposed rule change as follows:

STATEMENT OF THE TERMS OF SUBSTANCE OF THE PROPOSED RULE CHANGE

The proposed rule change would amend the Constitution of the Pacific Stock Exchange Incorporated ("PSE") to increase the number of authorized memberships from 220 to 742, with the newly authorized memberships to be sold by the Board of Governors only in accordance with the Options Funding Plan of 1975. Pursuant to the amendment, and to the Options Funding Plan of 1975 which is incorporated by reference in the amendment:

1. 522 new treasury memberships would be authorized.

2. 94 of these memberships would be offered for sale at $10,000 each to persons or firms not presently PSE members.

3. 214 of these memberships would be offered for sale at $5,000 each to existing PSE members and member firms.

4. 214 of these memberships would be offered for sale at $5,000 each to the purchasers of the memberships referred to in paragraph 3 above.

5. The purpose of the authorization and sale of these memberships is to provide requisite financing for beginning options trading on a separate options floor and to provide an adequate number of memberships for use in options trading.

6. The Board of Governors of PSE plans to require that all trading on the Options Trading Floor be restricted to members only, and has interpreted PSE's Constitution and Rules as prohibiting a member trading on the Options Trading Floor from having a floor representative on either of PSE's equity floors, with the practical result that existing members who desire to participate in options trading will need additional memberships.

7. The 94 memberships to be offered non-members, after the expiration of the offering to non-members, would be available for sale at the discretion of the PSE Board of Governors ("Board"), and the unsold portion of the 428 other new memberships, after the expiration of one year from the commencement of option trading on the PSE, would be available for sale at the discretion of the Board, subject to the Board's stated policy that sales would be made only in circumstances when an excessive imbalance of supply and demand existed and the Board determined it to be in the best interests of the memberships of the PSE.

8. All sales of treasury memberships made during the offering period that will precede the commencement of options trading are contingent upon receiving Securities and Exchange Commission approval of the PSE Options Trading Plan and upon sale of a number of memberships at least sufficient to raise a sum that, in the opinion of the Board, will meet the requirements for funding PSE's costs in beginning options trading, so that if these contingencies are not met the sales would be cancelled and the Board's authority to sell the 522 new memberships would be terminated.

9. All funds received from the sale of treasury memberships during the offering period will be held in a special segregated account, and if either of the contingencies referred to in paragraph 8 above are not met, such funds would be returned.

STATEMENT OF BASIS AND PURPOSE

The basis and purpose of the foregoing proposed rule change is as follows:

The purpose of the proposed rule change is to authorize sufficient additional memberships so that there will be an adequate number of memberships for use in options trading and so that, through sale of these additional memberships, sufficient funds will be produced to finance the beginning of options trading on PSE.

The proposed rule change, by substantially increasing the number of authorized memberships in the PSE, substantially increases the ability of any registered broker or dealer, or natural person associated with a registered broker or dealer, to become a member of PSE. This is particularly true since the Options Funding Plan provides that these memberships are to be offered for sale at relatively low prices ($10,000 for the 94 memberships to be offered to nonmembers and $5,000 for the 428 memberships to be available to members).

The proposed rule change, by facilitating the development of an options trading facility on PSE, contributes to competition in options trading and thus to the perfection of a free and open market in options.

A special meeting of PSE members has been called to vote on the proposed rule change and any member who desires to do so will be allowed to comment orally at that meeting. Proxies are being solicited by the Board of Governors for votes for or against the proposed rule change. Apart from this, comments are not being solicited.

The proposed rule change will not impose any burden on competition. Rather the proposed rule change will encourage competition. It will do this both by facilitating the development of a competing facility for trading options and by facilitating the entry of persons and firms into the business of trading securities on PSE.

Within 35 days of the date of publication of this notice in the FEDERAL REGISTER, or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the above-mentioned self-regulatory organization consents, the Commission will:

(A) by order approve such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons desiring to make written submissions should file 6 copies thereof with the Secretary of the Commission, Securities and Exchange Commission, Washington, D.C. 20549. Copies of the filing with respect to the foregoing and of all written submissions will be available for inspection in the Public Reference Room, 1100 L Street, N.W., Washington, D.C. Copies of such filing will also be available for inspection at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number referenced in the caption above and should be submitted on or before October 3, 1975.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.

[SEAL] GEORGE A. FITZSIMMONS, *Secretary.*

AUGUST 28, 1975.

[FR Doc.75-23281 Filed 9-2-75;8:45 am]

SMALL BUSINESS ADMINISTRATION

[SBLC No. 0002]

CAPCO SECURITIES, INC.

Application To Become Eligible as a Small Business Lending Company

Notice is hereby given concerning the filing of an application with the Small Business Administration (SBA) pursuant to Section 120.4(b) of the Regulations governing small business lending companies (SBLC's) (13 C.F.R., Section 120.4(b) (1975)), under the name of CAPCO Securities, Inc., 1025 Connecticut Ave., N.W., Washington, D.C., 20036, to become eligible to operate as an SBLC under the provisions of the Small Business Act (the Act), as amended (15 U.S.C. 634 and 636).

CAPCO Securities, Inc., will be a wholly owned subsidiary of CAPCO, Inc., of the same address. Officers, directors, and principal stockholders of CAPCO, Inc., are as follows:

Name	Title	Percent of voting securities
Robert A. Podesta, 505 North Lake Shore Dr., Chicago, Ill. 60611.	Chairman of board.	<10
Richard P. Whitney, 33 Cushing St., Providence, R.I. 02906.	President and director.	<10
Richmond T. Leeson, 569 Barney's Joy Rd., Dartmouth, Mass. 02714.	Vice president and treasurer.	<10
John H. Altorfer, 7405 North Edgewild Dr., Peoria, Ill. 61614.	Director	10
Andrew Gibson, Box 294, Ashfield, Mass. 01330.	do	
Maurice T. Reed, 4042 Pine Hill Dr., Jackson, Miss. 39206.	Stockholder	17
Charles Johnston, 3 Mast Hill Rd., Hingham, Mass. 02043.	do	11

Officers and directors of CAPCO, Inc., own 46% of the voting securities of that corporation. In addition, the Chicago Corporation, of which Mr. Podesta is an officer, director, and stockholder, owns 9% of the stock of CAPCO, Inc. Mr. Podesta disclaims any beneficial interest in the shares of the Company owned by the Chicago Corporation.

Officers, directors, and principal stockholders of CAPCO Securities, Inc., are as follows:

Name	Title	Percent of voting securities
Robert A. Podesta, 505 North Lake Shore Dr., Chicago, Ill. 60611.	Chairman of board.	----------
Richard P. Whitney, 33 Cushing St., Providence, R.I. 02906.	President and director.	----------
Richmond T. Leeson, 569 Barney's Joy Rd., Dartmouth, Mass. 02714.	Vice president and treasurer.	----------
John H. Altorfer, 7465 North Edgewild Dr., Peoria, Ill. 61614.	Director	----------
CAPCO, Inc., 1025 Connecticut Ave. NW., Washington, D.C. 20036.	----------	100

Messrs. Podesta, Whitney, and Altorfer have previously held significant positions in the Federal Government. Mr. Podesta was Assistant Secretary of Commerce for Economic Development from February 1969 to January 1973. Mr. Whitney, from March 1970 until March 1973, served as Assistant to the Secretary of Commerce and as a Vice President of Finance of the Overseas Private Investment Corporation. From February 1971 until January 1972, Mr. Altorfer was Special Assistant to the Secretary of Commerce.

CAPCO Securities, Inc., will begin operations with a minimum initial capitalization of $500,000, which will be derived from part of the proceeds of a private securities offering by CAPCO, Inc., the SBLC's parent. CAPCO Securities, Inc., will operate in the District of Columbia, elsewhere in the Middle Atlantic States, in New England, and in the East North Central States, with its principal office in the District of Columbia. A branch office is planned to be opened in Boston, Massachusetts, at an address as yet undecided.

Matters involved in SBA's consideration of the application include the general business reputation and character of the proposed owners and management and the probability of successful operations of the new company under their management, including adequate profitability and financial soundness, in accordance with the Act and Regulations.

Notice is further given that any interested person may, not later than fifteen (15) days from the date of publication of this Notice, submit to SBA, in writing, relevant comments on the proposed company.

Any communication should be addressed to: Director, Office of Program Development, Small Business Administration, 1441 "L" Street, N.W., Washington, D.C. 20416.

A copy of this Notice shall be published in a newspaper of general circulation in Washington, D.C., and Boston, Massachusetts.

Dated: August 27, 1975.

PETER F. MCNEISH,
Director,
Office of Program Development.

[FR Doc.75-23256 Filed 9-2-75;8:45 am]

UNITED STATES RAILWAY ASSOCIATION

[USRA Docket No. 76-17]

ERIE LACKAWANNA RAILWAY CO.

Proposed Interim Discontinuance of Passenger Service

The Trustees in Bankruptcy of the Erie Lackawanna Railway Company ("Erie") propose to discontinue commuter trains Nos. 28 and 29 operated by the railroad and have made a request to the United States Railway Association ("USRA") for the authorization required for that purpose under Section 304(f) of the Regional Rail Reorganization Act of 1973 ("the Act"), Pub. L. 93-236.

Section 304(f) provides:

> After [January 2, 1974], no railroad in reorganization may discontinue service or abandon any line of a railroad other than in accordance with the provisions of [the Act], unless it is authorized to do so by the Association and unless no affected State or local or regional transportation authority reasonably opposes such action, notwithstanding any provision of any other Federal law, the constitution or law of any State, or decision or order of or the pendency of any proceeding before any Federal or State court, agency, or authority.

The trains sought to be discontinued operate between Cleveland and Youngstown, Ohio, a distance of 66.2 miles, and constitute the only present rail passenger service between these points. Stations served include Cleveland Union Terminal, East 55th Street, Lee Road, North Randall, Solon, Geauga Lake, Aurora, Mantua, Jeddoe, Garrettsville-Hiram, Warren, Niles, and Youngstown, Ohio.

In support of its request, the Erie alleges that:

1. It must spend $3.00 in expenses for each $1.00 of gross revenues earned from providing the service.

2. It currently loses about $604.00 per trip.

3. Alternate public transportation is available within the Cleveland City Limits from the Cleveland Transit System; between Cleveland, Warren, and Youngstown and between Cleveland and North Randall from Greyhound Bus Lines. In addition, Cleveland Southeastern Trails has previously indicated an intent to furnish comparable commuter service between Aurora and Cleveland in the event the trains are discontinued.

This request is accompanied by exhibits providing more detailed information.

Pursuant to Section 304(f) of the Regional Rail Reorganization Act, USRA is publishing this notice upon receipt of the railroad's application. To assist USRA in its analysis and disposition of this request, all affected or interested parties are invited to submit written statements, views, arguments or comments either favoring or opposing the discontinuance proposal.

Any such submissions must identify, by its Docket No., the request to which it relates, and must be filed with the Docket Clerk, United States Railway Association, Room 2222, Trans Point Building, 2100 Second Street, S.W., Washington, D.C. 20595, by October 15, 1975, to enable timely consideration by USRA. The docket containing the original application and all submissions received shall be available for public inspection at that address and at the offices of the Ohio Department of Transportation, Division of Urban Mass Transportation, 25 South Front Street, Columbus, Ohio, between 8:00 a.m. and 5:00 p.m., Monday through Friday, the offices of the Public Utilities Commission of Ohio, 111 North High Street, Columbus, Ohio, between 9:00 a.m. and 5:00 p.m., Monday through Friday, and at the offices of the Railroad, Law Department, 1336 Midland Building, 101 Prospect Avenue, Cleveland, Ohio, and Superintendent's Office, 508 Binama Building, Youngstown, Ohio, between 9:00 a.m. and 5:00 p.m., Monday through Friday.

In addition to this publication, Erie shall, by September 1, 1975, make available a copy of this notice and invitation for written submission to each labor union whose members are employed in providing passenger service on that part of its line. It shall also post and prominently display a copy of this notice on each passenger train car and on each station on the line, continually during the period from September 1, 1975 to October 15, 1975.

This action is taken pursuant to Section 304(f) of the Regional Rail Reorganization Act of 1973, as amended, P.L. 93-236.

The Association will consider the application in the light of the public comments received and the requirements and purposes of the Act before rendering a decision on the merits of the request to discontinue the subject passenger service. The Association will deny any application which a State or local or regional transportation authority reasonably opposes, or where the authorization requested is inconsistent with the requirements and purposes of the Act; it will grant the application if that action is consistent with the requirements and purposes of the Act.

Dated at Washington, D.C. this 26th day of August, 1975.

JAMES A. HAGEN,
President,
United States Railway Association.

[FR Doc.75-23277 Filed 9-2-75;8:45 am]

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

NORTH CAROLINA STANDARDS

Notice of Approval

1. *Background.* Part 1953 of Title 29, Code of Federal Regulations prescribes procedures under section 18 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 667) (hereinafter called the Act) by which the Assistant Regional

Director for Occupational Safety and Health (hereinafter called the Assistant Regional Director) under a delegation of authority from the Assistant Secretary of Labor for Occupational Safety and Health (hereinafter called the Assistant Secretary) (29 CFR 1953.4) will review and approve standards promulgated pursuant to a State plan which has been approved in accordance with section 18(c) of the Act and 29 CFR Part 1902. On February 1, 1973, notice was published in the FEDERAL REGISTER (39 FR 3041) of the approval of the North Carolina plan and the adoption of Subpart I to Part 1952 containing the decision.

The North Carolina plan provides for the adoption of Federal standards as State standards by reference and additional State standards which are at least as effective as comparable Federal standards promulgated under section 6 of the Act. Section 1952.150(a) of Subpart I provides for the development and promulgation of additional laws and orders in all places of employment in the State. By letter dated January 27, 1975, from W. C. Creel, Commissioner of Labor, North Carolina Department of Labor to Donald E. MacKenzie, Assistant Regional Director, and incorporated as a part of the plan, the State submitted standards for "Shops Fabricating Structural Steel and Steel Plate." These standards were promulgated by the State following hearings on December 11, 1974, at Raleigh, North Carolina pursuant to the North Carolina Occupational Safety and Health Act of 1973 (Chapter 295, General Statutes).

2. *Decision.* Having reviewed the State submission in comparison with Federal standards, it has been determined that the State standards are at least as effective as comparable Federal standards and are hereby approved. These standards incorporate several standards developed by the American National Standards Institute (ANSI) and repromulgate for the fabricating structural steel and steel plate industries some of the general industry standards already promulgated by the State and approved by the Assistant Regional Director.

3. *Location of Supplement for Inspection and Copying.* A copy of the standard supplement, along with the approved plan, may be inspected and copied during normal business hours at the following locations: Office of the Commissioner of Labor, North Carolina Department of Labor, 11 West Edenton, Raleigh, North Carolina 26711; Office of the Assistant Regional Director, Suite 587, 1375 Peachtree Street, N.E., Atlanta, Georgia 30309; and Office of the Associate Assistant Secretary for Regional Programs, Room N3603, 200 Constitution Avenue, Washington, D.C. 20210.

4. *Public Participation.* Under 29 CFR 1953.2(c) the Assistant Secretary may prescribe alternative procedures to expedite the review process or for other good cause which may be consistent with applicable laws. The Assistant Secretary finds good cause exists for not publishing the supplement to the North Carolina State plan as a proposed change and making the Assistant Regional Director's approval effective on publication for the following reasons:

1. The State standard incorporates existing Federal standards and consensus standards related to the fabrication of steel.

2. The standards were adopted in accordance with procedural requirements of State law and further participation would be unnecessary.

This decision is effective September 3, 1975.

(Sec. 18, Pub. L. 91-596, 84 Stat. 1608 (29 U.S.C. 667)) Signed at Atlanta, Georgia, this 29th day of July, 1975.

DONALD E. MACKENZIE,
Assistant Regional Director.

[FR Doc.75-23218 Filed 9-2-75;8:45 am]

INTERSTATE COMMERCE COMMISSION

[Fourth Rev. Exemption No. 89]

PLAIN BOXCARS OF 40-FT.

Exemption Under Provision of Rule 19 of the Mandatory Car Service Rules Ordered in Ex Parte No. 241

It appearing, That the U.S. railroads own numerous 40-ft. plain boxcars; that under present conditions, there are substantial surpluses of these cars on the lines of the car owners; that return of these cars to the car owners would result in their being stored idle on these lines; that such cars can be used by other carriers for transporting traffic offered for shipments to points remote from the car owners; and that compliance with Car Service Rules 1 and 2 prevents such use of plain boxcars, resulting in unnecessary loss of utilization of such cars.

It is ordered, That pursuant to the authority vested in me by Car Service Rule 19, plain boxcars of railroad ownership described in the Official Railway Equipment Register, I.C.C. R.E.R. No. 396, issued by W. J. Trezise, or successive issues thereof, as having machinical designation "XM", with inside length 44 ft. 6 in. or less, and which bear the reporting marks assigned to United States railroads, shall be exempt from the provisions of Car Service Rules 1(a), 2(a), and 2(b). (See Exceptions 1, 2 and 3)

Exception No. 1: This exemption does not supersede United States customs regulations applicable to cars owned by Canadian or Mexican railroads.

Exception No. 2: This exemption shall not apply to cars subject to service orders issued by the Interstate Commerce Commission or to Directives issued by the Car Service Division of the Association of American Railroads, restricting the use of designated cars.

Exception No. 3: This exemption shall not apply to 40-ft. boxcars owned by the railroads named below:

Burlington Northern Inc., Reporting Marks: BN, CBQ, GN, NP, SPS.

Chicago, Milwaukee, St. Paul and Pacific Railroad Company, Reporting Marks: MILW.

The Kansas City Southern Railway Company, Reporting Marks: KCS.

Louisana & Arkansas Railway Company, Reporting Marks: LA.

SOO Line Railroad Company, Reporting Marks: SOO.

Effective August 22, 1975.

Expires September 15, 1975.

Issued at Washington, D.C., August 15, 1975.

INTERSTATE COMMERCE COMMISSION,
[SEAL] R. D. PFAHLER,
Agent.

[FR Doc. 75-23338, Filed 9-2-75; 8:45 am]

[Amdt. No. 1 to Fourth Rev. Exemption No. 99]

EXEMPTION UNDER PROVISION OF RULE 19 OF THE MANDATORY CAR SERVICE RULES ORDERED IN EX PARTE NO. 241

Upon further consideration of Fourth Revised Exemption No. 99 issued August 11, 1975.

It is ordered, That, under the authority vested in me by Car Service Rule 19, Fourth Revised Exemption No. 99 to the Mandatory Car Service Rules ordered in Ex Parte No. 241, be, and it is hereby amended to expire September 30, 1975.

This amendment shall become effective August 31, 1975.

Issued at Washington, D.C., August 20, 1975.

INTERSTATE COMMERCE COMMISSION,
[SEAL] R. D. PFAHLER,
Agent.

[FR Doc.75-23339 Filed 9-2-75;8:45 am]

[Exemption No. 100]

EXEMPTION UNDER PROVISION OF RULE 19 OF THE MANDATORY CAR SERVICE RULES ORDERED IN EX PARTE NO. 241

It appearing, That there is an emergency movement of military impedimenta from Kendaia, New York, to Leland, North Carolina; that the originating carrier has insufficient system cars of suitable dimensions immediately available for loading with this traffic; that sufficient cars of other ownerships having suitable dimensions are available on the lines of the originating carrier and on its connections; and that compliance with Car Service Rules 1 and 2 would prevent the timely assembly and use of such cars.

It is ordered, That pursuant to the authority vested in me by Car Service Rule 19, the Car Service Division of the Association of American Railroads is authorized to direct the movement to the Lehigh Valley Railroad Company (Robert C. Haldeman, Trustee), the railroads designated by the Car Service Division are authorized to move to, and the Lehigh Valley Railroad Company (Robert C. Haldeman, Trustee), is au-

thorized to accept, assemble, and load, not to exceed one hundred-fifty (150) empty cars, with military impedimenta from Kendaia, New York, to Leland, North Carolina, regardless of the provisions of Car Service Rules 1 and 2.

Effective August 21, 1975.

Expires September 10, 1975.

Issued at Washington, D.C., August 15, 1975.

INTERSTATE COMMERCE COMMISSION,
[SEAL] R. D. PFAHLER,
Agent.

[FR Doc.75-23340 Filed 9-2-75;8:45 am]

IRREGULAR-ROUTE MOTOR COMMON CARRIERS OF PROPERTY—ELIMINATION OF GATEWAY LETTER NOTICES

AUGUST 28, 1975.

The following letter-notices of proposals to eliminate gateways for the purpose of reducing highway congestion, alleviating air and noise pollution, minimizing safety hazards, and conserving fuel have been filed with the Interstate Commerce Commission under the Commission's *Gateway Elimination* Rules (49 CFR 1065), and notice thereof to all interested persons is hereby given as provided in such rules.

An original and two copies of protests against the proposed elimination of any gateway herein described may be filed with the Interstate Commerce Commission within 10 days from the date of this publication. A copy must also be served upon applicant or its representative. Protests against the elimination of a gateway will not operate too stay commencement of the proposed operation.

Successively filed letter-notices of the same carrier under these rules will be numbered consecutively for convenience in identification. Protests, if any, must refer to such letter-notices by number.

No. MC 1380 (Sub-No. E3), filed May 13, 1974. Applicant: COLONIAL MOTOR FREIGHT LINE, INC., P.O. Box 5468, High Point, N.C. 27262. Applicant's representative: Max H. Towery (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *General commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, commodities requiring special equipment, and those injurious or contaminating to other lading): (1) between points in that part of Tennessee north of U.S. Highway 421, on the one hand, and, on the other, points in that part of Virginia on and east of a line beginning at the Virginia-North Carolina State line, thence along U.S. Highway 17 to junction U.S. Highway 60, thence along U.S. Highway 60 to the Chesapeake Bay; (2) between points in that part of Tennessee within 150 miles of Charlotte, N.C. south of U.S. Highway 421 and on and north of a line beginning at the Tennessee-North Carolina State line, thence along U.S. Highway 23 to junction U.S. Highway 11E, thence along U.S. Highway 11E to the Virginia-Tennessee State line, on the one hand, and, on the other, points in that part of Virginia east of a line beginning at the Virginia-North Carolina State line, thence along Virginia Highway 35 to junction Virginia Highway 40, thence along Virginia Highway 40 to junction Virginia Highway 10, thence along Virginia Highway 10 to the eastern boundary of Prince George County, thence along the eastern boundary of Prince George County to the eastern border of Charles City County, thence along the eastern border of Charles City County to U.S. Highway 60, thence along U.S. Highway 60 to the Chesapeake Bay;

(3) Between points in that part of Tennessee south of a line beginning at the North Carolina-Tennessee State line, thence along U.S. Highway 70 to junction Tennessee Highway 107, thence along Tennessee Highway 107 to Greenville, Tenn., thence along U.S. Highway 11E to the boundary line of points within 150 miles of Charlotte, N.C., thence along the 150 miles of Charlotte, N.C., boundary to the Virginia-Tennessee State line, on the one hand, and, on the other, points in that part of Virginia east of a line beginning at the North Carolina-Virginia State line, thence along U.S. Highway 501 to junction U.S. Highway 360, thence along U.S. Highway 360 to junction U.S. Highway 60, thence along U.S. Highway 60 to the Atlantic Ocean; (4) between points in that part of Virginia on and south of a line beginning at the Virginia-North Carolina State line, thence along U.S. Highway 220 to junction U.S. Highway 58, thence along U.S. Highway 58 to junction U.S. Highway 360, thence along U.S. Highway 360 to junction U.S. Highway 60, thence along U.S. Highway 60 to the Atlantic Ocean, on the one hand, and, on the other, points in that part of South Carolina west of U.S. Highway 52 and within 150 miles of Charlotte, N.C.; (5) between points in that part of Virginia on and bounded by a line beginning at the Virginia-North Carolina State line, thence along U.S. Highway 29 to Danville, thence along U.S. Highway 360 to Rudimend, thence along U.S. Highway 250 to Charlottesville, thence along U.S. Highway 29 to the point of beginning, on the one hand, and, on the other, points in that part of South Carolina which are within 150 miles of Charlotte, N.C., and south and west of a line beginning at the North Carolina-South Carolina State line, thence along South Carolina Highway 57 to Fork, thence along South Carolina Highway 41 to junction U.S. Highway 501, thence along U.S. Highway 501 to the Atlantic Ocean; (6) between points in that part of Virginia on and bounded by a line beginning at the Virginia-North Carolina State line, thence along U.S. Highway 29 to Charlottesville, thence along U.S. Highway 250 to Staunton, thence along U.S. Highway 11 to junction U.S. Highway 21, thence along U.S. Highway 21 to the Virginia-North Carolina State line, thence along the Virginia-North Carolina State line to the point of beginning, on the one hand, and, on the other, all points in South Carolina within 150 miles of Charlotte, N.C.;

(7) Between points in that part of Virginia on and south of a line beginning at the North Carolina-Virginia State line, thence along U.S. Highway 21 to junction U.S. Highway 11, thence along U.S. Highway 11 to the North Carolina-Virginia State line, on the one hand, and, on the other, points in that part of South Carolina west of a line beginning at the North Carolina-South Carolina State line, thence along U.S. Highway 321 to Chester, thence along South Carolina Highway 121 to Saluda, thence along U.S. Highway 378 to the Georgia-South Carolina line; (8) between points in that part of Virginia east of a line beginning at the North Carolina-Virginia State line, thence along U.S. Highway 17 to junction U.S. Highway 60, thence along U.S. Highway 60 to the Atlantic Ocean and points on U.S. Highway 60 between Norfolk and Williamsburg, Va., including Williamsburg, on the one hand, and, on the other, points in that part of North Carolina within 150 miles of Charlotte, N.C., and on and west of a line beginning at the North Carolina-South Carolina States line, thence along North Carolina Highway 18 to junction North Carolina Highway 10, thence along North Carolina Highway 10 to junction North Carolina Highway 127, thence along North Caroline Highway 127 to junction U.S. Highway 70 thence along U.S. Highway 70 to junction North Carolina Highway 16, thence along North Carolina Highway 16 to junction U.S. Highway 421, thence along U.S. Highway 421 to the North Carolina-Tennessee State line; (9) between points in Virginia bounded by a line beginning at the North Carolina-Virginia State line, thence along U.S. Highway 501 to South Boston, Va., thence along U.S. Highway 360 to Richmond (serving all points in said highways comprising the western boundary), thence along U.S. Highway 60 to junction U.S. Highway 17, thence along U.S. Highway 17 to the North Carolina-Virginia State line (serving no point on said highways comprising the eastern boundary), on the one hand, and, on the other, points in that part of North Carolina within 150 miles of Charlotte, N.C., and west of a line beginning at the North Carolina-South Carolina State line, thence along North Carolina Highway 18 to junction North Carolina Highway 10, thence along North Carolina Highway 10 to junction U.S. Highway 127, thence along U.S. Highway 127 to junction U.S. Highway 321, thence along U.S. Highway 321 to junction U.S. Highway 221, thence along U.S. Highway 221 to the Tennessee-Virginia State line;

(10) Between points in Virginia on U.S. Highway 250 between Staunton and Richmond (including Staunton but not including Richmond), on the one hand, and, on the other, points in that part of North Carolina within 150 miles of Charlotte, N.C., and west of a line beginning at the North Carolina-South Carolina State line, thence along North Caro-

lina Highway 18 to junction North Carolina Highway 10, thence along North Carolina Highway 10 to junction U.S. Highway 127, thence along U.S. Highway 127 to junction U.S. Highway 321, thence along U.S. Highway 321 to junction U.S. Highway 221, thence along Highway 221 to the Tennessee-Virginia State line; (11) between points in Virginia bounded by a line beginning at the North Carolina-Virginia State line, thence along U.S. Highway 501 to South Boston, Va., thence along U.S. Highway 360 to Richmond, thence along U.S. Highway 250 to Staunton, thence along U.S. Highway 11 to Roanoke, thence along U.S. Highway 220 to the North Carolina-Virginia State line, serving points on U.S. Highway 220, on the one hand, and, on the other, points in that part of North Carolina on and west of U.S. Highway 25; (12) between points in Virginia bounded by a line beginning at the Virginia-North Carolina State line, thence along U.S. Highway 21 to Wytheville, thence along U.S. Highway 11 to Bristol, Va., thence along the North Carolina-Virginia State line to the point of beginning, on the one hand, and, on the other, points in North Carolina east of U.S. Highway 1 that are within 150 miles of Charlotte, N.C. The purpose of his filing is to eliminate the gateway of Charlotte, N.C.

No. MC 8535 (Sub-E40), filed July 16, 1975. Applicant: GEORGE TRANSFER, P.O. Box 500, Parkton, Md. 21120. Applicant's representative: James B. Nestor (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Aluminum and aluminum products*, from points in Alabama, west of the counties of Jackson, De Kalb, Etowah, Calhoun, Cleburne, Clay, Coosa, Elmore, Montgomery, Crenshaw, and Covington, to points in Connecticut, Massachusetts, Rhode Island, and Vermont. The purpose of this filing is to eliminate the gateway of the facilities of National Southwire Aluminum Co., Southwire Company, and National Aluminum Corporation, at or near Hawesville, Ky.

No. MC 8535 (Sub-E41), filed July 16, 1975. Applicant: George Transfer, P.O. Box 500, Parkton, Md. 21120. Applicant's representative: James B. Nestor (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Aluminum and aluminum products*, from points in Jackson County, Alabama on, south, or west of a line beginning at the Tennessee-Alabama State line and extending along Alabama Highway 65 to junction Alabama Highway 146, thence along Alabama Highway 146 to junction Alabama Highway 79, thence along Alabama Highway 79 to junction Alabama Highway 35, and thence along Alabama Highway 35 to the Jackson-De Kalb County line, to points in Connecticut, Massachusetts, Rhode Island, and Vermont. The purpose of this filing is to eliminate the gateway of the facilities of National Southwire Aluminum Co., at or near Hawesville, Ky.

No. MC 8535 (Sub-E42), filed July 16, 1975. Applicant: GEORGE TRANSFER, P.O. Box 500, Parkton, Md. 21120. Applicant's representative: James B. Nestor (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Aluminum and aluminum products*, requiring rigging, special equipment or specialized handling, from points in Kentucky, west of Oldham, Shelby, Spencer, Nelson, Marion, Taylor, Adair, Russell, and Wayne Counties, to points in Connecticut, Massachusetts, Rhode Island, and Vermont. The purpose of this filing is to eliminate the gateway of points in Hancock County, Kentucky.

No. MC 31462 (Sub-No. E40), filed May 13, 1974. Applicant: PARAMOUNT MOVERS, INC., P.O. Box 309, Lancaster, Tex. 75146. Applicant's representative: R. L. Rork (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *Household goods*, as defined by the Commission, between points in Arkansas on and north of a line beginning on the Mississippi River and Memphis, Arkansas, on Interstate Highway 55, thence along Interstate Highway 55 to junction U.S. Highway 70, thence along U.S. Highway 70 to junction U.S. Highway 79, thence along U.S. Highway 79 to junction Arkansas Highway 1, thence along Arkansas Highway 1 to junction U.S. Highway 49, thence along U.S. Highway 49 to junction Arkansas Highway 1, thence along Arkansas Highway 1 to junction Arkansas Highway 54, thence along Arkansas Highway 54 to junction U.S. Highway 65, thence along U.S. Highway 65 to junction Arkansas Highway 4, thence along Arkansas Highway 4 to junction Arkansas Highway 15, thence along Arkansas Highway 15 to El Dorado, Ark., thence along El Dorado to junction U.S. Highway 167, thence along U.S. Highway 167 to the Arkansas-Louisiana State line, on the one hand, and, on the other, points in North Carolina. The purpose of this filing is to eliminate the gateways of Cairo, Ill., and points within 25 miles thereof, and points in Tennessee and Georgia.

No. MC 31462 (Sub-No. E76), filed May 13, 1974. Applicant: PARAMOUNT MOVERS, INC., P.O. Box 309, Lancaster, Tex. 75146. Applicant's representative: R. L. Rork (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Household goods*, as defined by the Commission, between points in Georgia, on the one hand, and, on the other, points in Montana. The purpose of this filing is to eliminate the gateways of points in Tennessee, Cairo, Ill., and points within 25 miles thereof; Burlington, Iowa, and points within 50 miles thereof; Alden, Minn., and points within 35 miles thereof; and Williston, N. Dak., and points in North Dakota within 200 miles of Williston.

No. MC 31462 (Sub-No. E188), filed May 13, 1974. Applicant: PARAMOUNT MOVERS, INC., P.O. Box 309, Lancaster, Tex. 75146. Applicant's representative: R. L. Rork (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Household goods*, as defined by the Commission, between points in Iowa on, south, and east of a line beginning at the Iowa-Minnesota State line on U.S. Highway 59, thence along U.S. Highway 59 to junction U.S. Highway 30, thence along U.S. Highway 30 to the Iowa-Nebraska State line, on the one hand, and, on the other, points in Kansas. The purpose of this filing is to eliminate the gateways of Omaha, Nebr., and points in Nebraska within 100 miles of Omaha, and Kansas City, Mo., and points within 30 miles.

No. MC 31462 (Sub-No. E306), filed May 13, 1974. Applicant: PARAMOUNT MOVERS, INC., P.O. Box 309, Lancaster, Tex. 75146. Applicant's representative: R. L. Rork (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Household goods*, as defined by the Commission, between points in Mississippi, on the one hand, and, on the other, points in New Hampshire. The purpose of this filing is to eliminate the gateways of Cairo, Ill., and points within 25 miles thereof, Ft. Wayne, Ind., and points in Indiana within 40 miles of Ft. Wayne, and Hoosick Falls, N.Y.

No. MC 45736 (Sub-E3), filed June 3, 1974. Applicant: GUIGNORD FREIGHT LINES, INC., P.O. Box 26067, Charlotte, N.C. 28213. Applicant's representative: Edward G. Villalon, Suite 1032, 13th & Pennsylvania Ave. NW., Washington, D.C. 20004. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *General commodities*, except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and commodities requiring special equipment; (1) between points in Kentucky located within 225 miles of Concord, N.C., on the one hand, and, on the other, points in South Carolina east of a line beginning at the North Carolina-South Carolina State line and extending along U.S. Highway 21 to junction U.S. Highway 321, to junction South Carolina Highway 3, to junction U.S. Highway 301, to the South Carolina-Georgia State line (Concord, N.C.)*; (2) between points in Virginia within 225 miles of Concord, N.C., which are east of Virginia Highway 16, on the one hand, and, on the other, points in South Carolina (except Marlboro, Dillon, Marion, Horry, and Georgetown Counties) (Concord, N.C.)*; (3) between points in Virginia within 225 miles of Concord, N.C., which are east of Virginia Highway 16, on the one hand, and, on the other, Savannah, Ga. (Concord, N.C., and Sumter County, S.C.)*; (4) between points in Virginia on and south of a line beginning at the Atlantic Ocean and extending along U.S. Highway 60 to junction U.S. Highway 250, to junction U.S. Highway 11, to

junction Virginia Highway 16 to the Virginia-North Carolina State line, on the one hand, and, on the other, (A) points in South Carolina (except Marlboro, Dillon, Marion, Horry, and Georgetown Counties) (Concord and Charlotte, N.C.)*, (B) points in Georgia within 225 miles of Concord, N.C. (Concord, N.C.)*, (C) Savannah, Ga. (Concord and Charlotte, N.C., and Sumter, S.C.)*. The purpose of this filing is to eliminate the gateways indicated by asterisks above.

No. MC 45736 (Sub-E4), filed June 3, 1974. Applicant: GUIGNORD FREIGHT LINES, INC., P.O. Box 26067, Charlotte, N.C. 28213. Applicant's representative: Edward G. Villalon, Suite 1032, 13th & Pennsylvania Ave. NW., Washington, D.C. 20004. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *General commodities*, except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and commodities requiring special equipment; (1) between points in West Virginia within 225 miles of Concord, N.C., on the one hand, and, on the other, (A) points in South Carolina (Concord, N.C.)*, (B) Savannah, Ga. (Concord, N.C., and Sumter County, S.C.)*; (2) between points in Kentucky and West Virginia located within 225 miles of Concord, N.C., on the one hand, and, on the other, Savannah, Ga. (Concord, N.C., and Sumter County, S.C.)*. The purpose of this filing is to eliminate the gateways indicated by asterisks above.

No. MC 45736 (Sub-E5), filed June 3, 1974. Applicant: GUIGNORD FREIGHT LINES, INC., P.O. Box 26067, Charlotte, N.C. 28213. Applicant's representative: Edward G. Villalon, Suite 1032, 13th & Pennsylvania Ave. NW., Washington, D.C. 20004. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *General commodities*, except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and commodities requiring special equipment, between Asheville, N.C., on the one hand, and, on the other, points in Virginia on and south of a line beginning at the Virginia-North Carolina State line and extending along Virginia Highway 168, to junction U.S. Highway 60, to junction U.S. Highway 250, to junction U.S. Highway 11, to junction U.S. Highway 60, to junction U.S. Highway 501, to junction U.S. Highway 29 to the Virginia-North Carolina State line. The purpose of this filing is to eliminate the gateway of Concord, N.C.

No. MC 45736 (Sub-E6), filed June 3, 1974. Applicant: GUIGNORD FREIGHT LINES, INC., P.O. Box 26067, Charlotte, N.C. 28213. Applicant's representative: Edward G. Villalon, Suite 1032, 13th & Pennsylvania Ave. NW., Washington, D.C. 20004. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *General commodities*, except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and commodities requiring special equipment, between Belmont, Charlotte, Gastonia, McAdenville, Monroe, and Stanley, N.C., on the one hand, and, on the other, points in Virginia south of a line beginning at the Atlantic Ocean and extending along U.S. Highway 60 to junction U.S. Highway 250, to junction U.S. Highway 11, to the Virginia-Tennessee State line. The purpose of this filing is to eliminate the gateway of Concord, N.C.

No. MC 45736 (Sub-E7), filed June 3, 1974. Applicant: GUIGNORD FREIGHT LINES, INC., P.O. Box 26067, Charlotte, N.C. 28213. Applicant's representative: Edward G. Villalon, Suite 1032, 13th & Pennsylvania Ave. NW., Washington, D.C. 20004. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Textile commodities*: (A) from points in North Carolina within 225 miles of Concord, N.C. (except points west of a line beginning at the North Carolina-South Carolina State line and extending along North Carolina Highway 18 to junction U.S. Highway 21, to the North Carolina-Virginia State line, points in South Carolina east of U.S. Highway 221, and points in Georgia within 225 miles of Concord, N.C., (except points west of U.S. Highway 221), to Chicago, Ill. (Concord, N.C.)*; (B) from Savannah, Ga., to Chicago, Ill. (Sumter County, S.C., and Concord, N.C.)*. The purpose of this filing is to eliminate the gateways as indicated by asterisks above.

No. MC 45736 (Sub-E8), filed June 3, 1974. Applicant: GUIGNORD FREIGHT LINES, INC., P.O. Box 36067, Charlotte, N.C. 28713. Applicant's representative: Edward G. Villalon, Suite 1032, 13 & Pennsylvania Ave. NW., Washington, D.C. 20004. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Textile commodities;* (A) from points in North Carolina on, south, and east of a line beginning at the Atlantic Ocean and extending along U.S. Highway 70 to junction U.S. Highway 64, to junction U.S. Highway 21, to the North Carolina-South Carolina State line, points in Georgia within 225 miles of Concord, N.C., to Columbus, Ohio (Concord, N.C.)*; (B) from Savannah, Ga., to Columbus, Ohio (Sumter County, S.C., and Concord, N.C.)*. The purpose of this filing is to eliminate the gateways as indicated by asterisks above.

No. MC 45736 (Sub-E9), filed June 3, 1974. Applicant: GUIGNORD FREIGHT LINES, INC., P.O. Box 26067, Charlotte, N.C. 28213. Applicant's representative: Edward G. Villalon, Suite 1032, 13th & Pennsylvania Ave. NW., Washington, D.C. 20004. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Textile commodities;* (A) from points in North Carolina in and west of Anson, Iredell, Montgomery, Rowan, Stanley, Watuga, and Wilkes Counties, points in South Carolina, and points in Georgia within 225 miles of Concord, N.C., to Baltimore and Perryville, Md. (Concord, N.C.)*; (B) from Savannah, Ga., to Baltimore and Perryville, Md. (Sumter County, S.C., and Concord, N.C.)*; (C) from points in Alabama on and north of U.S. Highway 278 (except points west and north of U.S. Highways 231 and U.S. Highway 72), to Baltimore and Perryville, Md. (Sumter, S.C., and Concord, N.C.)*. The purpose of this filing is to eliminate the gateways indicated by asterisks above.

No. MC 45736 (Sub-E10), filed June 3, 1974. Applicant: GUIGNORD FREIGHT LINES, INC., P.O. Box 26067, Charlotte, N.C. 28213. Applicant's representative: Edward G. Villalon, Suite 1032, 13th and Pennsylvania Ave. NW., Washington, D.C. 20004. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Textile commodities;* (A) from points in Georgia within 225 miles of Concord, N.C., points in North Carolina in and west of Davidson, Davie, Iredell, Montgomery, Randolph, Richmond, Watuga, and Wilkes Counties, and points in South Carolina, Philadelphia, Pa., and New York, N.Y. (Concord, N.C.)*; (B) from Savannah, Ga., to Philadelphia, Pa., and New York, N.Y. (Sumter County, S.C., and Concord, N.C.)*; (C) from points in Alabama on and north of U.S. Highway 278, to Philadelphia, Pa., and New York, N.Y. (Sumter, S.C., and Concord, N.C.)*. The purpose of this filing is to eliminate the gateways as indicated by asterisks above.

No. MC 45736 (Sub-No. E11), filed June 3, 1974. Applicant: GUIGNARD FREIGHT LINES, INC., P.O. Box 26067, Charlotte, N.C. 28213. Applicant's representative: Edward G. Villalon, Suite 1032. 13th & Pennsylvania Ave. NW., Washington, D.C. 20004. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Beer*, from Philadelphia, Pa., (a) to points in South Carolina and points in Georgia within 225 miles of Concord, N.C. (Concord, N.C.)*, (b) to Savannah, Ga. (Concord, N.C., and Sumter County, S.C.)*, and (c) to points in Alabama on and north of U.S. Highway 278 (Concord, N.C., and Sumter, S.C.)*; and (2) *empty beer containers*, (a) from points in South Carolina and points in Georgia within 225 miles of Concord, N.C. to Philadelphia, Pa. (Concord, N.C.)*, (b) from Savannah, Ga., to Philadelphia, Pa. (Sumter County, S.C., and Concord, N.C.)*, and (c) from points in Alabama on and north of U.S. Highway 278 to Philadelphia, Pa. (Sumter, S.C., and Concord, N.C.)*. The purpose of this filing is to eliminate the gateways indicated by asterisks above.

No. MC 45736 (Sub-No. E12), filed June 3, 1974. Applicant: GUIGNARD FREIGHT LINES, INC., P.O. Box 26067, Charlotte, N.C. 28213. Applicant's representative: Edward G. Villalon, Suite 1032, 13th & Pennsylvania Ave. NW., Washington, D.C. 20004. Authority sought to

operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Furniture, new and furniture veneer stock*, from points in North Carolina within 225 miles of Concord, N.C. (except points east of U.S. Highway 301), and points west of a line beginning at the North Carolina-Virginia State line and extending along U.S. Highway 21 to junction North Carolina Highway 268, thence along North Carolina Highway 268 to junction U.S. Highway 321, thence along U.S. Highway 321 to the North Carolina-South Carolina State line, points in Virginia within 225 miles of Concord, N.C., which are east of U.S. Highway 21, and points in West Virginia within 225 miles of Concord, N.C., to points in Florida east of Florida Highway 71. The purpose of this filing is to eliminate the gateways of Concord, N.C., and Sumter, S.C.

No. MC 45736 (Sub-No. E13), filed June 3, 1974. Applicant: GUIGNARD FREIGHT LINES, INC., P.O. Box 26067, Charlotte, N.C. 28213. Applicant's representative: Edward G. Villalon, Suite 1032, 13th & Pennsylvania Ave. NW., Washington, D.C. 20004. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Lubricating oils and greases*, in containers, from St. Marys, W. Va.; (a) to points in Georgia within 225 miles of Concord, N.C., points in South Carolina, and points in North Carolina on and south of a line beginning at the Atlantic Ocean and extending along U.S. Highway 70 to junction U.S. Highway 17, thence along U.S. Highway 17 to junction U.S. Highway 264, thence along U.S. Highway 264 to junction North Carolina Highway 43, thence along North Carolina Highway 43 to junction U.S. Highway 64, thence along U.S. Highway 64 to junction North Carolina Highway 98, thence along North Carolina Highway 98 to junction U.S. Highway 15, thence along U.S. Highway 15 to junction U.S. Highway 64, thence along U.S. Highway 64 to junction U.S. Highway 321, thence along U.S. Highway 321 to junction North Carolina Highway 150, thence along North Carolina Highway 150 to the North Carolina-South Carolina State line (Concord, N.C.) *; and (b) to Savannah, Ga. (Concord, N.C., and Sumter County, S.C.) *. The purpose of this filing is to eliminate the gateways indicated by asterisks above.

No. MC 45736 (Sub-No. E14), filed June 3, 1974. Applicant: GUIGNARD FREIGHT LINES, INC., P.O. Box 26067, Charlotte, N.C. 28213. Applicant's representative: Edward G. Villalon, Suite 1032, 13th & Pennsylvania Ave. NW., Washington, D.C. 20004. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Hardware, plumbing supplies*, and *building materials* (except commodities requiring special equipment), from points in the New York, N.Y., commercial zone, as defined by the Commission, Baltimore and Sparrows Point, Md.; Cincinnati, Dover, and Cleveland, Ohio; Uniontown, Johnstown, Ellwood City, Philadelphia, Ambler, and Monaca, Pa.; Barba, Newark, Camden, Metuchen, and Millington, N.J.; Edgemore, Del.; and Alcoa, Tenn., to Concord, N.C. The purpose of this filing is to eliminate the gateway of Wilkes County, N.C.

No. MC 45736 (Sub-No. E15), filed June 3, 1974. Applicant: GUIGNORD FREIGHT LINES, INC., P.O. Box 26067, Charlotte, N.C. 28213. Applicant's representative: Edward G. Villalon, Suite 1032, 13th & Pennsylvania Ave. NW., Washington, D.C. 20004. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Hardware, plumbing supplies*, and *building materials* (except commodities requiring special equipment), from Cleveland and Dover, Ohio, to (a) points in South Carolina (Wilkes County and Concord, N.C.) *; and (b) Savannah, Ga. (Wilkes County and Concord, N.C., and Sumter County, S.C.) *. The purpose of this filing is to eliminate the gateways indicated by asterisks above.

No. MC 50069 (Sub-No. E74), filed May 15, 1974. Applicant: REFINERS TRANSPORT & TERMINAL CORP., 445 Earlwood Avenue, Oregon, Ohio 43616. Applicant's representative: Jack A. Gollan (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Petroleum products*, in bulk, in tank vehicles, from Latonia, Ky., and points within 10 miles thereof; (a) to points in Illinois (Seymour, Ind.) *; (b) to points in Indiana (Cleves, Ohio) *; (c) to points in Missouri within 135 miles of East St. Louis, Ill. (Cleves, Ohio, New Goshen, Ind., and East St. Louis, Ill.) *; (d) to points in Pennsylvania bounded by a line beginning at the Ohio-Pennsylvania State line and extending along U.S. Highway 22 to Blairsville, Pa., thence to the Pennsylvania-New York State line (Cincinnati, Ohio) *; (e) to points in West Virginia on and west of a line beginning at Point Pleasant, W. Va., and extending along U.S. Highway 35 to Charleston, W. Va., thence along U.S. Highway 21 to the West Virginia-Virginia State line (Ironton, Ohio) *; and (f) to points in New York on and west of a line beginning at Deposit, N.Y., thence along New York Highway 8 to Utica, N.Y., thence along New York Highway 49 to Rome, N.Y., thence along New York Highway 69 to Camden, N.Y., thence along New York Highway 13 to Port Ontario, N.Y. (Cincinnati, Ohio, and Titusville, Pa.) *. (2) *Petroleum chemicals* (except acetone, ethyl acetate, alcohol, vodka, gin, proprietary anti-freeze preparations, and choline chloride), in bulk, in tank vehicles, from Latonia, Ky., and points within ten miles thereof, to points in Iowa, Missouri, Minnesota, and Wisconsin (Cleves, Ohio, and Terre Haute, Ind.) *. (3) *Petroleum products* (except petroleum chemicals), from Latonia, Ky., and points within 10 miles thereof, to points in Virginia on and east of a line beginning at the West Virginia-Virginia State line and extending along U.S. Highway 250 to Charlottesville, thence along Virginia Highway 20 to junction U.S. Highway 15, thence along U.S. Highway 15 to the Virginia-North Carolina State line (Midland, Pa., and Congo, W. Va.) *. The purpose of this filing is to eliminate the gateways indicated by asterisks above.

No. MC 50069 (Sub-E77), filed May 15, 1974. Applicant: REFINERS TRANSPORT & TERMINAL CORPORATION, 445 Earlwood Avenue, Oregon, Ohio 43616. Applicant's representative: Jack A. Golian (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Petroleum products*, in bulk, in tank vehicles, from Lawrenceville, Illinois, and points within 10 miles thereof; (A) to points in Ohio and Kentucky east of U.S. Highway 127; (B) to points in Pennsylvania bounded by a line beginning at the Ohio-Pennsylvania State line and extending along U.S. Highway 22 to Blairsville, Pennsylvania, thence due north to the Pennsylvania-New York State line; (C) to points in West Virginia on and west of a line beginning at Sisterville, West Virginia, and extending along West Virginia Highway 18 to Troy, West Virginia, thence along West Virginia Highway 47 to Linn, West Virginia, thence along U.S. Highway 119 to Glennville, West Virginia, thence along West Virginia Highway 5 to Napier, West Virginia, thence along U.S. Highway 19 to Summersville, West Virginia, thence along West Virginia Highway 41 to junction U.S. Highway 19, thence along U.S. Highway 19 to Bluefield, West Virginia, thence to the West Virginia-Virginia State line. (2) *Petroleum chemicals*, except acetone, ethyl acetate, alcohol, vodka, gin, proprietary anti-freeze preparations, and choline chloride, in bulk, in tank vehicles, from Lawrenceville, Illinois, and points within 10 miles thereof, to points in Iowa and the Lower Peninsula of Michigan and Wisconsin. (3) *Petroleum products*, except petroleum chemicals, in bulk, in tank vehicles, from Lawrenceville, Illinois, and points within 10 miles thereof, to points in Connecticut, Delaware, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, Vermont, District of Columbia, and points in Virginia on and east of a line beginning at the Virginia-West Virginia State line and extending along Virginia Highway 30 to junction U.S. Highway 220, thence along U.S. Highway 220 to the Virginia-North Carolina State line. The purpose of this filing is to eliminate the gateways of Seymour, Indiana, in (1A) above; Seymour, Indiana, and Columbus, Ohio, in (1B) above; Seymour, Indiana, and Ironton, Ohio, in (1C) above; Terre Haute, Indiana, in (2) above; and Seymour, Indiana, East Liverpool, Ohio, Midland, Pennsylvania, and Congo, West Virginia, in (3) above.

No. MC 50069 (Sub-E78), filed May 15, 1974. Applicant: REFINERS TRANSPORT & TERMINAL CORPORATION, 445 Earlwood Avenue, Oregon, Ohio 43616. Applicant's representative: Jack

A. Gollan (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Petroleum products*, in bulk, in tank vehicles, from Robinson, Illinois, and points within 10 miles thereof; (A) to points in Kentucky east of Interstate Highway 75 and points in Ohio; (B) to points in Pennsylvania bounded by a line beginning at the Ohio-Pennsylvania State line and extending along U.S. Highway 22 to Blairsville, Pennsylvania, thence due north to the Pennsylvania-New York State line; (C) to points in West Virginia on and west of a line beginning at Sisterville, West Virginia, and extending along West Virginia Highway 18 to Troy, West Virginia, thence along West Virginia Highway 47 to Linn, West Virginia, thence along U.S. Highway 119 to Glennville, West Virginia, thence along West Virginia Highway 5 to Napier, West Virginia, thence along U.S. Highway 18 to Summersville, West Virginia, thence along West Virginia Highway 41 to junction U.S. Highway 19, thence along U.S. Highway 19 to Bluefield, West Virginia, thence to the West Virginia-Virginia State line; (D) to points in New York on and west of a line beginning at the New York-Pennsylvania State line and extending north to Deposit, N.Y., thence along N.Y. Highway 8 to Utica, N.Y., thence along N.Y. Highway 49 to Rome, N.Y., thence along N.Y. Highway 69 to Camden, N.Y., thence along N.Y. Highway 13 to Port Ontario, N.Y.

(2) *Petroleum chemicals*, except acetone, ethyl acetate, alcohol, vodka, gin, proprietary anti-freeze preparations, and choline chloride, in bulk, in tank vehicles, from Robinson, Illinois, and points within 10 miles thereof, to points in Iowa, the Lower Peninsula of Michigan, and Wisconsin. (3) *Petroleum products*, except petroleum chemicals, in bulk, in tank vehicles, from Robinson, Illinois, and points within 10 miles thereof, to points in New Jersey, Connecticut, Delaware, Massachusetts, New Hampshire, Rhode Island, Vermont, Maryland, District of Columbia, points in Virginia on and east of a line beginning at the West Virginia-Virginia State line and extending along Virginia Highway 39 to junction U.S. Highway 220, thence along U.S. Highway 220 to the Virginia-North Carolina State line. The purpose of this filing is to eliminate the gateways of Seymour, Indiana, in (1A) above; Seymour, Indiana, and Columbus, Ohio, in (1B) above; Seymour, Indiana, and Ironton, Ohio, in (1C) above; Seymour, Indiana, Columbus, Ohio, and Titusville, Pennsylvania, in (1D) above; Terre Haute, Indiana, in (2) above; Canton, Ohio, Seymour, Indiana, and Congo, West Virginia, in (3) above.

No. MC 50069 (Sub-E79), filed May 15, 1974. Applicant: REFINERS TRANSPORT & TERMINAL CORPORATION, 445 Earlwood Avenue, Oregon, Ohio 43616. Applicant's representative: Jack A. Gollan (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Petroleum products*, in bulk, in tank vehicles, from Midland, Pennsylvania, and points within 10 miles thereof, (A) to points in Illinois; (C) to points in Missouri within 135 miles of East St. Louis, Illinois. (2) *Petroleum products*, except petroleum chemicals, in bulk, in tank vehicles, from Midland, Pennsylvania, and points within 10 miles thereof, to points in Kentucky, Ohio, Wisconsin, New Jersey, New York, Tennessee, North Carolina, South Carolina, Virginia, Georgia, Alabama, Connecticut, Delaware, Massachusetts, New Hampshire, Rhode Island, Vermont, Maryland, and the District of Columbia. (3) *Petroleum chemicals*, except acetone, ethyl acetate, alcohol, vodka, gin, proprietary anti-freeze preparations, and choline chloride, in bulk, in tank vehicles, from Midland, Pennsylvania, and points within 10 miles thereof, to points in Iowa and Missouri. The purpose of this filing is to eliminate the gateways of Canton, Ohio, in (1A) above; Canton, Ohio, and Huntington County, Indiana, in (1B) above; Canton, Ohio, Huntington County, Indiana, and East St. Louis, Illinois, in (1C) above; Congo, West Virginia, in (2) above; and Canton, Ohio, Huntington County, Indiana, and Peoria, Illinois, in (3) above.

No. MC 50069 (Sub-E80), filed May 15, 1974. Applicant: REFINERS TRANSPORT & TERMINAL CORPORATION, 445 Earlwood Avenue, Oregon, Ohio 43616. Applicant's representative: Jack A. Gollan (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Petroleum products*, in bulk, in tank vehicles, from Pittsburgh, Pennsylvania, and points within 10 miles thereof; (A) to points in Illinois; (B) to points in Indiana; (C) to points in the Lower Pennsylvania of Michigan; (D) to points in Missouri within 135 miles of East St. Louis, Illinois. (2) *Petroleum products*, except petroleum chemicals, in bulk, in tank vehicles, from Pittsburgh, Pennsylvania, and points within 10 miles thereof, to points in Kentucky, Ohio, Wisconsin, Alabama, Connecticut, New Hampshire, Massachusetts, Delaware, Rhode Island, Vermont, New Jersey, New York, North Carolina, Tennessee, Georgia, Virginia, and South Carolina. (3) *Petroleum chemicals*, except acetone, ethyl acetate, alcohol, vodka, gin, proprietary anti-freeze preparations, and choline chloride, in bulk, in tank vehicles, from Pittsburgh, Pennsylvania, and points within 10 miles thereof; (A) to points in Iowa and Minnesota; (B) to points in Missouri. The purpose of this filing is to eliminate the gateways of Canton, Ohio, and Niles, Michigan, in (1A) above; Canton, Ohio, in (1B) above; Canton, Ohio, in (1C) above; Seymour, Indiana, and East St. Louis, Illinois, in (1D) above; Congo, West Virginia, in (2) above; and Canton, Ohio, Huntington County, Indiana, and Peoria, Illinois, in (3A) above; Canton, Ohio, and Terre Haute, Indiana, in (3B) above.

No. MC 50069 (Sub-E81), filed May 15, 1974. Applicant: REFINERS TRANSPORT & TERMINAL CORPORATION, 445 Earlwood Avenue, Oregon, Ohio 43616. Applicant's representative: Jack A. Gollan (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Petroleum products*, in bulk, in tank vehicles, from Lima, Ohio, and points within 10 miles thereof; (A) to points in Illinois; (B) to points in Indiana north and west of a line beginning at the Indiana-Illinois State line and extending along U.S. Highway 30 to junction U.S. Highway 31, thence along U.S. Highway 31 to the Michigan-Indiana State line; (C) to points in Missouri within 135 miles of East St. Louis, Illinois. (2) *Petroleum chemicals*, except acetone, ethyl acetate alcohol, vodka, gin, proprietary anti-freeze preparations, and choline chloride, in bulk, in tank vehicles, from Lima, Ohio, and points within 10 miles thereof, to points in Iowa and Missouri. The purpose of this filing is to eliminate the gateways of Huntington County, Indiana, in (1A) above; South Bend, Indiana, and Niles, Michigan, in (1B) above; Huntington County, Indiana, and East St. Louis, Illinois, in (1C) above; and Huntington County, Indiana, and Peoria, Illinois, in (2) above.

No. MC 50069 (Sub-E82), filed May 15, 1974. Applicant: REFINERS TRANSPORT & TERMINAL CORPORATION, 445 Earlwood Avenue, Oregon, Ohio 43616. Applicant's representative: Jack A. Gollan (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Petroleum products*, in bulk, in tank vehicles, from Findlay, Ohio, and points within 10 miles thereof; (A) to points in Illinois; (B) to points in Indiana north and west of a line beginning at the Illinois-Indiana State line and extending along U.S. Highway 30 to junction U.S. Highway 31, thence along U.S. Highway 31 to the Indiana-Michigan State line; (C) to points in Missouri within 135 miles of East St. Louis, Illinois. (2) *Petroleum chemicals*, except acetone, ethyl acetate, alcohol, vodka, gin, proprietary anti-freeze preparations, and choline chloride, in bulk, in tank vehicles, from Findlay, Ohio, and points within 10 miles thereof, to points in Iowa and Missouri. The purpose of this filing is to eliminate the gateways of Huntington County, Indiana, in (1A) above; South Bend, Indiana, and Niles, Michigan, in (1B) above; Huntington County, Indiana, and East St. Louis, Illinois, in (1C) above; and Huntington County, Indiana, and Peoria, Illinois, in (2) above.

No. MC 50069 (Sub-E83), filed May 15, 1974. Applicant: REFINERS TRANSPORT & TERMINAL CORPORATION, 445 Earlwood Avenue, Oregon, Ohio 43616. Applicant's representative: Jack A. Gollan (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Petroleum products*, in bulk, in tank vehicles, from Toledo,

Ohio and points within 10 miles thereof; (A) to points in Illinois; (B) to points in Missouri within 135 miles of East St. Louis, Illinois. (2) *Petroleum chemicals*, except acetone, ethyl acetate, alcohol, vodka, gin, proprietary anti-freeze preparations, and choline chloride, in bulk, in tank vehicles, from Toledo, Ohio, and points within 10 miles thereof, to points in Iowa west and south of a line beginning at the Iowa-South Dakota State line and extending along U.S. Highway 65 to junction U.S. Highway 20, thence along U.S. Highway 20 to junction Iowa Highway 14, thence along Iowa Highway 14 to junction U.S. Highway 30, thence along U.S. Highway 30 to the Iowa-Illinois State line and points in Missouri. The purpose of this filing is to eliminate the gateways of Huntington County, Indiana, in (1A) above; Huntington County, Indiana, and East St. Louis, Illinois, in (1B) above; and Huntington County, Indiana, and Peoria, Illinois, in (2) above.

No. MC 50069 (Sub-E84), filed May 15, 1974. Applicant: REFINERS TRANSPORT & TERMINAL CORPORATION, 445 Earlwood Avenue, Oregon, Ohio 43616. Applicant's representative: Jack A. Gollan (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Petroleum products*, in bulk, in tank vehicles, from East Chicago, Indiana, and points within 10 miles thereof; (A) to points in Ohio; (B) to points in Pennsylvania north and west of a line beginning at the Ohio-Pennsylvania north and west of a line beginning at the Ohio-Pennsylvania State line and extending along U.S. Highway 22 to Blairsville, Pennsylvania, thence due north to the Pennsylvania-New York State line; (C) to points in West Virginia south and west of a line beginning at Point Pleasant, West Virginia, and extending along U.S. Highway 35 to Charleston, West Virginia, thence along U.S. Highway 19 to the West Virginia-Virginia State line; (D) to points in Kentucky on and east of Interstate Highway 75. (2) *Petroleum products*, except petroleum chemicals, in bulk, in tank vehicles; (A) to points in Connecticut, Delaware, Massachusetts, New Hampshire, Rhode Island, Vermont, Maryland, District of Columbia, points in Virginia east of a line beginning at the West Virginia-Virginia State line, and extending along Virginia Highway 39 to junction U.S. Highway 220, thence along U.S. Highway 220 to the Virginia-North Carolina State line; (B) to points in New Jersey and New York. The purpose of this filing is to eliminate the gateways of Niles, Michigan, and Toledo, Ohio, in (1A) above; Niles, Michigan, and Toledo, Ohio, in (1B) above; Niles, Michigan, and Ironton, Ohio, in (1C) above; Niles, Michigan, East Liverpool, Ohio, Midland, Pennsylvania, and Congo, W. Virginia, in (2A) above; Niles, Michigan, Toledo, Ohio, and Petrolia, Pa., in (2B) above.

No. MC 50069 (Sub-E85), filed May 15, 1974. Applicant: REFINERS TRANSPORT & TERMINAL CORPORATION, 445 Earlwood Avenue, Oregon, Ohio 43616. Applicant's representative: Jack A. Gollan (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Petroleum products*, in bulk, in tank vehicles, from Joliet, Illinois, and points within 10 miles thereof; (A) to points in New York on and west of a line beginning at the New York-Pennsylvania State line and extending north to Deposit, N.Y., thence along N.Y. Highway 8 to Utica, N.Y., thence along N.Y. Highway 49 to Rome, N.Y., thence along N.Y. Highway 69 to Camden, N.Y., thence along N.Y. Highway 13, to Port Ontario, N.Y.; (B) to points in Ohio; (C) to points in Michigan on and east of a line beginning at the Ohio-Michigan State line and extending along U.S. Highway 217 to Lansing, Michigan, thence along Michigan Highway 43 to junction Interstate Highway 96, thence along Interstate Highway 96 to junction Michigan Highway 59, thence along Michigan Highway 59 to junction U.S. Highway 10, thence along U.S. Highway 10 to Detroit, Michigan; (D) to points in Pennsylvania bounded by a line beginning at the Ohio-Pennsylvania State line and extending along U.S. Highway 22 to Blairsville, Pennsylvania, thence due north to the Pennsylvania-New York State line; (E) to points in West Virginia bounded by a line beginning at Point Pleasant, West Virginia, and extending along U.S. Highway 35 to Charleston, West Virginia, thence along U.S. Highway 21 to the West Virginia-Virginia States line. (2) *Petroleum products*, except petroleum chemicals, in bulk, in tank vehicles, from Joliet, Illinois, and points within 10 miles thereof, to points in Connecticut, Delaware, Massachusetts, New Hampshire, Rhode Island, Vermont, Maryland, District of Columbia, and points in Virginia on and east of a line beginning at the Virginia-West Virginia State line and extending along Virginia Highway 39 to junction U.S. Highway 220, thence along U.S. Highway 220 to the Virginia-North Carolina State line. The purpose of this filing is to eliminate the gateways of Niles, Michigan, and Toledo, Ohio, and Titusville, Pennsylvania, in (A) above; Niles, Michigan, in (1B) above; South Bend, Indiana, in (1C) above; Niles, Michigan, and Toledo, Ohio, in (1D) above; Niles, Michigan, and Ironton, Ohio, in (1E) above; Niles, Michigan, East Liverpool, Ohio, Midland, Pa., and Congo, West Virginia, in (2) above.

No. MC 50069 (Sub-No. E103), filed May 15, 1974. Applicant: REFINERS TRANSPORT & TERMINAL CORPORATION, 445 Earlwood Avenue, Oregon, Ohio 43616. Applicant's representative: Jack A. Gollan (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Petroleum lubricating greases*, in bulk, in tank vehicles, from Woodhaven Village, Mich.; (A) to points in Pennsylvania; (B) to points in Connecticut, Delaware, Massachusetts, New Hampshire, New Jersey, Rhode Island, Vermont, Maryland, the District of Columbia, points in Virginia on and east of a line beginning at the Virginia-West Virginia State line and extending along Virginia Highway 39 to junction U.S. Highway 220, thence along U.S. Highway 220 to the Virginia-North Carolina State line, points in North Carolina on and east of U.S. Highway 220, and points in South Carolina on and east of U.S. Highway 25; and (C) to points in New York. The purpose of this filing is to eliminate the gateways of (A) Youngstown, Ohio; (B) Canton, Ohio, and Congo, W. Va.; and (C) Youngstown, Ohio, and Karns City, Pa.

No. MC 50069 (Sub-E107), filed May 15, 1974. Applicant: REFINERS TRANSPORT & TERMINAL CORPORATION, 445 Earlwood Avenue, Oregon, Ohio 43616. Applicant's representative: Jack A. Gollan (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Petroleum products*, except liquified petroleum gas, in bulk, in tank vehicles, from Mercer County, Pennsylvania; (A) to points in Illinois north of Interstate Highway 80; (B) to points in Illinois south of U.S. Highway 136; (C) to points in Indiana; (D) to points in the Lower Peninsula of Michigan; (E) to points in Missouri within 135 miles of East St. Louis, Illinois. (2) *Petroleum chemicals*, except acetone, ethyl acetate, alcohol, vodka, gin, proprietary anti-freeze preparations, and choline chloride, in bulk, in tank vehicles, from Mercer County, Pennsylvania; (A) to points in Iowa and Minnesota; (B) to points in Missouri. (3) *Petroleum products*, except petroleum chemicals, in bulk, in tank vehicles, from Mercer County, Pennsylvania, to points in Kentucky, Wisconsin, Alabama, Georgia, points in Virginia on and east of a line beginning at the Virginia-West Virginia State line and extending along Virginia Highway 39 to junction U.S. Highway 220, thence along U.S. Highway 220 to the Virginia-North Carolina State line, points in North Carolina on and east of U.S. Highway 220, points in South Carolina and points in Tennessee. The purpose of this filing is to eliminate the gateways of Toledo, Ohio, and Niles, Michigan, in (1A) above; Canton, Ohio, and Huntington County, Indiana, in (1B) above; Canton, Ohio, in (1C) above; Toledo, Ohio, in (1D) above; Canton, Ohio, New Goshen, Indiana, and East St. Louis, Illinois, in (1E) above; Canton, Ohio, Huntington County, Indiana, and Peoria, Illinois, in (2A) above; Canton, Ohio, and Terre Haute, Indiana, in (2B) above; East Liverpool, Ohio, Midland, Pennsylvania, and Congo West Virginia, in (3) above;

No. MC 52657 (Sub-No. E41) (Correction), filed June 4, 1974, published in the FEDERAL REGISTER July 8, 1975. Applicant: ARCO AUTO CARRIERS, INC., 2140 W. 79th Street, Chicago, Ill. 60620. Applicant's representative: S. J. Zangri (same

as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Truck bodies;* (2) between points in Kansas, on the one hand, and, on the other, points in Connecticut, Delaware, Florida (except that part west of a line beginning at the Georgia-Florida State line near Edith, Ga., thence along U.S. Highway 441 to junction Florida Highway 247, thence along Florida Highway 247 to junction U.S. Highway 129, thence along U.S. Highway 129 to junction Florida Highway 345, thence along Florida Highway 345 to the Gulf of Mexico near Cedar Key, Fla.), Georgia (except that part west of a line beginning at the North Carolina-Georgia State line near Sweetgum, thence along Georgia Highway 60 to junction U.S. Highway 129, thence along U.S. Highway 129 to junction Interstate Highway 75, thence along Interstate Highway 75 to the Georgia-Florida State line), Maine, Maryland, Massachusetts, Michigan (Lower Peninsula), New Hampshire, New Jersey, New York, North Carolina, Pennsylvania, Rhode Island, South Carolina, Tennessee (except that part west of a line beginning at the Tennessee-Georgia State line near Conasanga, Tenn., thence along U.S. Highway 441 to junction Tennessee Highway 163, thence along Tennessee Highway 163 to junction U.S. Highway 11, thence along U.S. Highway 11 to junction Tennessee Highway 33, thence along Tennessee Highway 33 to the Virginia-Tennessee State line near Kyles Ford, Tenn.), Vermont, Virginia, West Virginia, and the District of Columbia. The purpose of this filing is to eliminate the gateway of Mattoon, Ill. The purpose of this partial correction is to correct the highway description. The remainder of this letter-notice remains as previously published.

No. MC 60014 (Sub-No. E27), filed June 4, 1974. Applicant: AERO TRUCKING, INC., P.O. Box 308, Monroeville, Pa. 15146. Applicant's representative: William J. Rorison (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Commodities*, requiring special equipment, restricted to that, or provided that, the loading or unloading, which necessitate the special equipment, is performed by the consignor or consignee, or both, between those points in Pennsylvania on and west of a line beginning at the New York-Pennsylvania State line and extending along Pennsylvania Highway 14 to junction Pennsylvania Highway 154, thence along Pennsylvania Highway 154 to junction U.S. Highway 220, thence along U.S. Highway 220 to junction Pennsylvania Highway 42, thence along Pennsylvania Highway 42 to junction Pennsylvania Highway 239, thence along Pennsylvania Highway 239 to junction Pennsylvania Highway 93, thence along Pennsylvania Highway 93 to junction U.S. Highway 209, thence along U.S. Highway 209 to junction Pennsylvania Highway 248, thence along Pennsylvania Highway 248 to junction U.S. Highway 22, thence along U.S. Highway 22 to the Pennsylvania-New York State line, on the one hand, and, on the other, points in Connecticut. The purpose of this filing is to eliminate the gateways of points in New York within 10 miles of Greenwich, Conn., and Greenwich, Conn.

No. MC 60014 (Sub-No. E28), filed June 4, 1974. Applicant: AERO TRUCKING, INC., P.O. Box 308, Monroeville, Pa. 15146. Applicant's representative: William J. Rorison (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Commodities*, requiring special equipment, restricted so that or provided that, the loading or unloading, which necessitate the special equipment, is performed by the consignor or consignee or both, between those points in Pennsylvania on and south of a line beginning at the Ohio-Pennsylvania State line and extending along Pennsylvania Highway 358 to junction U.S. Highway 62, thence along U.S. Highway 62 to junction U.S. Highway 6, thence along U.S. Highway 6 to junction Pennsylvania Highway 321, thence along Pennsylvania Highway 321 to junction U.S. Highway 219, thence along U.S. Highway 219 to junction Pennsylvania Highway 255, thence along Pennsylvania Highway 255 to junction Pennsylvania Highway 120, thence along Pennsylvania Highway 120 to junction U.S. Highway 220, thence along U.S. Highway 220 to junction Pennsylvania Highway 118, thence along Pennsylvania Highway 118 to junction Pennsylvania Highway 309, thence along Pennsylvania Highway 309 to junction U.S. Highway 11, thence along U.S. Highway 11 to junction U.S. Highway 6, thence along U.S. Highway 6 to junction Pennsylvania Highway 652, thence along Pennsylvania Highway 652 to the New York-Pennsylvania State line, on the one hand, and, on the other, points in Maine, and between points in Pennsylvania, on the one hand, and, on the other, those points in Maine on and east of a line beginning at the United States-Canada International Boundary line and extending along U.S. Highway 201 to junction U.S. Highway 2, thence along U.S. Highway 2 to junction Maine Highway 156, thence along Maine Highway 156 to junction Maine Highway 133, thence along Maine Highway 133 to junction Maine Highway 140, thence along Maine Highway 140 to junction Maine Highway 117, thence along Maine Highway 117 to junction U.S. Highway 302, thence along U.S. Highway 302 to the Maine-New Hampshire State line. The purpose of this filing is to eliminate the gateways of points in New York within 10 miles of Greenwich, Conn., Greenwich, and points within 35 miles of Boston, Mass.

No. MC 60014 (Sub-No. E51), filed June 4, 1974. Applicant: AERO TRUCKING, INC., P.O. Box 308, Monroeville, Pa. 15146. Applicant's representative: William J. Rorison (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Commodities*, requiring special equipment, restricted so that, or provided that, the loading or unloading, which necessitate the special equipment, is performed by the consignor or consignee or both, (1) between those points in New York on and south of a line beginning at the Pennsylvania-New York State line and extending along New York Highway 79 to junction New York Highway 17, thence along New York Highway 17 to junction New York Highway 97, thence along New York Highway 97 to junction U.S. Highway 6, thence along U.S. Highway 6 to junction Interstate Highway 87, thence along Interstate Highway 87 to junction U.S. Highway 1, thence along U.S. Highway 1 to the New York-Connecticut State line, on the one hand, and, on the other, those points in Connecticut on and east of a line beginning at the New York-Connecticut State line and extending along Connecticut Highway 15 to junction Interstate Highway 91, thence along Interstate Highway 91 to the Connecticut-Massachusetts State line; and (2) between those points in New York on and south of a line beginning at the New Jersey-New York State line and extending along U.S. Highway 202 to junction Interstate Highway 87, thence along Interstate Highway 87 to junction U.S. Highway 1, thence along U.S. Highway 1 to the New York-Connecticut State line, on the one hand, and, on the other, points in Connecticut; and (3) between those points in New York on and south of a line beginning at Lake Ontario and extending along New York Highway 31, thence along New York Highway 31 to junction New York Highway 96, thence along New York Highway 96 to junction U.S. Highway 20, thence along U.S. Highway 20 to junction Interstate Highway 81, thence along Interstate Highway 81 to the New York-Pennsylvania State line, on the one hand, and, on the other, those points in Connecticut on and east of a line beginning at the New York-Connecticut State line and extending along Interstate Highway 84 to junction Connecticut Highway 8, thence along Connecticut Highway 8 to junction U.S. Highway 6/202, thence along U.S. Highway 6/202 to junction Interstate Highway 84, thence along Interstate Highway 84 to junction Interstate Highway 91, thence along Interstate Highway 91 to junction Connecticut Highway 159, thence along Connecticut Highway 159 to the Connecticut-Massachusetts State line. The purpose of this filing is to eliminate the gateways of points in New York within 10 miles of Greenwich, Conn., and Greenwich, Conn.

No. MC 60014 (Sub-No. E78), filed June 4, 1974. Applicant: AERO TRUCKING, INC., P.O. Box 308, Monroeville, Pa. 15146. Applicant's representative: William J. Rorison (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Iron and steel articles*, which by reason of size or weight require the use of special equipment, (1) between those points in West Virginia on and north of a line beginning at the Ohio-West Virginia State line and ex-

tending along West Virginia Highway 47 to junction U.S. Highway 33/119, thence along U.S. Highway 33/119 to junction U.S. Highway 33, thence along U.S. Highway 33 to the West Virginia-Virginia State line, on the one hand, and, on the other, points in Mississippi; (2) between those points in West Virginia on and north of a line beginning at the Ohio-West Virginia State line and extending along U.S. Alternate Highway 50 to junction U.S. Highway 50, thence along U.S. Highway 50 to junction West Virginia Highway 20, thence along West Virginia Highway 20 to junction U.S. Highway 119, thence along U.S. Highway 119 to junction U.S. Highway 19, thence along U.S. Highway 19 to junction U.S. Highway 33, thence along U.S. Highway 33 to the West Virginia-Virginia State line, on the one hand, and, on the other, those points in Tennessee on and west of a line beginning at the Kentucky-Tennessee State line and extending along U.S. Highway 27 to junction Tennessee Highway 62, thence along Tennessee Highway 62 to junction Tennessee Highway 84, thence along Tennessee Highway 84 to junction Tennessee Highway 111, thence along Tennessee Highway 111 to junction Tennessee Highway 56, thence along Tennessee Highway 56 to the Tennessee-Alabama State line; (3) between those points in West Virginia on and north of a line beginning at the Ohio-West Virginia State line and extending along U.S. Alternate Highway 50 to junction U.S. Highway 50, thence along U.S. Highway 50 to the West Virginia-Maryland State line, on the one hand, and, on the other, points in Alabama.

(4) Between those points in West Virginia on and north of a line beginning at the Ohio-West Virginia State line and extending along West Virginia Highway 7 to junction U.S. Highway 250, thence along U.S. Highway 250 to junction U.S. Highway 33, thence along U.S. Highway 33 to the West Virginia-Virginia State line, on the one hand, and, on the other, those points in Kentucky on and west of a line beginning at the Ohio-Kentucky State line and extending along U.S. Highway 27 to junction U.S. Highway 27/68, thence along U.S. Highway 27/68 to junction U.S. Highway 27, thence along U.S. Highway 27 to the Kentucky-Tennessee State line; and (5) between those points in West Virginia on and north of a line beginning at the West Virginia-Ohio State line and extending along West Virginia Highway 95 to junction West Virginia Highway 47, thence along West Virginia Highway 47 to junction U.S. Highway 33/119, thence along U.S. Highway 33/119 to junction U.S. Highway 33, thence along U.S. Highway 33 to the West Virginia-Virginia State line, on the one hand, and, on the other, those points in Alabama on and west of a line beginning at the Alabama-Tennessee State line and extending along U.S. Highway 231/431 to junction U.S. Alternate Highway 72, thence along U.S. Alternate Highway 72 to junction U.S. Highway 31, thence along U.S. Highway 31 to junction Interstate Highway 65, thence along Interstate Highway 65 to junction Alabama Highway 69, thence along Alabama Highway 69 to junction Alabama Highway 14, thence along Alabama Highway 14 to junction Alabama Highway 10, thence along Alabama Highway 10 to junction Alabama Highway 47, thence along Alabama Highway 47 to junction Alabama Highway 83, thence along Alabama Highway 83 to junction Alabama Highway 84, thence along Alabama Highway 84 to the Alabama-Georgia State line. The purpose of this filing is to eliminate the gateways of Wheeling and Beechbottom, W. Va.

No. MC 60014 (Sub-No. E81), filed June 4, 1974. Applicant: AERO TRUCKING, INC., P.O. Box 308, Monroeville, Pa. 15146. Applicant's representative: William J. Rorison (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Commodities*, the transportation of which, by reason of their size or weight, requires the use of special equipment, between those points in West Virginia on, north and east of a line beginning at the Ohio-West Virginia State line and extending along U.S. Alternate Highway 50 to junction West Virginia Highway 16, thence along West Virginia Highway 16 to junction West Virginia Highway 5, thence along West Virginia Highway 5 to junction U.S. Highway 19, thence along U.S. Highway 19 to junction U.S. Highway 60, thence along U.S. Highway 60 to the West Virginia-Virginia State line, on the one hand, and, on the other, those points in the Upper Peninsula of Michigan, and between points in West Virginia, on the one hand, and, on the other, those points in the Upper Peninsula of Michigan on and north of a line beginning at the United States-Canada International Boundary line and extending along Interstate Highway 75 to junction U.S. Highway 2, thence along U.S. Highway 2 to the Michigan-Wisconsin State line. The purpose of this filing is to eliminate the gateways of Brooke, Hancock, Marshall and Ohio Counties, W. Va., Columbiana, Cuyahoga, Mahoning, Summit, and Trumbull Counties, Ohio, and points in that part of Ohio on and east of a line extending from Mansfield to Pomeroy, Ohio, along Ohio Highway 13 to junction thereof with U.S. Highway 33, thence along U.S. Highway 33 to Pomeroy, and, on and south of U.S. Highway 30 extending from Mansfield to the Ohio-West Virginia State line.

No. MC 60014 (Sub-No. E83), filed June 4, 1974. Applicant: AERO TRUCKING, INC., P.O. Box 308, Monroeville, Pa. 15146. Applicant's representative: William J. Rorison (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Commodities*, the transportation of which, by reason of size or weight, require the use of special equipment, between points in Illinois, on the one hand, and, on the other, those points in Delaware, New Jersey, New York, Pennsylvania, those in West Virginia north and east of a line beginning at the Ohio-West Virginia State line and extending along West Virginia Highway 7 to junction U.S. Highway 250, thence along U.S. Highway 250 to junction U.S. Highway 119/250, thence along U.S. Highway 119/250 to junction U.S. Highway 250, thence along U.S. Highway 250 to the West Virginia-Virginia State line, and the District of Columbia. The purpose of this filing is to eliminate the gateways of Columbiana, Cuyahoga, Mahoning, Summit and Trumbull Counties, Ohio, points in Pennsylvania on and west of a line extending from the Pennsylvania-Maryland State line north along unnumbered highway to York, Pa., thence along Interstate Highway 83 (formerly U.S. Highway 111) to Harrisburg, Pa., thence along Pennsylvania Highway 147 (formerly portion Pennsylvania Highway 14) to junction U.S. Highway 220, (formerly portion Pennsylvania Highway 14), thence along U.S. Highway 220 to junction U.S. Highway 15 (formerly portion Pennsylvania Highway 14), thence along U.S. Highway 15 to Trout Run, Pa., thence along U.S. Highway 15 to the Pennsylvania-New York State line, and Brooke, Hancock, Marshall and Ohio Counties, W. Va.

No. MC 65941 (Sub-No. E3), filed April 11, 1974. Applicant: TOWER LINES, INC., P.O. Box 6010, Wheeling, W. Va. 26003. Applicant's representative: George V. Thieroff (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Textiles, textile products, chemicals, and lumber*, from points in North Carolina and South Carolina on, north and west of U.S. Highway 1, and points in Georgia on and north of a line beginning at the Atlantic Ocean and extending along U.S. Highway 80 to junction U.S. Highway 280, thence along U.S. Highway 280 to the Georgia-Alabama State line, to points in Pennsylvania south and west of a line beginning at the Ohio-Pennsylvania State line and extending along U.S. Highway 422 to junction Pennsylvania Highway 66, thence along Pennsylvania Highway 66 to junction U.S. Highway 119, thence along U.S. Highway 119 to the Pennsylvania-West Virginia State line, restricted against the transportation of traffic from points in Vance, Granville, Persan, Coswell, Forsyth, Gulford, Alamance, Orange, Rockingham, Stokes, Surry, Yadkin, Durham, Franklin, and Wake Counties, N.C., to points in Fayette County, Pa. The purpose of this filing is to eliminate the gateway of Wheeling, W. Va.

No. MC 65941 (Sub-No. E16), filed May 9, 1974. Applicant: TOWER LINES, INC., P.O. Box 6010, Wheeling, W. Va. 26003. Applicant's representative: George V. Thieroff (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Iron and steel articles*, as defined by the Commission, from points in Ashtabula, Lake, Geauga, Trumbull, Mahoning, Belmont, Wayne,

Medina, Lorain, Portage, Carroll, Jefferson, Harrison, Summit, Cuyahoga, Erie, and Huron Counties, Ohio, points in Monongalia, Marion, Tyler, Ohio, Hancock, Harrison, Wetzel, Marshall, and Brooke Counties, W. Va., and points in Pennsylvania on and west of U.S. Highway 219, to points in Tennessee east of U.S. Highway 31; and (2) *steel flooring grates*, from Nashville, Tenn., to the origin territory described in (1) above. The purpose of this filing is to eliminate the gateway of Wheeling, W. Va.

No. MC 78228 (Sub-No. E66), filed May 30, 1975. Applicant: J. MILLER EXPRESS, INC., 152 Wabash St., Pittsburgh, Pa. 15220. Applicant's representative: Thomas M. Mulroy, 2310 Grant Bldg., Pittsburgh, Pa. 15219. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Foundry sand additives* (except in bulk), from those points in Ohio on, south, and west of a line beginning at Lake Erie, and extending along Ohio Highway 57 to junction Interstate Highway 80, thence along Interstate Highway 80 to junction Ohio Highway 8, thence along Ohio Highway 8 to junction Ohio Highway 303, thence along Ohio Highway 303 to Hudson, Ohio, thence along Ohio Highway 91 to Canton, Ohio, thence along Interstate Highway 77 to the Ohio River, to those points in New York on and east of a line beginning at Lake Ontario and extending along the Niagara River to Lake Erie, thence along Lake Erie along New York Highway 75 to Hamburg, N.Y., thence along U.S. Highway 62 to the Pennsylvania-New York State line and on and west of New York Highway 12. The purpose of this filing is to eliminate the gateway of Wadsworth, Ohio.

No. MC 78228 (Sub-No. E67), filed May 30, 1975. Applicant: J. MILLER EXPRESS, INC., 152 Wabash St., Pittsburgh, Pa. 15220. Applicant's representative: Thomas M. Mulroy, 2310 Grant Bldg., Pittsburgh, Pa. 15219. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Foundry sand additives* (except in bulk), from Cleveland, Ohio, and those points in Ohio on and east of a line beginning at Lake Erie and extending along U.S. Highway 42 to Medina, Ohio, thence along Ohio Highway 3 to Wooster, Ohio, thence along U.S. Highway 250 to junction Interstate Highway 77, thence along Interstate Highway 77 to the Ohio-West Virginia State line to Ft. Wayne, Ind., and those points in Allen, Whitley, Kosciusko, Elkhart, St. Joseph, Marshall, LePorte, Porter, and Lake Counties, Ind., north of U.S. Highway 30. The purpose of this filing is to eliminate the gateway of Wadsworth, Ohio.

No. MC 78228 (Sub-No. E69), filed May 30, 1975. Applicant: J. MILLER EXPRESS, INC., 152 Wabash St., Pittsburgh, Pa. 15220. Applicant's representative: Thomas M. Mulroy, 2310 Grant Bldg., Pittsburgh, Pa. 15219. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Foundry sand additives* (except in bulk), from those points in Ohio on and bounded by a line beginning at Lake Erie, and extending along Ohio Highway 91 to junction U.S. Highway 224, thence along U.S. Highway 224 to junction Ohio Highway 18, thence along Ohio Highway 18 to junction U.S. Highway 25, thence along U.S. Highway 25 to junction Interstate Highway 475, thence along Interstate Highway 475 to the Ohio-Michigan State line to Lake Erie, thence along Lake Erie to the origin points to points in West Virginia (except points in Brooke, Cabell, and Hancock Counties and points north of U.S. Highway 60). The purpose of this filing is to eliminate the gateway of Wadsworth, Ohio.

No. MC 78228 (Sub-No. E70)., filed May 30, 1975. Applicant: J. MILLER EXPRESS, INC., 152 Wabash St., Pittsburgh, Pa. 15220. Applicant's representative: Thomas M. Mulroy, 2310 Grant Bldg., Pittsburgh, Pa. 15219. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Foundry sand additives* (except in bulk), from those points in Ohio on, south, and east of a line beginning at the Pennsylvania-Ohio State line and extending along U.S. Highway 322 to junction Ohio Highway 45, thence along Ohio Highway 45 to junction Ohio Highway 88, thence along Ohio Highway 88 to junction Ohio Highway 59, thence along Ohio Highway 59 to junction Ohio Highway 18, thence along Ohio Highway 18 to junction Interstate Highway 71, thence along Interstate Highway 71 to junction Ohio Highway 89, thence along Ohio Highway 89 to junction Ohio Highway 95, thence along Ohio Highway 95 to junction Ohio Highway 179, thence along Ohio Highway 179 to junction Ohio Highway 60, thence along Ohio Highway 60 to junction Ohio Highway 37, thence along Ohio Highway 37 to junction Ohio Highway 78, thence along Ohio Highway 78 to junction Ohio Highway 377, thence along Ohio Highway 377 to junction U.S. Alternate Highway 50, thence along U.S. Alternate Highway 50 to junction Ohio Highway 329, thence along Ohio Highway 329 to junction Ohio Highway 144, and thence along Ohio Highway 144 to the Ohio-West Virginia State line, to points in Michigan. The purpose of this filing is to eliminate the gateway of Wadsworth, Ohio.

No. MC 78228 (Sub-No. E71), filed May 30, 1975. Applicant: J. MILLER EXPRESS, INC., 152 Wabash Street, Pittsburgh, Pa. 15220. Applicant's representative: Thomas M. Mulroy, 2310 Grant Bldg., Pittsburgh, Pa. 15219. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Foundry sand additives* (except in bulk), from those points in Ohio on and east of a line beginning at Cleveland, Ohio, and extending along U.S. Highway 42 to junction Ohio Highway 89, thence along Ohio Highway 89 to junction Ohio Highway 95, thence along Ohio Highway 95 to junction Ohio Highway 179, thence along Ohio Highway 179 to junction Ohio Highway 60, thence along Ohio Highway 60 to junction Ohio Highway 37, thence along Ohio Highway 37 to junction Ohio Highway 377, thence along Ohio Highway 377 to junction U.S. Alternate Highway 50, thence along U.S. Alternate Highway 50 to junction Ohio Highway 329, thence along Ohio Highway 329 to junction Ohio Highway 144, and thence along Ohio Highway 144 to the Ohio-West Virginia State line, to those points in Michigan on, north, or west of a line beginning at Detroit, Mich., and extending along U.S. Highway 12 to junction U.S. Highway 27, and thence along U.S. Highway 27 to the Michigan-Ohio State line. The purpose of this filing is to eliminate the gateway of Wadsworth, Ohio.

No. MC 78228 (Sub-No. E72), filed May 30, 1975. Applicant: J. MILLER EXPRESS, INC., 152 Wabash St., Pittsburgh, Pa. 15220. Applicant's representative: Thomas M. Mulroy, 2310 Grant Bldg., Pittsburgh, Pa. 15219. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Foundry sand additives* (except in bulk), from those points in Ohio on and east of a line beginning at Lake Erie and extending along Ohio Highway 58 to junction U.S. Highway 42, thence along U.S. Highway 42 to junction U.S. Highway 23, thence along U.S. Highway 23 to junction U.S. Highway 50, thence along U.S. Highway 50 to junction Ohio Highway 41, thence along Ohio Highway 41 to the Ohio-Kentucky State line, to those points in Michigan on and north of a line beginning at Lake Huron and extending along Michigan Highway 55 to junction Michigan Highway 66, thence along Michigan Highway 66 to junction Michigan Highway 42, thence along Michigan Highway 42 to junction Michigan Highway 37, thence along Michigan Highway 37 to junction Michigan Highway 115, and thence along Michigan Highway 115 to Lake Michigan. The purpose of this filing is to eliminate the gateway of Wadsworth, Ohio.

No. MC 78228 (Sub-No. E73), filed May 30, 1975. Applicant: J. MILLER EXPRESS, INC., 152 Wabash St., Pittsburgh, Pa. 15220. Applicant's representative: Thomas M. Mulroy, 2310 Grant Bldg., Pittsburgh, Pa. 15219. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Foundry sand additives*, from those points in Ohio on and west of a line beginning at Lake Erie, thence along Ohio Highway 45 to Warren, Ohio, thence along Ohio Highway 5 to junction Ohio Highway 225, thence along Ohio Highway 225 to Alliance, Ohio, thence along Ohio Highway 183 to junction Ohio Highway 800 to Dover, Ohio, thence along Ohio Highway 39 to junction Ohio Highway 93, thence along Ohio Highway 93 to junction U.S. Highway 36, thence along U.S. Highway 36 to junction Ohio Highway 79, thence along Ohio Highway 79 to junction Ohio Highway 668, thence

along Ohio Highway 668 to junction U.S. Highway 22, thence along U.S. Highway 22 to Lancaster, thence along Ohio Highway 159 to Chillicothe, thence along U.S. Highway 50 to junction Ohio Highway 41, thence along Ohio Highway 41 to the Ohio-Kentucky State line to those points in Delaware on and south of a line beginning at the Delaware-Maryland State line, thence along Delaware Highway 44 to Pearson, Del., thence along Delaware Highway 8 to the Delaware River, restricted against the transportation of liquid commodities in bulk, in tank vehicles. The purpose of this filing is to eliminate the gateway of Wadsworth, Ohio.

No. MC 78228 (Sub-No. E74), filed May 30, 1975. Applicant: J. MILLER EXPRESS, INC., 152 Wabash St., Pittsburgh, Pa. 15220. Applicant's representative: Thomas M. Mulroy, 2310 Grant Bldg., Pittsburgh, Pa. 15219. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Foundry sand additives*, from points in Ohio (except points in Ashtabula County), to points in Rhode Island, restricted against the transportation of liquid commodities in bulk, in tank vehicles. The purpose of this filing is to eliminate the gateway of Wadsworth, Ohio.

No. MC 78228 (Sub-No. E75), filed May 30, 1975. Applicant: J. MILLER EXPRESS, INC., 152 Wabash St., Pittsburgh, Pa. 15220. Applicant's representative: Thomas M. Mulroy, 2310 Grant Bldg., Pittsburgh, Pa. 15219. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Foundry sand additives*, from points in Ohio (except points in Ashtabula and Lake Counties), to points in Vermont, restricted against the transportation of liquid commodities in bulk, in tank vehicles. The purpose of this filing is to eliminate the gateway of Wadsworth, Ohio.

No. MC 78228 (Sub-No. E76), filed May 30, 1975. Applicant: J. MILLER EXPRESS, INC., 152 Wabash St., Pittsburgh, Pa. 15220. Applicant's representative: Thomas M. Mulroy, 2310 Grant Bldg., Pittsburgh, Pa. 15219. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Foundry sand additives*, from points in Ohio (except points in Ashtabula County), to points in Vermont on and north of a line beginning at Lake Champlain, thence along U.S. Highway 2 to the Vermont-New Hampshire State line, restricted against the transportation of liquid commodities in bulk, in tank vehicles. The purpose of this filing is to eliminate the gateway of Wadsworth, Ohio.

No. MC 78228 (Sub-No. E77), filed May 30, 1975. Applicant: J. MILLER EXPRESS, INC., 152 Wabash St., Pittsburgh, Pa. 15220. Applicant's representative: Thomas M. Mulroy, 2310 Grant Bldg., Pittsburgh, Pa. 15219. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Foundry sand additives*, from points in Ohio (except points in Ashtabula County, Ohio), to points in New Hampshire, restricted against the transportation of liquid commodities in bulk. The purpose of this filing is to eliminate the gateway of Wadsworth, Ohio.

No. MC 78228 (Sub-No. E78), filed May 30, 1975. Applicant: J. MILLER EXPRESS, INC., 152 Wabash St., Pittsburgh, Pa. 15220. Applicant's representative: Thomas M. Mulroy, 2310 Grant Bldg., Pittsburgh, Pa. 15219. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Foundry sand additives*, from points in Ohio to those points in Maine on, north, and east of a line beginning at the Atlantic Ocean, near Belfast, Maine, thence along Maine Highway 137 to junction U.S. Highway 201, thence along U.S. Highway 201 to the United States-Canada International Boundary line, restricted against the transportation of liquid commodities in bulk, in tank vehicles. The purpose of this filing is to eliminate the gateway of Wadsworth, Ohio.

No. MC 78228 (Sub-No. E79), filed May 30, 1975. Applicant: J. MILLER EXPRESS, INC., 152 Wabash St., Pittsburgh, Pa. 15220. Applicant's representative: Thomas M. Mulroy, 2310 Grant Bldg., Pittsburgh, Pa. 15219. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Foundry sand additives*, from points in Ohio (except points in Ashtabula County, Ohio), to points in Maine, restricted against the transportation of liquid commodities in bulk, in tank vehicles. The purpose of this filing is to eliminate the gateway of Wadsworth, Ohio.

No. MC 78228 (Sub-No. E81), filed May 30, 1975. Applicant: J. MILLER EXPRESS, INC., 152 Wabash Street, Pittsburgh, Pa. 15220. Applicant's representative: Thomas M. Mulroy, 2310 Grant Bldg., Pittsburgh, Pa. 15219. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Foundry sand additives*, from those points in Pennsylvania west of a line beginning at the Ohio-Pennsylvania State line, thence along U.S. Highway 422 to New Castle, Pa., thence along Pennsylvania Highway 18 to Rochester, Pa., thence along Pennsylvania Highway 68 to the Ohio-Pennsylvania State line to points in Maine, restricted against the transportation of liquid commodities in bulk, in tank vehicles. The purpose of this filing is to eliminate the gateway of Wadsworth, Ohio.

No. MC 78228 (Sub-No. E82), filed May 30, 1975. Applicant: J. MILLER EXPRESS, INC., 152 Wabash Street, Pittsburgh, Pa. 15220. Applicant's representative: Thomas M. Mulroy, 2310 Grant Bldg., Pittsburgh, Pa. 15219. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Foundry sand additives*, from those points in Pennsylvania on, south, and west of a line beginning at the Ohio-Pennsylvania State line and extending along U.S. Highway 6 to Meadville, Pa., thence along U.S. Highway 322 to Franklin, Pa., thence along Pennsylvania Highway 8 to junction Pennsylvania Highway 308, thence along Pennsylvania Highway 308 to junction Pennsylvania Highway 8, thence along Pennsylvania Highway 8 to Pittsburgh, Pa., thence along Pennsylvania Highway 88 to the Pennsylvania-West Virginia State line to those points in Maine on, north, and east of a line beginning at the United States-Canada International Boundary line, thence along Interstate Highway 95 to junction Maine Highway 212, thence along Maine Highway 212 to junction Maine Highway 11, thence along Maine Highway 11 to the United States-Canada International Boundary line, restricted against the transportation of liquid commodities in bulk in tank vehicles. The purpose of this filing is to eliminate the gateway of Wadsworth, Ohio.

No. MC 92983 (Sub-No. E17), filed June 4, 1974. Applicant: AMERICAN BULK TRANSPORT CO., Kansas City, Mo. 64142. Applicant's representative: H. B. Foster (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Soybean oil, corn oil, and salad oils*, in bulk, in tank vehicles, from Memphis, Tenn., to points in North Dakota and South Dakota; (2) *animal fats and oils*, in bulk, in tank vehicles, (a) from Memphis, Tenn., to points in Arodstock and Washington Counties, Me., and (b) from Memphis, Tenn., to points in the Upper Peninsula of Michigan; (3) *fats and oils and blends thereof*, in bulk, in tank vehicles, (a) from Memphis, Tenn., to points in Nevada, (b) from Memphis, Tenn., to points in Idaho, Oregon, Washington, and Wyoming, (c) from Memphis, Tenn., to points in California, and (d) from Memphis, Tenn., to Keokuk and Clinton, Iowa; (4) *corn syrup*, in bulk, in tank vehicles, (a) from Memphis, Tenn., to points in Franklin and Clinton Counties, N.Y., (b) from Memphis, Tenn., to points in South Dakota and North Dakota, (c) from Memphis, Tenn., to points in Minnesota, (d) from Memphis, Tenn., to points in Tennessee located in Hamilton, Meigs, Bradley, McMinn, Polk, Monroe, Blount, Sevier, Cocke, Green, Washington, Sullivan, Johnson, Carter, and Unicorn Counties, (e) from Memphis, Tenn., to points in Florida, (f) from Memphis, Tenn., to points in Iowa located west of Winneshiek, Fayette, Black Hawk, Tama, Poweshiek, Mahaska, Monroe, and Appanoose Counties, (g) from Memphis, Tenn., to points located in, north, and west of Miami, Franklin, Osage, Lyon, Chase, Marion, Harvey, Sedgewick, Kingman, and Harper Counties, Kans., (h) from Memphis, Tenn., to points in Colorado and Nebraska, (i) from Memphis, Tenn., to points in California, Oregon, and Washington, and (j) from Memphis, Tenn., to points in Kansas located in and west of Brown, Jackson, Shawnee, Osage, Coffey, Woodson, Neosho, and Labette Counties;

(5) *Dry and liquid chemicals*, in bulk, in tank vehicles, (a) from points in Tennessee (except Knoxville) to points in Wisconsin located in and west of Iron, Price, Taylor, Clark, Jackson, Juneau, Sauk, Iowa, and LaFayette Counties, (b) from points in Tennessee located in and south and west of Dyer, Crockett, Madison, Chester, and McNairy to points in Wisconsin located in, north, and west of Manitowoc, Calumet, Fon Du Lac, Dodge, Dane, and Green Counties, (c) from points in Tennessee located in Shelby County to points in Wisconsin (except Kenosha County), (d) from points in Tennessee (except Knoxville) to points in Iowa (except Fremont County), and (e) from points in Tennessee (except Shelby County and Knoxville) to points in Iowa; (6) *dry chemicals*, in bulk, (a) from points in Tennessee (except Knoxville), located in, north, and east of Bradley, McMinn, Loudon, Anderson, and Campbell Counties, to points in Colorado located in and west of Mesa, Delta, Montrose, Ouray, San Juan, and La Plata Counties, (b) from points in Tennessee (except Knoxville) to points in Idaho and Montana, (c) from points in Tennessee (except Knoxville), to points in California located in and north of Mono, Tuolumne, Mariposa, Stanislaus, Alameda, and San Mateo Counties, (d) from points in Tennessee (except Knoxville) located in, north, and east of Dyer, Crockett, Madison, Chester, and McNairy Counties to points in California, (e) from points in Tennessee (except Knoxville) located in and east of Hancock, Grainger, Knox, Loudin, McMinn, and Bradley Counties, to points in Arizona and points in New Mexico located in, north, and west of Hidalgo, Grant, Sierra, Socorro, Torrance, Santa Fe, Mora, and Colfax Counties, (f) from points in Tennessee (except Knoxville) located in, north, and east of Hamilton, Sequatche, Warren, Cannon, Rutherford, Davidson, Cheatham, and Montgomery Counties to points in Arizona located in Maricopa, Gila, and Apache Counties to points in New Mexico located in McKinley, Sandoval, Los Alamos, Rio Arriba, and San Juan Counties.

(g) From points in Tennessee (except Knoxville) located in, north and east of Stewart, Houston, Humphreys, Hickman, Maury, Marshall, and Lincoln Counties to points in Arizona located in Yuma, Yavapai, Coconino, and Navajo Counties, (h) from points in Tennessee (except Knoxville), to points in Nevada located in, north and west of Esmeralda, Mineral, Churchill, Lander, Eureka, and White Pine Counties and to points in Utah located north and west of Tooele, Utah, Wasatch, and Summit Counties, (i) from points in Tennessee (except Knoxville), located in, north, and east of Dyer, Crockett, Gibson, Carroll, Henderson, Decatur, and Wayne to points in Nevada and to points in Utah located in, north, and west of Grand Wayne, Garfield, Kane, and Washington Counties, and (j) from points in Tennessee (except Knoxville) to points located in, north and east of Stewart, Houston, Humphreys, Hickman, Maury, and Giles Counties, to points in Utah; (7) *dry chemicals* (except petroleum and petroleum products), in bulk, from points in Tennessee (except Knoxville), to points in Minnesota and South Dakota; (8) *dry chemicals*, in bulk, (a) from points in Tennessee (except Knoxville) to points in North Dakota, and (b) from points in Tennessee (except Knoxville) to points in Washington; (9) *fertilizer* (except anhydrous ammonia), in bulk, in tank vehicles, from Memphis, Tenn., (except Woodstock and the site of the Oklahoma-Mississippi Pipeline Terminal), to points in Louisiana within 150 miles of Greenville, Miss.; and (10) *chemicals*, in bulk, in tank vehicles, (a) from points in Tennessee to points in North Dakota, South Dakota, Wyoming, Idaho, Montana, Arizona, California, Nevada, Oregon, and Utah, and (b) from points in Tennessee, to points in Colorado and Nebraska. The purpose of this filing is to eliminate the gateways of (1) Clinton, Iowa; (2) Dubuque, Iowa; (3) (a) Nebraska, (b) Kansas, (c) Colorado, (d) Missouri; (4) (a) St. Louis, Mo., and Clinton, Iowa, (b) and (c) North Kansas City, Mo., (d) and (e) Birmingham, Ala., (f) through (h) North Kansas City, Mo., (i) North Kansas City, Mo., and Colorado, (j) Muskogee, Okla.;

(5) Burlington, Iowa, and points within 10 miles thereof; (6) (a) Burlington, Iowa, and Saginaw, Mo., and points within 15 miles thereof, (b) Burlington, Iowa, and points in the Kansas City, Kans., Commercial Zone that are within Missouri, (c) through (j) Burlington, Iowa, and Kansas City, Mo.; (7) Burlington, Iowa, and Windham, Iowa, and points within 15 miles thereof; (8) (a) Burlington and Des Moines, Iowa, (b) Burlington, Iowa, and Kansas City, Mo.; (9) Greenville, Miss.; (10) (a) those points in the Kansas City, Kans., Commercial Zone that are within Missouri (Turner, Kans., is now part of Kansas City, (b) Olathe, Kans., a point in Kansas City, Kans., Commercial Zone (Turner, Kans., is now part of Kansas City), (c) those points in the Kansas City, Kans., Commercial Zone that are within Missouri (Turner, Kans., is now part of Kansas).

No. MC 102567 (Sub-No. E2), (Correction), filed June 3, 1974, re-published in the FEDERAL REGISTER July 1, 1975. Applicant: McNAIR TRANSPORT, INC., 2040 North Loopwest, Houston, Tex. 77018. Applicant's representative: Tom Wright (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Such petroleum products as are liquid chemicals* (except liquefied petroleum gases), in bulk, in tank vehicles, from those points in Texas which are within 150 miles of Henderson, Tex., including Henderson, Tex., and which are south of a line beginning at Chilton, Tex., and extending along Texas Highway 7 to junction U.S. Highway 287, thence along U.S. Highway 287 to the Texas-Louisiana State line, to points in Alabama. The purpose of this filing is to eliminate the gateway of the plant site of American Cyanamid Company at Avondale, La. The purpose of this correction is to clarify the commodity description.

No. MC 102567 (Sub-No. E3), (Correction), filed June 3, 1974, re-published in the FEDERAL REGISTER July 1, 1975. Applicant: McNAIR TRANSPORT, INC., P.O. Drawer 5357, Bossier City, La. 71010. Applicant's representative: Jo E. Shaw, Houston First Saving Bldg., Houston, Tex. 77002. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Such petroleum products as are liquid chemicals* (except liquefied petroleum gases), in bulk, in tank vehicles, from Henderson, Tex., and points in Texas within 150 miles of Henderson, to those points in Alabama south of a line beginning at the Alabama-Mississippi State line and extending along Alabama Highway 56 to junction Interstate Highway 65, thence along Interstate Highway 65 to junction Alabama Highway 10, thence along Alabama Highway 10 to the Alabama-Georgia State line. The purpose of this filing is to eliminate the gateway of the plant site of American Cyanamid Company at Avondale, La. The purpose of this correction is to correct the commodity description.

No. MC 106497 (Sub-No. E2), (Correction), filed May 14, 1974, published in the FEDERAL REGISTER July 1, 1975. Applicant: PARKHILL TRUCK COMPANY, P.O. Box 912, Joplin, Mo. 64801. Applicant's representative: T. M. Tallon (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Commodities*, the transportation of which because of size or weight require the use of special equipment or handling, and *self-propelled articles*, each weighing 15,000 pounds or more, and *related machinery, tools, parts, and supplies* moving in connection therewith, restricted to commodities which are transported on trailers, between points in Ohio, on the one hand, and, on the other, points in Arkansas, Colorado, Illinois, Iowa, Kansas, Louisiana, Missouri, New Mexico, Oklahoma, Oregon, Texas, and Washington. The purpose of this filing is to eliminate the gateways of Indiana and Wyoming. The purpose of this correction is to correct the commodity description.

No. MC 106497 (Sub-No. E3), filed May 14, 1974. Applicant: PARKHILL TRUCK COMPANY, P.O. Box 912, Joplin, Mo. 64801. Applicant's representative: T. M. Tallon (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Commodities*, the transportation of which because of their size or weight requires the use of special equipment or handling; (2) *Parts* of commodities described in (1) above which do not require special equipment when moving in the same shipment or the same bill of lading from a single consignor as commodities described in (1) above; and (3) *Self-propelled articles*, each weighing 15,000 pounds or more, and

lated machinery, tools, parts, and supplies moving in connection therewith (restricted to self-propelled article, which are transported on trailers), between points in Kentucky, on the one hand, and, on the other, points in Colorado, New Mexico, Oregon, and Washington. The purpose of this filing is to eliminate the gateways of Indiana and Wyoming.

No. MC 106603 (Sub E16), filed May 10, 1974. Applicant: DIRECT TRANSIT LINES, INC., P.O. Box 8008, Grand Rapids, Mich. 49508. Applicant's representative: Martin J. Leavitt. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *roofing materials*, which are building contractors' materials, as defined by the Commission, from those points in Illinois north of a line beginning at the Illinois-Indiana State line and extending along Illinois Highway 114 to junction Illinois Highway 17, thence along Illinois Highway 17 to junction Illinois Highway 102, thence along Illinois Highway 102 to junction Illinois Highway 53, thence along Illinois Highway 53 to junction Interstate Highway 80, thence along Interstate Highway 80 to the Illinois-Indiana State line, to those points in the Upper Peninsula of Michigan west and north of a line beginning at the Michigan-Wisconsin State line and extending along U.S. Highway 45 to junction Michigan Highway 28, thence along Michigan Highway 28 to junction U.S. 41, thence along U.S. Highway 41 to Lake Superior. The purpose of this filing is to eliminate the gateway of Whiting, Ind., and Wilmington, Ill.

No. MC 106603 (Sub-E17), filed May 10, 1974. Applicant: DIRECT TRANSIT LINES, INC., P.O. Box 8008, Grand Rapids, Mich. 49508. Applicant's representative: Martin J. Leavitt. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *roofing materials*, which are building contractors materials, as defined by the Commission, from those points in Illinois north of a line beginning at the Illinois-Indiana State line and extending along Interstate Highway 70, to junction Interstate Highway 55, thence along Interstate Highway 55 to junction U.S. Highway 66, thence along U.S. Highway 66 to junction Illinois Highway 54, thence along Illinois Highway 54 to junction Interstate Highway 74, thence along Interstate Highway 74 to the Illinois-Indiana State line, to those points in the Upper Peninsula of Michigan on and east of U.S. Highway 41. The purpose of this filing is to eliminate the gateway of Whiting, Ind., and Wilmington, Ill.

No. MC 106603 (Sub-E18), filed May 10, 1974. Applicant: DIRECT TRANSIT LINES, INC., P.O. Box 8008, Grand Rapids, Mich. 94508. Applicant's representative: Martin J. Leavitt. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *roofing materials* which are building contractors' materials as described by the Commission, from those points in Illinois on and south of Interstate Highway 70 to those points in the Upper Peninsula of Michigan. The purpose of this filing is to eliminate the gateway of Whiting, Ind., and Wilmington, Ill.

No. MC 106603 (Sub-E19), filed May 10, 1974. Applicant: DIRECT TRANSIT LINES, INC., P.O. Box 8008, Grand Rapids, Mich. 49508. Applicant's representative: Martin J. Leavitt. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *building and roofing materials* which are building contractors' materials, from points in Illinois to those points in the Lower Peninsula of Michigan. The purpose of this filing is to eliminate the gateway of Whiting, Ind.

No. MC 106920 (Sub-No. E93) (Correction), filed June 3, 1974, published in the FEDERAL REGISTER February 13, 1975. Applicant: RIGGS FOOD EXPRESS, INC., P.O. Box 26, New Bremen, Ohio 45869. Applicant's representative: E. Stephen Heisley, 666 Eleventh St., N.W., Washington, D.C. 20001. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Commodities classified as dairy products* under B in the Appendix to the report in *Modification of Permits of Motor Contract Carriers of Packing House Products*, 48 M.C.C. 628, except in bulk, in tank vehicles, concentrated whole milk and concentrated skim milk, in containers, from points in Wisconsin south of a line beginning at the Iowa-Wisconsin State line and extending along Wisconsin Highway 60 to junction U.S. Highway 41, thence along U.S. Highway 41 to junction Wisconsin Highway 74, thence along Wisconsin Highway 74 to Lake Michigan, to points in Tennessee bounded by a line beginning at the Kentucky-Tennessee State line and extending along Interstate Highway 65 to junction U.S. Highway 31, thence along U.S. Highway 31 to junction Tennessee Highway 99, thence along Tennessee Highway 99 to junction U.S. Alternate Highway 31, thence along U.S. Alternate Highway 31 to junction Tennessee Highway 64, thence along Tennessee Highway 64 to junction Tennessee Highway 130, thence along Tennessee Highway 130 to junction Tennessee Highway 55, thence along Tennessee Highway 55 to junction Tennessee Highway 56, thence along Tennessee Highway 56 to the Kentucky-Tennessee State line, and thence along the Kentucky-Tennessee State line to the point of origin. The purpose of this filing is to eliminate the gateways of Darke, Mercer, and Auglaize Counties, Ohio. The purpose of this correction is to correct the highway description.

No. MC 106920 (Sub-No. E100) (Correction), filed June 3, 1974, published in the FEDERAL REGISTER February 13, 1975. Applicant: RIGGS FOOD EXPRESS, INC., P.O. Box 26, New Bremen, Ohio 45869. Applicant's representative: E. Stephen Heisley, 666 Eleventh St. NW., Washington, D.C. 20001. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Commodities classified as dairy products* under B in the appendix to the report in *Modification of Permits of Motor Contract Carriers of Packinghouse Products*, 48 M.C.C. 628, from points in Missouri on and east of a line beginning at the Iowa-Missouri State line and extending along U.S. Highway 61 to junction U.S. Highway 36, thence along U.S. Highway 36 to junction U.S. Highway 63, thence along U.S. Highway 63 to junction U.S. Highway 54, thence along U.S. Highway 54 to junction Missouri Highway 73, thence along Missouri Highway 73 to junction Missouri Highway 32, thence along Missouri Highway 32 to junction Missouri Highway 39, thence along Missouri Highway 39 to junction Interstate Highway 44, thence along Interstate Highway 44 to the Kansas-Missouri State line, to points in Virginia on and south of a line beginning at the Chesapeake Bay and extending along U.S. Highway 360 to junction Virginia Highway 54, thence along Virginia Highway 54 to junction U.S. Highway 33, thence along U.S. Highway 33 to the Virginia-West Virginia State line, and on and north of a line beginning at the Virginia-West Virginia State line and extending along U.S. Highway 250 to junction Virginia Highway 6 to junction U.S. Highway 29, thence along U.S. Highway 29 to junction Virginia Highway 56, thence along Virginia Highway 56 to junction U.S. Highway 60, thence along U.S. Highway 60 to junction U.S. Highway 15, thence along U.S. Highway 15 to junction U.S. Highway 460, thence along U.S. Highway 460 to junction Virginia Highway 40, thence along Virginia Highway 40 to junction U.S. Highway 301, thence along U.S. Highway 301 to the Virginia-North Carolina State line. The purpose of this filing is to eliminate the gateways of Darke, Mercer, and Auglaize Counties, Ohio. The purpose of this correction is to correct the territorial description above.

No. MC 107002 (Sub-No. E331), filed May 12, 1974. Applicant: MILLER TRANSPORTERS, INC., P.O. Box 1123, Jackson, Miss. 39205. Applicant's representative: John J. Borth (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum products* (except liquefied petroleum gases), in bulk, in tank vehicles, from Chalmette and Meraux, La., to points in Georgia. The purpose of this filing is to eliminate the gateway of Mississippi (except Crupp, Rogerslacy, and Zetus), and Tuscaloosa or Mobile, Ala.

No. MC 107064 (Sub-No. E1), filed May 21, 1974. Applicant: STEERE TANK LINES, INC., P.O. Box 2998, Dallas, Tex. 75221. Applicant's representative: H. L. Rice, Jr., (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Fertilizer* and *fertilizer ingredients* (except petroleum products and potash), dry, in bulk; (1) from points in that part of Texas on and west of U.S.

Highway 83 (except points in Hamford, Ochiltree, Roberts, Hamphill, Wheeler, and Collinsworth Counties) to points in Nebraska; (2) from points in that part of Texas in and west of Dallam, Hartley, Oldhow, Deaf Smith, Castro, Lamb, Lubbock, Lynn, Dawson, Martin, Midland, Crane, Pecos, and Brewster Counties to points in Kansas; and (3) from points in Dallam, Sherman, Hansford, Hartley, Moore, Hutchinson, Roberts, Oldham, Potter, Carson, Gray, Deaf Smith, Randall, Armstrong, Donley, Parmer, Castro, Swisher, Briscoe, Hall, Bailey, Lamb, Hale, Floyd, Motley, Cochran, Hockley, Lubbock, Crosby, Dickens, Yoakum, Terry, Lynn, Gaiza, Rent, Gaines, Dawson, Borden, Scurry, Andres, Martin, Howard, Mitchell, Nolan, Ector, Midland, Glasscock, Sterling, Coke, Tom Green, and Irion Counties, Tex., to points in that part of Colorado east of the Continental Divide. The purpose of this filing is to eliminate the gateway of Sheerin, Tex.

No. MC 107993 (Sub-No. E2), filed June 4, 1974. Applicant: J. J. WILLIS TRUCKING CO., P.O. Box 20096, Dallas, Tex. 75220. Applicant's representative: Joseph P. Willis (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Commodities*, other than the following commodities: machinery, equipment, materials, and supplies used in, or in connection with, the discovery, development, production, refining, manufacture, processing, storage, transmission, and distribution of natural gas and petroleum and their products and by-products, machinery, materials, equipment, and supplies used in, or in connection with, the construction, operation, repair, servicing, maintenance, and dismantling of pipelines, including the stringing and picking up thereof, which, because of size or weight, require the use of special equipment, and *related machinery parts* and *related contractors' equipment and supplies* when their transportation is incidental to the transportation of commodities which by reason of their size or weight require the use of special equipment; (1) between points in Pima, Santa Cruz, and Yuma Counties, Ariz., on the one hand, and, on the other, Pueblo, El Paso, Larimer, Otero, Las Animas, and Denver Counties, Colo.; (2) between points in Santa Cruz County, Ariz., on the one hand, and, on the other, Moffat County, Colo.; (3) between points in Gila, Yavapai, and Maricopa Counties, Ariz., on the one hand, and, on the other, Otero and Las Animas Counties, Colo.; (4) between points in Maricopa, Navajo, Pima, Pinal, Santa Cruz, Yavapai, and Yuma Counties, Ariz., and points in that part of Coconino County, Ariz., on and south of U.S. Highway 66, on the one hand, and, on the other, Logan, Washington, Sedgwick, Phillips, Yuma, Lincoln, Kit Carson, Cheyenne, Kiowa, Crowley, Bent, Prowers, and Baca Counties, Colo.

(5) Between points in Greenlee, Graham, and Cochise Counties, Ariz., on the one hand, and, on the other, points in that part of Colorado on and north and east of a line from the Colorado-New Mexico State line extending along U.S. Highway 550 to Montrose, Colo., thence along U.S. Highway 50 to the Colorado-Utah State line; (6) between points in Arizona, on the one hand, and, on the other, points in Oklahoma; (7) between points in Moffat, Routt, Jackson, Larimer, Boulder, Weld, Logan, Sedgwick, Morgan, Phillips, Washington, Yuma, Adams, Denver, Arapahoe, Douglas, Elbert, Lincoln, Kit Carson, El Paso, Cheyenne, Pueblo, Crowley, Kiowa, Otero, Bent, Prowers, and Baca Counties, Colo., on the one hand, and, on the other, Quay, DeBaca, Curry, Roosevelt, Chavis, Lea, Grant, Sierra, Otero, Eddy, Hidalgo, Luna, and Dona Ana Counties, N. Mex.; (8) between points in Moffat, Routt, Jackson, Larimer, Boulder, Weld, Logan, Sedgwick, Morgan, Phillips, Washington, Yuma, Adams, Denver Arapahoe, Douglas, Elbert, Lincoln, Kit Carson, El Paso, Cheyenne, Pueblo, Crowley, Kiowa, Otero, Bent, Prowers, Baca, Rio Blanco, Garfield, Eagle, Grand, Summit, Gilpin, Jefferson, Clear Creek, Mesa, Pitkin, Lake, Park, Delta, Gunnison, Chaffee, Fremont, Saguache, Custer, Huerfano, and Las Animas Counties, Colo., on the one hand, and, on the other, points in Hidalgo and Quay Counties, N. Mex.; (9) between points in Logan, Sedgwick, Phillips, Washington, Yuma, Kit Carson, Cheyenne, Kiowa, Bent, Prowers, and Baca Counties, Colo., on the one hand, and, on the other, points in Bernalillo, Torrance, and Socorro Counties, N. Mex.; (10) between points in Kit Carson County, Colo., on the one hand, and, on the other, points in McKinley, Sandoval, Los Alamos, and Santa Fe Counties, N. Mex.; (11) between points in Mesa County, Colo., on the one hand, and, on the other, points in Otero County, N. Mex.

(12) Between points in Colorado, on the one hand, and, on the other, points in that part of Texas west and south of a line beginning at the New Mexico-Texas State line and extending along U.S. Highway 80 to junction U.S. Highway 54 to El Paso, Tex., thence along U.S. Highway 80 to Abilene, Tex., and thence along U.S. Highway 84 to the Texas-Louisana State line; (13) between points in New Mexico (except those in Union County), on the one hand, and, on the other, points in Oklahoma (except those in Cimarron County); and (14) between points in Oklahoma, on the one hand, and, on the other, points in that part of Texas west and south of a line beginning at the New Mexico-Texas State line and extending along U.S. Highway 80 to junction U.S. Highway 54, thence along U.S. Highway 54 to El Paso, Tex., thence along U.S. Highway 84 to the Texas-Louisiana State line. The purpose of this filing is to eliminate the gateways of points in that part of Texas east and north of a line beginning at the New Mexico-Texas State line and extending along U.S. Highway 80 to junction U.S. Highway 54, thence along U.S. Highway 54 to El Paso, Tex., thence along U.S. Highway 80 to Abilene, Tex., and thence along U.S. Highway 84 to the Texas-Louisiana State line, including points on the indicated portions of the highways specified.

No. MC 108207 (Sub-No. E2) (Correction), filed April 9, 1974, published in the FEDERAL REGISTER July 28, 1975. Applicant: FROZEN FOOD EXPRESS, INC., P.O. Box 5888, Dallas, Tex. 75222. Applicant's representative: Mike Smith (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (A) *Frozen foods*, and *meats, meat by-products*, and *meat products*, as defined by the Commission (except canned or packaged meats and canned or packaged meat products, other than canned hams, packaged hams, and packaged bacon), *dairy products* as defined by the Commission, *salad dressing*, *yeast*, and *uncooked bakery goods*; (B) *Frozen foods*, and *meats, meat products*, and *meat by-products* as defined by the Commission (except canned or packaged meat products, other than canned hams, packaged hams, and packaged bacon), from points in Mississippi to points in New Mexico, Arizona, and California. The purpose of this filing is to eliminate the gateway of points in Texas. The purpose of this partial correction is to include (B) above. The remainder of this letter-notice remains as previously published.

No. MC 109637 (Sub-E1), filed June 4, 1974. Applicant: SOUTHERN TANK LINES, INC., 10 West Baltimore Avenue, Lansdowne, Pa. 19050. Applicant's representative: John E. Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petrochemicals*, in bulk, in tank vehicles, from East Liverpool, Ohio to points in Alabama, Arkansas, Mississippi, points in Georgia on and west of U.S. Highway 441 and points in Tennessee on and west of U.S. Highway 127. The purpose of this filing is to eliminate the gateways of Madison, Ind. and Robertson County, Tennessee.

No. MC 109637 (Sub-E2), filed June 4, 1974. Applicant: SOUTHERN TANK LINES, INC., 10 West Baltimore Ave., Lansdowne, Pa. 19050. Applicant's representative: John E. Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petrochemicals*, in bulk, in tank vehicles, from Lawrenceville, Illinois to points in Alabama on and south of U.S. Highway 72, points in North Carolina on and west of U.S. Highway 77, and points in Georgia and South Carolina. The purpose of this filing is to eliminate the gateways of Louisville, Ky. and Robertson County, Tennessee.

No. MC 109637 (Sub-E8), filed May 29, 1974. Applicant: SOUTHERN TANK LINES, INC., TEN WEST BALTIMORE AVENUE, LANSDOWNE, PA. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Chemicals*, in bulk, in tank vehicles

from Robertson County, Tennessee to points in Kansas, Louisiana, Oklahoma, Texas, and points in Illinois north and west of a line beginning at the Iowa-Illinois State line and extending along U.S. Highway 24 to junction U.S. Highway 66, thence along U.S. Highway 66 to Chicago, Ill., and points in Missouri north and west of a line beginning at the Kansas-Missouri State line and extending along U.S. Highway 24 to junction U.S. Highway 65 thence along U.S. Highway 65 to the Iowa-Missouri State line. The purpose of this filing is to eliminate the gateway of Calvert City, Kentucky.

No. MC 109637 (Sub-E9), filed May 29, 1974. Applicant: SOUTHERN TANK LINES, INC., Ten West Baltimore Avenue, Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Liquid chemicals*, in bulk, in tank vehicles from McIntosh, Ala., to points in Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Nebraska, Ohio, points in Missouri north and east of a line beginning at the Illinois-Missouri State line and extending along U.S. Highway 60 to junction U.S. Highway 63, thence along U.S. Highway 63 to the Iowa-Missouri State line, and points in West Virginia, except Brooke, Hampshire, Hancock, Kanawha, Monongalia and Ohio Counties. The purpose of this filing is to eliminate the gateway of Calvert City, Kentucky.

No. MC 109637 (Sub-E11), filed May 29, 1974. Applicant: SOUTHERN TANK LINES, INC., Ten West Baltimore Avenue, Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum products* (except benzol, toluol and tylol), as described in Appendix XIII, in bulk, in tank vehicles, from Daviess County and West Point, Ky., to points in Illinois south of U.S. Highway 24. The purpose of this filing is to eliminate the gateway of Troy, Indiana.

No. MC 109637 (Sub-E12), filed May 29, 1974. Applicant: SOUTHERN TANK LINES, INC., Ten West Baltimore Avenue, Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum and Petroleum Products* as described in Appendix XIII, in bulk, in tank vehicles (except asphalt and asphalt derivatives from Columbia Park, Ohio and except petroleum naphtha and styrene and coal spray oil), from Columbia Park, Ohio to points in Illinois south of a line beginning at the Illinois-Kentucky State line and extending along State Highway 13 to junction State Highway 149, thence along State Highway 149 to junction State Highway 3, thence along State Highway 3 to East St. Louis, Illinois. The purpose of this filing is to eliminate the gateway of West Point, Kentucky and Troy, Indiana.

No. MC 109637 (Sub-E13), filed May 29, 1974. Applicant: SOUTHERN TANK LINES, INC., TEN WEST BALTIMORE AVENUE, LANSDOWNE, PA. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum products* as described in Appendix XIII in bulk, in tank vehicles, from East Liverpool, Ohio to points in Missouri, points in Tennessee on and west of U.S. Highway 25E and points in Kentucky on and west of U.S. Highway 75. The purpose of this filing is to eliminate the gateway of Madison, Ind.

No. MC 109637 (Sub-E15), filed May 29, 1974. Applicant: SOUTHERN TANK LINES, INC., Ten West Baltimore Avenue, Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum products* as described in Appendix XIII, in bulk, in tank vehicles, from Lawrenceville, Ill. to points in Ohio south and east of a line beginning at the Ohio-Indiana State line and extending along U.S. Highway 40 to junction Interstate Highway 75, thence along Interstate Highway 75 to junction State Highway 65, thence along State Highway 65 to junction State Highway 109, thence along State Highway 109 to the Ohio-Michigan State line. The purpose of this filing is to eliminate the gateway of Louisville, Ky., and Madison, Indiana.

No. MC 109637 (Sub-E17), filed May 29, 1974. Applicant: SOUTHERN TANK LINES, INC., Ten West Baltimore Avenue, Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum Products* as described in Appendix XIII (except Dry Petrochemicals to points in Illinois), in bulk, in tank vehicles, from West Point, Ky. to points in Illinois on and north of U.S. Highway 50. The purpose of this filing is to eliminate the gateway of the Petroleum Products terminal of the LaGloria Oil & Gas Company near Seymour, Indiana.

No. MC 109637 (Sub-E18), filed May 29, 1974. Applicant: SOUTHERN TANK LINES, INC., Ten West Baltimore Avenue, Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum products* as described in Appendix XIII, in bulk, in tank vehicles, from Lucas County, Ohio to points in Tennessee on and west of U.S. Highway 25E. The purpose of this filing is to eliminate the gateway of Louisville, Ky.

No. MC 109637 (Sub-E19), filed May 29, 1974. Applicant: SOUTHERN TANK LINES, INC., Ten West Baltimore Avenue, Landsdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum Products*, in bulk, in tank vehicles (except Anhydrous Ammonia and dry petrochemicals to points in Illinois) from Pascagoula, Miss., to points in Illinois on and north of a line beginning at the Indiana-Illinois State line and extending along U.S. Highway 36 to Decatur, Illinois, thence along State Highway 121 to junction U.S. Highway 136, thence along U.S. Highway 131 to the Illinois-Iowa State line. The purpose of this filing is to eliminate the gateways of Louisville, Kentucky and the Petroleum Products terminal of the LaGloria Oil & Gas Co., near Seymour, Indiana.

No. MC 109637 (Sub-E22), filed May 29, 1974. Applicant: SOUTHERN TANK LINES, INC., Ten West Baltimore Avenue, Landsdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum products* as described in Appendix XIII, in bulk, in tank vehicles, from Evansville, Ind., to points in Tennessee on and east of a line beginning at the Kentucky-Tennessee State line and extending along U.S. Highway 27 to junction State Highway 62, thence along State Highway 62 to junction U.S. Highway 129, thence along U.S. Highway 129 to the Tennessee-North Carolina State line. The purpose of this filing is to eliminate the gateway of Louisville, Ky.

No. MC 109637 (Sub-E26), filed May 29, 1974. Applicant: SOUTHERN TANK LINES, INC., Ten West Baltimore Avenue, Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum and Petroleum Products* as described in Appendix XIII (except those of which are also named in Appendix XV, in bulk, in tank vehicles, from Henderson, West Point, and Daviess County, Ky. to points in Virginia. The purpose of this filing is to eliminate the gateway of Jacksonville, Ind. and Louisville, Ky.

No. MC 109637 (Sub-E30), filed May 29, 1974. Applicant: SOUTHERN TANK LINES, INC., Ten West Baltimore Avenue, Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petrochemicals*, in bulk, in tank vehicles, from Jefferson County, Ky., Clark and Floyd Counties, Ind., to points in Alabama, Arkansas, Georgia, Mississippi and points in Barry, Barton, Carter, Christian, Dade, Douglas, Greene, Howell, Jasper, Lawrence, McDonald, Newton, Oregon, Ozark, Ripley, Stone, Shannon, Taney, Texas, Vernon, Webster, and Wright Counties, Missouri. The purpose of this filing is to eliminate the gateway of Roberson County, Tenn.

No. MC 109637 (Sub-E37), filed May 29, 1974. Applicant: SOUTHERN

TANK LINES, INC., Ten West Baltimore Avenue, Landsdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petrochemicals*, in bulk, in tank vehicles from Madison, Ind., to points in Arkansas, Kansas, Louisiana, Nebraska, Oklahoma, Texas and points in Florida on and south of State Highway 40 and points in Escambia and Santa Rosa Counties, Fla. The purpose of this filing is to eliminate the gateway of Calvert City, Ky.

No. MC 109637 (Sub-E37), filed May 29, 1974. Applicant: SOUTHERN TANK LINES, INC., Ten West Baltimore Avenue, Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petrochemicals*, in bulk, in tank vehicles, from Old Shawneetown, Ill., to points in Ohio on and east of Interstate Highway 75, and points in Alabama, Arkansas, Florida, Georgia, Kansas, Louisiana, Michigan, Minnesota, Mississippi, Nebraska, Oklahoma, South Carolina, Tennessee, Texas, and West Virginia (except Brooke, Hampshire, Hancock, Kanawha, Monongalia, and Ohio Counties, W. Va.). The purpose of this filing is to eliminate the gateway of Calvert City, Kentucky.

No. MC 109637 (Sub-No. E38), filed May 29, 1974. Applicant: SOUTHERN TANK LINES, INC., Ten West Baltimore Avenue, Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petrochemicals*, in bulk, in tank vehicles, from Covington, Ky., to points in Alabama, Georgia, Mississippi and points in Tennessee on and west of a line beginning at the Kentucky-Tennessee State line and extending along U.S. Highway 231 to junction U.S. Highway 70S, thence along U.S. Highway 70S to junction Tennessee Highway 30, thence along Tennessee Highway 30 to junction U.S. Highway 27, thence along U.S. Highway 27 to the Georgia-Tennessee State line. The purpose of this filing is to eliminate the gateways of Clark County, Ind., and Robertson County, Tenn.

No. MC 109637 (Sub-E39), filed May 29, 1974. Applicant: SOUTHERN TANK LINES, INC., Ten West Baltimore Avenue, Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petrochemicals*, in bulk, in tank vehicles, from Indianapolis, Ind., to points in Alabama, Georgia, Mississippi, and points in Arkansas on and west of U.S. Highway 63, and points in South Carolina on and west of U.S. Highway 76. The purpose of this filing is to eliminate the gateway of Jefferson County, Ky., and Robertson County, Tenn.

No. MC 109637 (Sub-E41), filed May 29, 1974. Applicant: SOUTHERN TANK LINES, INC., Ten West Baltimore Avenue, Landsdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petrochemicals*, in bulk, in tank vehicles, from Cincinnati, Ohio to points in Alabama, Arkansas, Georgia, Mississippi, Missouri, on and south of U.S. Highway 60, and points in Tennessee. The purpose of this filing is to eliminate the gateway of Robertson County, Tenn.

No. MC 109637 (Sub-E42), filed May 29, 1974. Applicant: SOUTHERN TANK LINES, INC., Ten West Baltimore Avenue, Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petrochemicals*, in bulk, in tank vehicles (except benzol, Toluol and xylol) from Louisville and West Point, Ky., to points in Kansas, Louisiana, Minnesota, Nebraska, Oklahoma, Texas. The purpose of this filing is to eliminate the gateway of Troy, Ind., and Calvert City, Kentucky.

No. MC 109637 (Sub-E43), filed May 29, 1974. Applicant: SOUTHERN TANK LINES, INC., Ten West Baltimore Avenue, Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petrochemicals*, in bulk, in tank vehicles (except benzol, toluol and xylol), from Lucas County, Ohio to points in Arkansas, points in Florida on and west of U.S. Highway 231, points in Kansas, and Louisiana, points in Missouri on and south of U.S. Highway 60, and points in Oklahoma, and Texas. The purpose of this filing is to eliminate the gateways of Jefferson County, Ky., Troy, Ind., and Calvert City, Ky.

No. MC 109637 (Sub-E44), filed May 29, 1974. Applicant: SOUTHERN TANK LINES, INC., Ten West Baltimore Avenue, Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petrochemicals*, in bulk, in tank vehicles, from Lucas County, Ohio to points in Alabama, Arkansas, Georgia, Mississippi, and points in Tennessee on and west of U.S. Highway 25E. The purpose of this filing is to eliminate the gateway of Jefferson County, Kentucky and Robertson County, Tennessee.

No. MC 109637 (Sub-E45), filed May 29, 1974. Applicant: SOUTHERN TANK LINES, INC., Ten West Baltimore Avenue, Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petrochemicals*, in bulk, in tank vehicles, from the Petroleum Products Terminal of the LaGloria Oil & Gas Co., near Seymour, Indiana, to points in Alabama, Arkansas, Georgia, Mississippi and points in South Carolina on and west of U.S. Highway 76. The purpose of this filing is to eliminate the gateways of Louisville, Kentucky and Robertson County, Tennessee.

No. MC 109637 (Sub-E46), filed May 29, 1974. Applicant: SOUTHERN TANK LINES, INC., Ten West Baltimore Avenue, Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petrochemicals*, in bulk, in tank vehicles (except benzol, toluol and xylol), from Owensboro, Kentucky to points in Arkansas, Escambia and Santa Rosa Counties, Florida and points in Florida on and south of State Highway 40, points in Kansas, Louisiana and Missouri on and south of U.S. Highway 60, and points in Oklahoma, and Texas. The purpose of this filing is to eliminate the gateway of Troy, Indiana and Calvert City, Kentucky.

No. MC 109637 (Sub-E47), filed May 29, 1974. Applicant: SOUTHERN TANK LINES, INC., Ten West Baltimore Avenue, Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petrochemicals*, in bulk, in tank vehicles, from the Petroleum Products Terminal of the LaGloria Oil & Gas Co., near Seymour, Ind., the Terminal site of the Texas Eastern Transmission Corp., at or near Lebanon, Warren County, Ohio and Hamilton County, Ohio to points in Arkansas, Florida, Louisiana, Oklahoma, Texas and points in Kansas on, west and south of a line beginning at the Nebraska-Kansas State line and extending along U.S. Highway 81 to junction State Highway 196, thence along State Highway 196 to junction U.S. Highway 54, thence along U.S. Highway 54 to the Kansas-Missouri State line. The purpose of this filing is to eliminate the gateway of Calvert City, Kentucky.

No. MC 109637 (Sub-E48), filed May 29, 1974. Applicant: SOUTHERN TANK LINES, INC., Ten West Baltimore Avenue, Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petrochemicals*, in bulk, in tank vehicles, as described in Appendix XIII, from The Terminal site of Texas Eastern Transmission Company at Lebanon, Ohio to points in Alabama, Arkansas, Mississippi, points in Missouri on and south of U.S. Highway 60, and points in Tennessee on and west of a line beginning at the Kentucky-Tennessee State line and extending along U.S. Highway 65 to junction U.S. Highway 41, thence along U.S. Highway 41 to the Tennessee-Georgia State line. The purpose of this filing is to eliminate the gateway of Jefferson County, Kentucky, and Robertson County, Tennessee.

No. MC 109637 (Sub-E51), filed May 29, 1974. Applicant: SOUTHERN TANK LINES, INC., Ten West Baltimore Avenue, Lansdowne, Pa. 19050. Applicant's representative: John Nelson, (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petrochemicals*, in bulk, in tank vehicles (except benzol, toluol and xylol), from the Terminal site of the Texas Eastern Transmission Corp. at or near Princeton, Gibson County, Indiana, to points in Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, Oklahoma, South Carolina, Tennessee, Texas, points on and west of U.S. Highway 81, and points in Kansas on, west and south of a line beginning at the Nebraska-Kansas State line and extending along U.S. Highway 81 to junction U.S. Highway 54, thence along U.S. Highway 54 to the Kansas-Missouri State line. The purpose of this filing is to eliminate the gateway of Calvert City, Ky.

No. MC 109637 (Sub-E57), filed May 29, 1974. Applicant: SOUTHERN TANK LINES, INC., Ten West Baltimore Avenue, Lansdowne, Pa. 19050. Applicant's representative: John Nelson, (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Whiskey*, in bulk, in tank vehicles, from points in Kentucky on and west of U.S. Highway 27 to points in Maryland, New York, and Pennsylvania. The purpose of this filing is to eliminate the gateway of Madison, Ind.

No. MC 109637 (Sub-E60), filed May 29, 1974. Applicant: SOUTHERN TANK LINES, INC., Ten West Baltimore Avenue, Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Liquefied petroleum gas*, in bulk, in tank vehicles, from Crossville, Ill., to points in Tennessee on and east of a line beginning at the Kentucky-Tennessee State line and extending along U.S. Highway 75 to Knoxville, Tenn., thence along U.S. Highway 129 to the Tennessee-North Carolina State line. The purpose of this filing is to eliminate the gateways of Daviess County, Ky., Troy, Ind., and Louisville, Ky.

No. MC 109637 (Sub-E62), filed May 29, 1974. Applicant: SOUTHERN TANK LINES, INC., Ten West Baltimore Avenue, Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Liquefied petroleum gas*, in bulk, in tank vehicles, from Crossville, Ill., to points in Indiana, on, south and east of a line beginning at the Ohio-Indiana State line and extending along U.S. Highway 40 to Indianapolis, thence along U.S. Highway 74 to junction U.S. Highway 421, thence along U.S. Highway 421 to the Kentucky-Indiana State line. The purpose of this filing is to eliminate the gateway of Daviess County, Kentucky.

No. MC 109637 (Sub-E67), filed May 29, 1974. Applicant: SOUTHERN TANK LINES, INC., Ten West Baltimore Avenue, Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Asphalt and Asphalt products*, in bulk, in tank vehicles, from the Site of the Kentucky Asphalt Terminal, Inc. near Louisville, Ky., to points in Missouri (except Butler, Dunkin, New Madrid, Mississippi, Stoddard, Scott, Wayne, Bollinger and Cape Girardeau Counties). The purpose of this filing is to eliminate the gateway of Madison, Ind.

No. MC 109637 (Sub-E68), filed May 29, 1974. Applicant: SOUTHERN TANK LINES, INC., Ten West Baltimore, Ave., Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Asphalt and asphalt products*, in bulk, in tank vehicles, from North Vernon, Ind., to points in Missouri on and west of U.S. Highway 65. The purpose of this filing is to eliminate the gateways of Louisville, Kentucky and Madison, Ind.

No. MC 109637 (Sub-E70), filed May 29, 1974. Applicant: SOUTHERN TANK LINES, INC., Ten West Baltimore Avenue, Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Asphalt and asphalt products*, in bulk, in tank vehicles, from North Vernon, Ind., to points in Tennessee west of U.S. Highway 25E (except Nashville and points within 10 miles thereof). The purpose of this filing is to eliminate the gateway of Bowling Green, Kentucky.

No. MC 109637 (Sub-E73), filed May 29, 1974. Applicant: SOUTHERN TANK LINES, INC., Ten West Baltimore Avenue, Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Liquid nitrogen fertilizer solutions*, in bulk, in tank vehicles, from Cincinnati, Ohio to points in Missouri, points in Kentucky on and west of U.S. Highway 31E, and points in Tennessee on and west of U.S. Highway 27. The purpose of this filing is to eliminate the gateway of Madison, Indiana.

No. MC 109637 (Sub-No. E76) filed May 29, 1974. Applicant: SOUTHERN TANK LINES, INC., 10 West Baltimore Ave., Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Animal fats and greases*, in bulk, in tank vehicles, from Owensboro, Ky., to points in Michigan, North Carolina, New Jersey, Delaware, Florida, Maryland, New York, Ohio, Pennsylvania, South Carolina, Virginia, West Virginia, District of Columbia, points in Georgia south and east of a line beginning at the Alabama-Georgia State line and extending along U.S. Highway 80 to junction U.S. Highway 25, thence along U.S. Highway 25 to the Georgia-South Carolina State line, and points in Louisiana on and south of U.S. Highway 90. The purpose of this filing is to eliminate the gateway of Jeffersonville, Ind.

No. MC 109637 (Sub-No. E80), filed May 29, 1974. Applicant: SOUTHERN TANK LINES, INC., 10 West Baltimore Ave., Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Calcium carbide residue, fly ash, plastic granules*, and *resin powder*, in bulk, in tank vehicles, from Ironton and South Point, Ohio, to points in Alabama, Arkansas, points in Georgia on and west of U.S. Highway 75, and points in Mississippi. The purpose of this filing is to eliminate the gateways of Louisville, Ky., and Robertson County, Tenn.

No. MC 109637 (Sub-No. E82), filed May 29, 1974. Applicant: SOUTHERN TANK LINES, INC., 10 West Baltimore Ave., Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Calcium carbide residue, fly ash, plastic granules*, and *resin powder*, in bulk, in tank vehicles, from Louisville, Ky., to points in Arkansas. The purpose of this filing is to eliminate the gateway of Robertson County, Tenn.

No. MC 109637 (Sub-No. E85), filed May 29, 1974. Applicant: SOUTHERN TANK LINES, INC., 10 West Baltimore Ave., Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Coal tar* and *coal tar products*, in bulk, in tank vehicles, from the plant site of Western Tar Products Corp., at or near Terre Haute, Ind., to points in Tennessee on and east of a line beginning at the Kentucky-Tennessee State line and extending along Interstate Highway 75 to Knoxville, Tenn., thence along U.S. Highway 129 to the North Carolina-Tennessee State line and points in West Virginia (except the site of the Celanese Corp., of American plant near Point Pleasant, W. Va., and points in Brooke, Hampshire, Hancock, Kanawha, Marion, Marshall, Monongalia, Ohio, Pleasants, and Wetzel Counties). The purpose of this filing is to eliminate the gateway of Cincinnati, Ohio.

No. MC 109637 (Sub-No. E86), filed May 29, 1974. Applicant: SOUTHERN TANK LINES, INC., 10 West Baltimore Ave., Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Coal tar* and *road tar*, in bulk, in tank vehicles, from Cincinnati, Ohio, to points in Illinois on and south of a line beginning

at the Illinois-Missouri State line and extending along Illinois Highway 104 to Taylorsville, thence along Illinois Highway 29 to junction Illinois Highway 16, thence long Illinois Highway 16 to junction U.S. Highway 150, thence along U.S. Highway 150 to the Illinois-Indiana State line. The purpose of this filing is to eliminate the gateways of Jeffersonville, Ind., and the plant site of the Kentucky Asphalt Terminal near Louisville, Ky.

No. MC 113843 (Sub.-No. E509), filed May 19, 1974. Applicant: REFRIGERATED FOOD EXPRESS, INC., 316 Summer Street, Boston, Mass. 02210. Applicant's representative: Lawrence T. Sheils (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Frozen prune juice*, from those points in Pennsylvania on and west of U.S. Highway 15, and on, north, and east of a line beginning at the Pennsylvania-New York State line and extending along Pennsylvania Highway 249 to junction Pennsylvania Highway 287, thence along Pennsylvania Highway 287 to junction Pennsylvania Highway 414, thence along Pennsylvania Highway 414 to junction Pennsylvania Highway 664, thence along Pennsylvania Highway 664 to junction U.S. Highway 220, thence along U.S. Highway 220 to junction Pennsylvania Highway 120, thence along Pennsylvania highway 120 to junction Pennsylvania Highway 477, thence along Pennsylvania Highway 477 to junction Pennsylvenia Highway 477 to junction Pennsylvania Highway 192 to junction U.S. Highway 15, to points in North Dakota. The purpose of this filing is to eliminate the gateway of the plant sites and storage facilities of Duffy-Mott Co., Inc., at or near Hamlin, Holley, or Williamson, N.Y.

By the Commission.

[SEAL] ROBERT L. OSWALD, *Secretary.*

[FR Doc.75-23334 Filed 9-2-75;8:45 am]

[Notice No. 845]

ASSIGNMENT OF HEARINGS

AUGUST 28, 1975.

Cases assigned for hearing, postponement, cancellation or oral argument appear below and will be published only once. This list contains prospective assignments only and does not include cases previously assigned hearing dates. The hearings will be on the issues as presently reflected in the Official Docket of the Commission. An attempt will be made to publish notices of cancellation of hearings as promptly as possible, but interested parties should take appropriate steps to insure that they are notified of cancellation or postponements of hearings in which they are interested.

MC 140824, Metro Cab, Inc., now being assigned October 20, 1975 (1 day), at Trenton, New Jersey, in a hearing room to be later designated.

MC 504 Sub 102, Harper Motor Lines, Inc., now being assigned October 7, 1975, at Atlanta, Georgia, will be held at the Holiday Inn—Downtown, 175 Piedmont Avenue, Northeast.

[SEAL] ROBERT L. OSWALD, *Secretary.*

[FR Doc.75-23335 Filed 9-2-75;8:45 am]

[Notice No. 66]

MOTOR CARRIER TRANSFER PROCEEDINGS

SEPTEMBER 2, 1975.

Application filed for temporary authority under Section 210a(b) in connection with transfer application under Section 212(b) and Transfer Rules, 49 CFR Part 1132:

MC-FC-76064. By application filed August 26, 1975, G & R TRUCKING, INC., 11973 Barden Tower Road, Florissant, MO 63033, seeks to lease the operating rights of SNOWBALL, LTD. (through the Internal Revenue Service and Lewis & Clark Mercantile Bank), 511 Baden Avenue, P.O. Box 13528, St. Louis, MO 63138, under section 210a(b). The transfer to G & R TRUCKING, INC., of the operating rights of SNOWBALL, LTD., is presently pending.

By the Commission.

[SEAL] ROBERT L. OSWALD, *Secretary.*

[FR Doc.75-23336 Filed 9-2-75;8:45 am]

[Notice No. 67]

MOTOR CARRIER BOARD TRANSFER PROCEEDINGS

SEPTEMBER 3, 1975.

Synopses of orders entered by the Motor Carrier Board of the Commission pursuant to Sections 212(b), 206(a), 211, 312(b), and 410(g) of the Interstate Commerce Act, and rules and regulations prescribed thereunder (49 CFR Part 1132), appear below:

Each application (except as otherwise specifically noted) filed after March 27, 1972, contains a statement by applicants that there will be no significant effect on the quality of the human environment resulting from approval of the application. As provided in the Commission's Special Rules of Practice any interested person may file a petition seeking reconsideration of the following numbered proceedings on or before September 24, 1975. Pursuant to Section 17(8) of the Interstate Commerce Act, the filing of such a petition will postpone the effective date of the order in that proceeding pending its disposition. The matters relied upon by petitioners must be specified in their petitions with particularity.

No. MC-FC-76003. By order entered August 27, 1975, the Motor Carrier Board approved the transfer to Southern Furniture Transport, Inc., Orlando, Fla., of the operating rights set forth in Certificates Nos. MC 67200 (Sub-No. 31) and MC 67200 (Sub-No. 33), issued February 24, 1969, and July 7, 1971, respectively, to The Furniture Transport Company, Inc., Milford, Conn., authorizing the transportation of new furniture, lamps, and grass matting, between points in Orange County, Fla., on the one hand, an, on the other, points in Florida; and new furniture, between points in Florida, Georgia, and Alabama, with certain restrictions. William J. Meuser, 86 Cherry St., P.O. Box 507, Milford, Conn. 06460, attorney for applicants.

No. MC-FC-76052. By order entered August 27, 1975, the Motor Carrier Board approved the transfer to Russell Hughes, Inc., Louisville, Ky., of the operating rights set forth in Certificate No. MC 114091 (Sub-No. 76), issued September 22, 1967, to Huff Transport Co., Inc., Louisville, Ky., authorizing the transportation of salt from the site of the Kentucky Asphalt Sales Terminal in Jefferson County, Ky., to points in Indiana. Marshall Kragen, 666 Eleventh St., NW., Washington, D.C. 20001, attorney for applicants.

No. MC-FC-76054. By order entered August 27, 1975, the Motor Carrier Board approved the transfer to Fitch Trucking, Inc., Allen, Nebr., of the operating rights set forth in Certificate No. MC 93078 (Sub-No. 1), issued March 28, 1967, to Fay Fitch, Allen, Nebr., authorizing the transportation of general commodities, household goods, and certain other specified commodities, between specified points and places in Nebraska, Iowa, and South Dakota. Duane L. Stromer, P.O. Box 82028, Lincoln, Nebr. 68501, representative for applicants.

[SEAL] ROBERT L. OSWALD, *Secretary.*

[FR Doc.75-23337 Filed 9-2-75;8:45 am]

federal register

WEDNESDAY, SEPTEMBER 3, 1975

PART II:

FEDERAL ELECTION COMMISSION

■

ADVISORY OPINIONS AND REQUESTS, AND INTERIM GUIDELINES

Title 11—Federal Elections

CHAPTER I—FEDERAL ELECTION COMMISSION

[Notice 1975-34]

NEW HAMPSHIRE SENATE ELECTION

Interim Guideline

On June 2, 1975, the Federal Election Commission issued an Interim Guideline (Notice 1975-1) which directed all individuals, committees, and others subject to the Federal Election Campaign Act of 1971, as amended, to file the July 10, 1975 quarterly report with either the Secretary of the Senate, the Clerk of the House of Representatives, or the Federal Election Commission, depending upon the nature of the candidacy involved. Today, with respect to the Special Election to fill the vacancy in the office of United States Senator from New Hampshire, scheduled for September 16, 1975, the Federal Election Commission issues a guideline which directs the parties involved in the New Hampshire election to file directly with the Commission, and which sets out other rules of general applicability with respect to complying with the Federal Election Campaign Act in the pre- and post-election periods.

Dated: August 21, 1975.

THOMAS B. CURTIS,
Chairman for the Federal Election Commission.

INTERIM GUIDELINE—NEW HAMPSHIRE SENATE ELECTION

I. Definitions. For purposes of this interim guideline the term

(a) "Candidate" means an individual whose name will appear on the ballot in the September 16, 1975 election to fill the New Hampshire Senate seat.

(b) "Election or special election" means the special election to be held on September 16, 1975, to fill the New Hampshire Senate seat.

(c) "Political committee" means a political committee which receives (or intends to receive) contributions or makes (or intends to make) expenditures with respect to the September 16, 1975 special election to fill the New Hampshire Senate seat.

(d) "Authorized committee" means a political committee which has been authorized in writing by a candidate to receive contributions or make expenditures for or in furtherance of the election of such candidate. Such authorization shall be provided to the chairman of such political committee and a copy shall be sent to the Commission.

II. Applicability of the Federal Election Campaign Act Amendments of 1974—A. General. For purposes of calculating the limitations on contributions and expenditures under 18 U.S.C. 608, the Commission has set July 30, 1975, the day that the Senate passed the Resolution declaring the New Hampshire Senate seat vacant, as a cutoff date. Subject to the next paragraph, all contributions received or expenditures made or incurred prior to July 31, 1975, will be considered as made with respect to the 1974 election, to which the limitations of 18 U.S.C. 608 did not apply. Such limitations will, however, apply to all contributions received or expenditures incurred subsequent to July 30, 1975, which contributions and expenditures shall be attributed to the September 16 special election, except to the extent that such contributions are earmarked for another purpose.

In the unique circumstances attending the holding of the September 16 special election, funds received or promised in writing subsequent to December 31, 1974 and prior to July 31, 1975 and which remained on hand as of July 30, 1975 may be expended or transferred for that special election by an authorized political committee to the extent that such contributions would be lawful under the Federal Election Campaign Act of 1971, as amended, and Title 18 U.S.C. All contributions to a candidate or his authorized political committee subsequent to December 31, 1974 and prior to July 31, 1975 must, however, be reviewed by the candidate or the appropriate committee treasurer. Such contributions shall be reviewed in reverse order of receipt, beginning with the last contribution received prior to July 31, 1975. To the extent that any contribution exceeds the limits set by 18 U.S.C. 608, such excess shall be set aside and excluded until the sum of the contributions so reviewed equals the amount of cash on hand on July 30, 1975, at which point an amount equal to the sum of the non-excluded portions of the contributions may be transferred to or expended on behalf of the candidate. If the excluded amounts, thus computed, or any portion thereof have already been transferred or expended, an equivalent sum shall be deducted from the current campaign funds of such candidate's authorized political committee or committees, and may not be used for the September 16 election, although such funds may be used for any other lawful purpose including the retirement of residual campaign debts from the 1974 election.

Excluded portions of contributions will not count against expenditure ceilings under the 1974 Act, but non-excluded portions will count against such ceilings. For example, if the most recent contribution was $500 contributed by an individual, which is non-excluded, that individual may not contribute more than $500 additional for the September 16 special election.

Each candidate must designate a new principal campaign committee to receive contributions and incur expenditures with respect to the September 16 special election.

B. Prior campaign debts and obligations. Debts and obligations of any candidate incurred with respect to the 1974 Senatorial election, or with respect to any subsequent recount activities, which remain outstanding will be subject to the guidelines set forth in the Commission's Policy Statement on Pre-1975 Campaign Debts (40 FR 32952 (August 5, 1975)) and Interim Guideline on the Reporting of Debts and Obligations (40 FR 32950 (August 5, 1975)). Reference is also made to Advisory Opinions 1975-5 and 6, 40 FR 31316 (July 25, 1975).

C. Multicandidate committees. Section 608(b)(2) of Title 18, United States Code establishes three requirements which multicandidate committees must satisfy before they qualify as a political committee subject to the $5,000 rather than the $1,000 contribution limitation. These requirements are: (1) Registration under 2 U.S.C. 433 for a period not less than six months; (2) the receipt of contributions from more than 50 persons; and (3) except for any state political party organization, the making of contributions to five or more candidates for federal office.

For the purpose of meeting these requirements for this election only, each political committee (1) must have been registered with one of the three previous supervisory officers for six months or more prior to the time the contribution is made, and, (2) with respect to the 1974 Congressional elections, each political committee must have received contributions from more than 50 persons and made contributions to five or more federal candidates. If a political committee meets these requirements, it may contribute $5,000 to a candidate in this election. If any of these requirements are not met, then the political committee is limited to a $1,000 contribution under section 608(b)(1).

D. Expenditures by national and state committees. National and state committees of political parties are entitled to make the expenditures provided in 18 U.S.C. 608(f) in connection with this election. Section 608(f) establishes separate expenditure limitations for political party committees in connection with a general election. The New Hampshire statute under which this election is to be held terms it a "special" election. For purposes of federal law, a general election is an election that is held to fill a vacancy in a federal office. Since the upcoming New Hampshire contest is such an election, it will be considered within the definition of general election.

E. New Hampshire State committees—establishment of segregated funds. Each New Hampshire state committee, and each subordinate committee of such state committees, which intends to solicit or receive contributions for or on behalf of, or make expenditures, or make transfers, in excess of $1,000, to or on behalf of any candidate for federal office shall:

(1) Establish a segregated federal campaign account in either a state or national bank which account may not receive contributions other than contributions earmarked for such account and any expenditure from which must be made exclusively for a candidate or candidates for federal office. Such segregated federal account may not receive transfers from another account established by a state committee or subordinate committee of a state committee unless such state or subordinate committee account is itself a segregated federal campaign account.

(2) File with the Commission reports and statements of receipts, contributions and expenditures made for such account.

III. *Candidate designations and reporting*—A. *Candidate designations.* (a) On or before September 8, 1975, each candidate shall file a Statement of Candidacy with the Commission on which such candidate shall—

(1) Designate a principal campaign committee, and

(2) Designate at least one national or state bank as a campaign depository, and

(b) Such candidate shall also file reports of personal receipts and expenditures in accordance with section V of this interim guideline unless a waiver of personal reporting is applied for and granted by the Commission.

B. *Waiver of candidate reporting.* (a) Upon written application to the Commission, a candidate may be relieved of the duty personally to file reports of receipts and expenditures if the candidate certifies that he will comply with the following conditions:

(1) Within five days after personally receiving any contribution the candidate will surrender possession of the entire contribution to the treasurer of his principal campaign committee without expending any of the proceeds thereof.

(2) Such candidate will not make any personal expenditure for his campaign, except that this paragraph does not preclude a candidate from conveying personal funds, or the personal funds of his immediate family, to such candidate's designated principal campaign committee so long as the amount of funds so transferred does not exceed the limit prescribed by 18 U.S.C. 608(a).

(b) After the candidate has submitted a verified statement that he will conform to the conditions specified above, the Commission, after such investigation as it deems necessary, may grant a formal waiver relieving the candidate from the obligation to comply personally with the reporting requirements in 2 U.S.C. 434.

(c) Such waiver will continue in effect only to the extent that the candidate complies with the conditions under which it was applied for and granted.

IV. Registration of political committees—A. *Registration.* (a) Unless already registered with the Commission or with one of the previous supervisory officers, each political committee which anticipates receiving contributions or making expenditures with respect to the special election during the remainder of calendar year 1975 in an aggregate amount exceeding $1,000 shall file a Statement of Organization with the Federal Election Commission on or before September 8, 1975, within 5 days after the date of its organization, or within 5 days after the date on which the committee has information which causes it to anticipate receiving such contributions or making such expenditures exceeding $1,000 whichever is later.

(b) Authorized committees which support only a candidate for the Senate seat, and no other candidate, shall file the Statement of Organization required by paragraph (a) of this section, and any amendment thereto, or termination thereof, with the affiliated principal campaign committee and, concurrently, shall file a copy of such Statement with the Commission together with a copy of its written authorization.

B. *Forms of filing.* (a) The Statement of Organization shall be filed on a form which may be obtained from the Federal Election Commission, 1325 K Street, NW., Washington, D.C. 20463, telephone (202) 382-5162. The Statement shall include the following:

(1) The name and address of the committee;

(2) The names, addresses, and relationships of affiliated or connected organizations (see paragraph (b) of this section);

(3) The area, scope, or jurisdiction of the committee.

(4) The name, address, and committee position of the custodian of books and accounts.

(5) The name, address, and committee position of other principal officers, including officers and members of the finance committee, if any.

(6) The name, address, office sought, and party affiliation of (i) each candidate for federal office whom the committee is supporting and (ii) each candidate whom the committee is supporting for nomination or election to any other federal office or to any public office whatever; and, additionally, if the committee is supporting the entire ticket of any party, the name of the party;

(7) A statement whether the committee's existence will continue beyond the calendar year;

(8) The plans for the disposition of residual funds which will be made in the event of dissolution;

(9) A listing of all banks, safety deposit boxes, or other repositories used;

(10) A statement listing any reports regarding candidates for federal office filed under state or local law by the committee with state or local officers, and the names, addresses, and positions of such officers and,

(11) If the committee is not a principal campaign committee but has been authorized by a candidate to receive contributions and/or make expenditures, a copy of the authorization shall be included in the copy filed with the Commission.

(b) (1) Affiliated organizations include all authorized committees of the same candidate;

(2) Connected organization includes any organization which is not a political committee but which organized or supports the registrant.

C. *Change or correction in information.* Any change or correction in the information previously filed in the Statement of Organization shall be reported to the Commission within 10 days following the date of the change or correction, it shall (1) be reported by letter to the Commission or to the principal campaign committee (whichever is appropriate); (2) identify the form and the item or schedule containing the information to be changed or corrected; and (3) be verified by oath or affirmation by the person required by law to submit such information at the time the change or correction is reported.

D. *Discontinuance of registration.* (a) Any political committee not having outstanding debts or obligations owed to or by it which, after having filed one or more Statements of Organization with the Commission, disbands or determines that it will no longer receive contributions or make expenditures during the calendar year in an aggregate amount exceeding $1,000, shall so notify the Commission.

(b) Such Notice of Termination shall be filed with the Commission or the principal campaign committee, where appropriate, and shall include a statement as to the disposition of residual funds if the committee is disbanding.

E. *Identification number.* Upon receipt of a Statement of Organization under this interim guideline, the Commission shall assign an identification number to the organization, acknowledge the receipt thereof, and notify political committee of the number assigned. This identification number shall be entered by the political committee on all subsequent reports or statements filed with the Commission under the Act, as well as on all communications concerning such reports or statements.

IV. Campaign depositories. Every political committee shall inform the Federal Election Commission, or its appropriate principal campaign committee, of the national or state bank(s) designated by its authorizing candidate as its campaign depository(ies) by listing them in its Statement of Organization.

V. Reports of receipts and expenditures—A. *Timing of reports.* The filing deadline for campaign finance disclosure reports as prescribed by the Act for the heretofore mentioned special election are as follows:

(a) Pre-election Report (10-day report). Filing date: Actual delivery to the Commission on or by September 6, 1975 or by registered or certified mail postmarked no later than September 4, 1975. Reports mailed first class will be considered filed only upon receipt by the Commission, regardless of date of postmark. Period Covered: From the last date of previous report filed or from date of organization through close of business September 1, 1975.

(b) Post-election report (30-day report). Filing date: On or by October 16, 1975—reports filed by registered or certified mail postmarked on or by such date shall be deemed filed as of the filing date. Period Covered: From September 2, 1975 through the close of business October 6, 1975.

(c) The timely filing of a post-election report as outlined in (b) above shall satisfy the requirements for filing a quarterly report on October 10, 1975.

(d) If any contribution of $1,000 or more is received subsequent to the fifteenth day but more than 48 hours before 12:01 a.m. of the day on which the

election is to be conducted, such information shall be reported directly to the Commission within 48 hours of receipt thereof. For purposes of this paragraph, report means—

(1) A letter signed by the treasurer or his designee hand delivered to the Commission within 48 hours of the receipt of the contribution, or

(2) A telegram to the Commission followed by a letter signed by the treasurer or his designee, sent registered or certified mail and postmarked within 48 hours of the receipt of the contribution.

B. *Contents of reports.* (a) Each report of receipts and expenditures required to be filed under this interim guideline by either a candidate or political committee shall contain the information required by 2 U.S.C. 434(b).

(b) Such reports may be filed on the Reports of Receipts and Expenditures forms issued previously by the Secretary of the Senate.

C. *Uniform reporting of contributions.* (a) Each contributor of an amount in excess of $100 shall be identified by full name and mailing address (occupation, and principal place of business, if any). If a contributor's name or address is known to have changed since an earlier contribution during the calendar year, the exact name or address previously used shall be noted.

(b) In each case when a contribution received from a person in a reporting period is added to previously unitemized contributions from the same contributor and the aggregate exceeds $100 within the calendar year, the full name and mailing address (occupation, and principal place of business, if any) of that contributor shall then be listed on the prescribed reporting forms.

(c) In determining the aggregate of a person's contributions, all such contributions from the same donor shall be listed under the same name.

(d) Absent evidence to the contrary, any contribution made by check, money order, or other written instrument shall be reported as a contribution by the last person signing the instrument prior to delivery to the candidate or committee.

D. *Uniform reporting of expenditures.* (a) Each expenditure by or on behalf of a candidate or committee in excess of $100 shall be itemized by and shall include the full name and residence or, in the case of a recipient other than an individual, other mailing address of the recipient.

(b) In each case when an expenditure made to a recipient in a reporting period is added to previously unitemized expenditures to the same recipient and the aggregate exceeds $100 within the calendar year, the full name and residence or, in the case of a recipient other than an individual, other mailing address of that recipient shall be listed on the prescribed reporting forms.

VI. Document filing—A. *Place of filing.* (a) All statements and reports, including any modifications or amendments thereto, required to be filed under 2 U.S.C. 433 and 2 U.S.C. 434, shall be filed in original form with the Federal Election Commission. A copy of each statement or report shall be filed with the New Hampshire Secretary of State or the equivalent New Hampshire state officer.

(b) Notwithstanding paragraph (a)—

(1) Authorized committees which support only a candidate for the Senate, and no other candidate shall file reports with the authorizing candidate's principal campaign committee, and shall concurrently file a copy of such report with the Commission;

(2) Authorized multicandidate committees shall file reports with the Commission, and, in addition, shall file with the authorizing candidate's principal campaign committee the information required by 2 U.S.C. 434(b) regarding contributions received and expenditures made on behalf of the authorizing candidate;

(3) A multicandidate committee (whether authorized or unauthorized) which receives contributions earmarked by a contributor for any candidate or an authorized committee thereof shall report such contribution to that candidate's principal campaign committee in addition to the Commission.

B. *Copies transmitted to Secretary of Senate.* Upon receiving a statement or report filed by (a) a candidate and/or by (b) any political committee supporting one or more such candidates, the Commission shall within one working day, if practicable, and in any event not later than the second working day after receiving the filed statement or report, furnish a microfilm (or suitable equivalent) copy thereof, together with an index, to the Secretary of the Senate.

C. *Originals transmitted to the Secretary of the Senate.* (a) After receiving a filed statement or report within 5 working days if practicable and in any event no later than 10 days after receiving it, the Commission shall transmit the original statement report filed by (1) a candidate for the New Hampshire Senate seat, and by (2) any political committee supporting such candidate, to the Secretary of the Senate as custodian for the Commission.

(b) For purposes of the above paragraph the phrase "any political committee supporting such candidate" means:

(1) The principal campaign committee designated by a candidate, and

(2) Any political committee required to file a statement or report with the principal campaign committee of a candidate.

VII. Formal requirements—A. *Authentication.* Each report or statement required to be filed with the Commission or with a principal campaign committee under this interim guideline by a treasurer of a political committee, a candidate, or by any other person, shall be signed by the person filing such report or statement.

B. *Preservation of records.* (a) Every person filing a report or statement with the Commission or with a principal campaign committee under this interim guideline shall preserve a copy thereof for a period of three years from the date of termination of the Committee, but in no event for a period of more than seven years from the last day of the calendar year in which the election was held for which the reports and statements were prepared.

(b) Every candidate, political committee, or other person required to file any report or statement with the Commission or with a principal campaign committee under this interim guideline shall maintain records with respect to the matters required to be reported, including vouchers, worksheets, receipts, bills and accounts, which will provide in sufficient detail the necessary information and data from which the filed reports and statements may be verified, explained or clarified, and checked for accuracy and completeness, and shall keep such records available for audit, inspection, or examination by the Commission or its authorized representatives, for a period of not less than three years from the date of termination of the committee, but in no event for a period of more than seven years from the last day of the calendar year in which the election was held for which the records and statements were prepared.

C. *Effect of acknowledgment and filing by the Commission.* Any acknowledgment by the Commission of the receipt of any statement of organization or any report or statement filed under this interim guideline is intended solely to inform the person filing the same of the receipt thereof by the Commission, and neither such acknowledgment nor the acceptance and filing of any such report or statement by the Commission shall constitute express or implied approval thereof, or in any manner indicate that the contents of any such report or statement fulfills the filing or other requirements of the Act or of this interim guideline thereunder.

D. *Personal responsibility of person signing statement.* (a) Each treasurer of a political committee, each candidate, and any other person required to file any report or statement with the Commission under these regulations and under this interim guideline shall be personally responsible for the timely and complete filing of such report or statement and for the accuracy of any information or statement contained therein.

(b) The treasurer of each candidate's principal campaign committee shall be responsible for collecting, compiling and filing with the Commission a complete report of all authorized contributions received or authorized expenditures made on behalf of such candidate. The pre- and post-election reports filed by such treasurer shall include—

(1) With respect to the principal campaign committee, all of the information required by 2 U.S.C. 434(b).

(2) With respect to contributions received and expenditures made by authorized committees other than the principal campaign committee, a summary sheet setting forth the totals for all contributions received and expenditures made by such committees but need not include a copy of such authorized committee reports so long as each such authorized

committee has mailed a copy of such report to the Commission pursuant to paragraph VI(A)(b) of this interim guideline.

(c) With respect to the pre-election report it shall be the responsibility of the treasurer of each committee other than principal campaign committee which is authorized to receive contributions or make expenditures to file a report containing the information required by 2 U.S.C. 434(b) complete as of the fifteenth day before the election with the treasurer of the appropriate principal campaign committee by the 12th day prior to the election.

(d) Any willfully false or fraudulent statements or representations in such a report or statement will subject the person making the same to the criminal penalties provided under 18 U.S.C. 1001.

Dated: August 21, 1975.

THOMAS B. CURTIS,
Chairman for the
Federal Election Commission.

[FR Doc.75-22659 Filed 9-2-75;8:45 am]

[Notice 1975-36]

DISBURSEMENT PROCEDURES FOR PUBLIC FINANCING OF CONVENTIONS

Interim Guideline

I. *Certification of entitlement to public funds for nominating convention expenses.* Title 26 U.S.C. 9008 authorizes the Federal Election Commission to certify to the Secretary of the Treasury for payments of the amounts to which the national committee of any major or minor party is entitled under 26 U.S.C. 9008 with respect to a presidential nominating convention, but the entitlement of each major party may not exceed the aggregate amount of $2,000,000.[1] The amount of each party's entitlement is adjusted annually based on increases in the Consumer Price Index. See 26 U.S.C. 9008(b)(5) and 18 U.S.C. 608(d).

II. *Information required to receive certifications for public funds.* To be eligible for public financing of their conventions, the national committees of the major parties shall submit or otherwise make available the following information to the Federal Election Commission in order that the Commission may forward the appropriate certification to the Secretary of the Treasury.

A. *For initial payment.* 1. Signature cards containing signatures of officials who have been authorized to sign requests for payment (Exhibit I);

2. The name and address of the commercial bank to be used as the committee's depository;

3. A request for an initial payment, supported by a statement projecting and describing estimated expenditures through the close of December 31, 1975. Specific dollar figures need not be assigned to the various itemized expenditure categories.

B. *For subsequent payments.* 1. Subsequent requests for disbursements after the initial disbursement shall be submitted quarterly commencing with January 1 in the year in which the convention will be held. Such requests should be submitted to the Commission within 10 days after the commencement of the quarter to which they relate.

2. The request is to include (a) a report in a form consistent with the requirements of 2 U.S.C. 434(b) of actual expenditures made during the previous period or quarter, and (b) the total amount of expenditures estimated through the close of the next quarter and the categories in which the proposed expenditures are to be made. No specific dollar figure need be assigned to the various itemized expenditure categories thus projected and described.

III. *Special approval for accelerated payment schedule.* Each quarterly disbursement will be based upon the legally permissible expenses projected for that quarter. The Commission will approve more than one disbursement per quarter where a showing is made that a deficit is likely to be incurred unless a further disbursement is made. Any request for such further disbursement should be supported by a summary of actual expenses previously incurred for the quarter together with the projected expenses which will occasion the deficit if a further disbursement is not forthcoming.

IV. *Transmittal of certification to Secretary of the Treasury.* Following Commission approval of any request for disbursement, the Commission shall forthwith transmit a certification for payment to the Secretary of the Treasury, who shall make payment in the amount certified to the national committee designated by the certification, but not to exceed the amounts in each account maintained under 26 U.S.C. 9008(a).

V. *Use of funds by committees.* Under 26 U.S.C. 9008(c), funds so disbursed shall be used only (1) to defray expenses incurred with respect to a presidential nominating convention (including the payment of deposits) by or on behalf of the national committee receiving such payments; or (2) to repay loans, the proceeds of which were used to defray such expenses, or otherwise to restore funds (other than contributions to defray such expenses received by such committee) used to defray such expenses. Any investment of public funds or their use in any other way which generates income is permissible only if the income so generated is used for the purposes described in this part V, and such income will be applied against the $2 million ceiling.

VI. *Repayments for funds improperly received or spent.* Repayments in an appropriate amount will be required from the national committees whenever they have (1) received payments in excess of their entitlement, (2) incurred expenses in excess of their spending limits, (3) improperly accepted private contributions to defray convention expenses, or (4) expended public funds in any manner other than to defray expenses incurred with respect to a presidential nominating convention. Repayments may not exceed the aggregate amounts actually received by a national committee under section 9008.

A. *Notification of need for repayment.* If the Commission determines that repayment is required in the circumstances stated above, it shall give written notification to the affected national committee of the amounts required to be paid and the reasons therefor.

B. *Collection of repayment by deduction from future payments.* The Commission may obtain such repayment by deducting such amount from the amount otherwise due the national committee for its next quarterly payment.

VII. *Post-convention Disbursements.* Pending the conclusion of any national convention, the Commission may in its discretion withhold an amount to be hereafter determined, but in any event not to exceed $200,000, which would otherwise bring the aggregate funds disbursed to the total allowed by law. Such withheld funds, if any, shall be subject to post-convention disbursement and such disbursement shall be made in the manner provided for in Part II-B above, except that such request shall include a list of all accounts payable and the purpose for which the expense was incurred. Post convention payments shall be subject to audit by the Commission and deduction of unauthorized expenditures in addition to other requirements imposed by law.

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[1] Under 26 U.S.C. 9008(b) the National committees of both major and minor parties are entitled to payments from public funds to defray expenses which they have incurred with respect to a presidential nominating convention. For a minor party to be entitled to its proportionate share of public funds for 1975 or 1976 convention expenses, its 1972 presidential candidate must have received (as the presidential candidate of that party) at least 5 percent of the total popular vote received by all presidential candidates in 1972. Accordingly, since no minor party presidential candidate received that many votes in 1972, there is no minor party that can qualify for convention funds in 1975 or 1976.

EXHIBIT 1

Standard Form Funds	AUTHORIZED SIGNATURE CARD FOR PAYMENT	Account Number
Issued in Favor of (Recipient)	Issued by (Federal Agency)	
SIGNATURES OF AUTHORIZED INDIVIDUALS	☐ Only one Signature Required or ☐ Any Two Signatures Required Sign or Countersign	
Typed Name and Signature	Typed Name and Signature	
Typed Name and Signature	Typed Name and Signature	
I CERTIFY THAT THE SIGNATURES ABOVE ARE OF THE AUTHORIZED INDIVIDUALS	APPROVED:	
Date and Signature of Authorizing Official (Recipient)	Date and Signature of Agency Certifying Officer	

VIII. *Commission's audit authority.* National committees affected by the foregoing should note the Commission's general authority and duties under 2 U.S.C. 437d and 438.

Dated: August 25, 1975.

NEIL STAEBLER,
Vice-Chairman for the Federal Election Commission.

[FR Doc.75-22940 Filed 9-2-75;8:45 am]

FEDERAL ELECTION COMMISSION

[Notice 1975-35; A.O. 1975-7, -17]

MEMBERS OF CONGRESS; CONSTITUENT SERVICES CONTRIBUTIONS AND EXPENDITURES AND CAMPAIGN CONTRIBUTIONS FROM PARTNERSHIPS

Advisory Opinions

The Federal Election Commission announces the publication today of Advisory Opinions 1975-7 and 1975-17. The Commission's opinions are in response to questions raised by individuals holding Federal office, candidates for Federal office and political committees, with respect to whether any specific transaction or activity by such individual, candidate, or political committee would constitute a violation of the Federal Election Campaign Act of 1971, as amended, of Chapter 95 or Chapter 96 of Title 26 United States Code, or of sections 608, 610, 611, 613, 614, 615, 616, or 617 of Title 18 United States Code.

ADVISORY OPINION 1975-7

CONTRIBUTIONS AND EXPENDITURES RELATING TO THE CONSTITUENT SERVICES OF CONGRESS

This advisory opinion is rendered under 2 U.S.C. 437f in response to requests for advisory opinions submitted by Mr. Thomas J. Kern for Congressman Dave Evans, Congressman John P. Murtha, and Senator Jake Garn, which were published together as AOR 1975-7 in the July 2, 1975, FEDERAL REGISTER (40 FR 28044). Interested parties were given an opportunity to submit written comments relating to the requests.

The requests generally ask the Commission, under the Federal Election Campaign Act of 1971, as amended, and Title 18 of the United States Code (the Act), what types of contributions to and expenditures by an office account are permissible, and how these accounts shall be reported and administered. Specifically, the following requests were made:

(a) Thomas J. Kern, administrative assistant for Congressman Dave Evans, states that the Congressman has established two fundraising entities to support the Representative's political activities. One entity is the principal campaign committee of the Congressman and the other is an office account (called here a "constituent service fund") set up to collect funds to assist Congressman Evans in providing services for his constituents.

Donations to the office account will be used for printing newsletters; holding neighborhood office hours; conducting meetings and seminars with representatives of governmental and private agencies, and with elected and appointed officials of the cities, counties and towns of the District; holding periodic open house activities at the District and Washington offices, providing constituents with flags, publications and certain other items that must be purchased; and for other expenses incurred in connection with the Congressman's services for his constituents. The account will not be used to present or promote the views of any political party or philosophy or to influence the re-election of Congressman Evans. Mr. Kern asks whether the office account is a political committee under the Act. He also asks how the sponsor of a fundraising event for the benefit of an office account should be identified, and what disclosure requirements are applicable to the use of the proceeds from such an event;

(b) Congressman John P. Murtha states that he has established a franking account (called here a "public service committee") which is used solely to defray the cost of newsletters, reports, and questionnaires sent to constituents. Congressman Murtha asks whether a corporation may make a donation to such an account without violating the statutory provisions governing political contributions; and

(c) Senator Jake Garn asks whether an incumbent Senator or Representative may engage in attitudinal research with his constituency for purposes of measuring the voters' sentiments on policy issues, job approval perceptions, and the like, without having these expenditures allocated against any applicable spending limitation. The proposed polls will ask questions for statistical purposes, open end questions, and forced response questions, but will not ask questions relating to political trial heats. Senator Garn asks further whether the fact that a Member of Congress is a candidate will make any difference in the use of issue-oriented opinion research.

As stated in AO 1975-14 on "Contributions by Banks, Corporations, and Labor Unions to Defray Constituent Service Expenses" (40 FR 34084, August 13, 1975), "[i]t is clear that the Federal Election Commission has the duty to formulate general policy with respect to the Act (2 U.S.C. 437d(a)(9)), has the power to regulate amounts contributed to a holder of Federal office in order to defray expenses arising in connection with that office (2 U.S.C. 439a), has the power to formulate general policy regarding contributions and expenditures (18 U.S.C. 608), and has the power to formulate general policy regarding contributions or expenditures by national banks, corporations or labor organizations (18 U.S.C. 610)." Congress has the discretion and power to appropriate sufficient money for staff salaries, newsletters, stationery, travel, constituent services, and the other legislative expenses of a Member of Congress to assure the performance of the Member's legislative duties. Accordingly, except for money raised pursuant to 39 U.S.C. 3210(f), additional money which is raised by a Member or his supporters shall be treated as a contribution made for purposes of influencing a Federal election and shall be controlled by all appropriate limitations. Similarly, except for money expended pursuant to 39 U.S.C. 3210(f), additional money which is expended from an office account shall be treated as an expenditure intended for purposes of influencing a Federal election and shall be controlled by all appropriate limitations. As provided in 3210(f) of Title 39, United States Code, money which is contributed and expended for the preparation or printing of material to be mailed under the frank shall be treated as a contribution or expenditures for disclosure purposes of the Act, although not for purposes of the contribution and expenditure limitations provided in 18 U.S.C. 608.

The Commission intends to apply its policy on office accounts as follows:

(a) It is the opinion of the Commission that an office account established to provide services for the constituents of a Congressman shall report as if such account is a political committee and contributions to, expenditures by, and the general operation of an office account should be reported and otherwise treated as provided in Notice 1975-18 of the Federal Election Commission "Office Accounts and Franking Accounts; Excess Campaign Contributions" (40 FR 32951, August 5, 1975). See also AO 1975-14, supra. As provided in Notice 1975-18 and AO 1975-14, all private contributions received by or on behalf of a Federal officeholder for use by his office account may be deposited in such account or an account of the officeholder's principal campaign committee, pursuant to 2 U.S.C. 437b. Also as provided in Notice 1975-18, money received for the preparation or printing of material to be sent under the frank (e.g., a newsletter), other than funds appropriated for legislative activities shall be deposited in a separate segregated franking account which shall report as provided in that notice.

Monies expended from such accounts, other than the franking account, will be counted toward the officeholder's campaign expenditure limits under 18 U.S.C. 608(c). A Congresman holding a fundraiser should identify that the fundraising is being conducted by either the Congressman's principal campaign committee, his office account or his franking account.

The Commission also is requested to provide guidance as to whether a person holding a fundraiser for the benefit of an office account should state that a donation to the office account is not tax deductible or subject to a tax credit. The Commission is unable to provide such guidance as it lacks authority to rule with regard to such tax consequences. Reference should be made to sections 41 and 128, Title 26, United States Code.

(b) It is the opinion of the Commission that corporate contributions to a franking account, used solely to defray the cost of newsletters, reports, and questionnaires sent to constituents, are prohibited under 18 U.S.C. 610. While exempt from the limitations in 18 U.S.C. 608 (see 39 U.S.C. 3210(f)), contributions and expenditures for the preparation or printing of material to be mailed under the frank shall otherwise be treated as contributions and expenditures for purposes of the Act, (including the pertinent provisions of Title 18). Since the proposed contribution would be derived from general corporate funds, and not from separate voluntary funds to sup-

port the franking accounts of Congressmen, the contribution by the corporation would be prohibited under 18 U.S.C. 610.

(c) A Member of Congress may, of course, make expenditures for attitudinal research within his constituency for purposes of measuring the voter's sentiments on policy issues, job approval perceptions, and the like. However, unless the expenditures for the attitudinal research are paid from funds appropriated for legislative purposes by Congress or from a Congressional franking account and are used to print or prepare matter mailed under the frank, they will be treated as an expenditure from the Member's office account and will be subject to the limitations provided in 18 U.S.C. 608 as well as the other provisions of the Act. See Notice 1975–18, supra. The fact that a Member of Congress is an announced candidate thus would not make any difference in how expenditures for attitudinal research will be treated.

The provisions of this opinion represent the opinion of the Commission as to the effect of 2 U.S.C. 437(a)(9), 2 U.S.C. 439a, 18 U.S.C. 608, 18 U.S.C. 610, and 39 U.S.C. 3210(f) on contributions and expenditures from the office or franking account of a Federal officeholder.

The provisions of this opinion are reflected in the proposed regulations which the Commission has submitted to Congress, see Notice 1975–18, supra.

Pursuant to the Administrative Procedure Act the Commission will hold public hearings on the proposed regulation on September 16 and 17, 1975, at the U.S. Court of Claims in Washington, D.C.

ADVISORY OPINION 1975–17

CAMPAIGN CONTRIBUTIONS FROM A PARTNERSHIP

This advisory opinion is rendered under 2 U.S.C. 437(f) in response to a request for an advisory opinion, submitted by Congressman Neal and published in the July 17, 1975 FEDERAL REGISTER (40 FR 30259). Interested parties were given an opportunity to submit written comments relating to the request.

The question raised in Congressman Neal's request is "[h]ow much money in campaign contributions may a candidate for Federal office accept from a partnership" under the Federal Election Campaign Act of 1971, as amended in 1974.

Section 608(b)(1) of Title 18, United States Code, states that:

(1) Except as otherwise provided by paragraphs (2) and (3) *no person* shall make contributions to any candidate with respect to any election for Federal office which, in the aggregate, exceed $1,000 (italic added for emphasis).[2]

[2] The exceptions to 18 U.S.C. 608(b)(1) are not relevant to the question of the amount a candidate may receive from a partnership, and contributions to a candidate for nomination to the office of President are subject to an overall $1,000 limit during the entire pre-nomination period. See 18 U.S.C. 608(b)(5).

Section 591(g) of Title 18, United States Code, defines "person" as an individual, *partnership*, committee, association, corporation, or any other organization or group of persons, * * *" (italic added for emphasis).

It is the opinion of the Commission that the cited statutory provisions impose a $1,000 limit on the amount a partnership may contribute to a candidate for Federal office with respect to each separate election wherein that candidate seeks nomination or election. The Commission further concludes that when a partnership makes a contribution to a candidate for Federal office it counts against each individual partner's limitation under 18 U.S.C. 608(b)(1) in direct proportion to each partner's share of partnership profits. For example, in the case of a four member partnership (each partner having an equal share) which makes a $1,000 contribution to a Federal candidate, one-fourth of the $1,000, or $250, is counted toward each individual partner's limit. Therefore, each partner may contribute no more than an additional $750 to the same Federal candidate with respect to the same election.

Under the general theory of partnership law a partner is an agent for the partnership, and the partnership has no legal capacity to act as a person in its own right. Therefore, even though a partnership is a "person" for purposes of 18 U.S.C. 608(b), as well as 2 U.S.C. 431, *et seq.* contributions made in the partnership's name must be attributed to the individual partners in relation to each partner's interest in the partnership profits. Furthermore, when a contribution is made in the partnership name without accompanying information as to each partner's proportionate share thereof, the candidate or committee recipient must obtain a written statement providing the requisite information within 30 days after receiving the contribution.

If this information is not timely obtained the contribution must be returned. Otherwise, the candidate or committee will be regarded as in violation of 18 U.S.C. 614 which prohibits an individual from making a contribution in the name of another "person," i.e. partnership, and also prohibits the knowing acceptance of such a contribution.

Dated: August 22, 1975.

NEIL STAEBLER,
Vice Chairman for the Federal Election Commission.

[FR Doc.75-22941 Filed 9-2-75;8:45 am]

[Notice 1975–33; A.O. 1975–10]

INTERNAL TRANSFERS OF FUNDS BY CANDIDATES OR COMMITTEES

Advisory Opinion

The Federal Election Commission announces the publication today of Advisory Opinion 1975–10. The Commission's opinions are in response to questions raised by individuals holding Federal Office, candidates for Federal office and political committees, with respect to whether any specific transaction or activity by such individual, candidate, or political committee would constitute a violation of the Federal Election Campaign Act of 1971, as amended, of Chapter 95 or Chapter 96 of Title 26 United States Code, or of sections 608, 610, 611, 613, 614, 615, 616, or 617 of Title 18 United States Code.

ADVISORY OPINION 1975–10

INTERNAL TRANSFERS OF FUNDS BY CANDIDATES OR COMMITTEES

This advisory opinion is rendered under 2 U.S.C. 437f in response to four requests, published as AOR 1975–10 in the July 9, 1975 FEDERAL REGISTER (40 FR 28944). All of the requests relate to various types of transfers of funds by candidates or political committees. Interested parties were given an opportunity to submit written comments pertaining to the requests.

A. *Request of Congressman John J. McFall.* The issue presented is whether a principal campaign committee of a candidate for Federal office may transfer funds from a checking account at a designated campaign depository to a savings account in the same bank or to a savings account in another financial institution which is not a designated campaign depository.

Section 437b(a)(1) of Title 2, U.S. Code, provides that "[e]ach candidate shall designate one or more national or State banks as his campaign depositories." This section further requires that the principal campaign committee shall maintain a checking account at the designated depository, shall deposit any contributions received by it into such account, and shall make all expenditures from said checking account. The statute is silent as to the establishment and use of savings accounts.

It is clear that the statute requires all contributions and all expenditures to pass through the checking account at the designated campaign depository. However, the statute would not preclude a transfer from a checking account to a savings account if full disclosure is made and the committee retains its complete control of the funds so transferred at all times.

To assure compliance with the reporting requirements of 2 U.S.C. 434(b) and the specific language of section 437b(a)(1) that all contributions and all expenditures flow through the checking account at the designated depository, the Commission will require:

(1) That all funds transferred from the checking account described above to any savings account, certificates of deposit or other interest bearing account be reflected clearly on the reporting forms required to be filed with the Commission under 2 U.S.C. 434(b);

(2) That all funds transferred out of the designated checking account, as described above, be eventually transferred back into such account and clearly reflected on the reporting forms required to be filed with the Commission under 2 U.S.C. 434(b);

(3) That any interest earned from funds transferred to any savings account, certificates of deposit or other interest-bearing account be timely reflected on the reports required to be filed with the Federal Election Commission under 2 U.S.C. 434;

(4) That no expenditures be made from any funds transferred to an account other than the checking account at the designated campaign depository.

B. *Request of Thomas Coleman.* This request raises the question as to how one should report the transfer of surplus campaign funds remaining from an election campaign for local or State office to a Federal election campaign committee. The Commission's response to this question should not be construed as adversely affecting any donor's rights provided by State law as to the use of the donor's original contribution made in connection with a campaign for State or local elective office.

Funds received by a political committee which are transferred from any other source are contributions as defined in 2 U.S.C. 431(e)(3). As such, they are required to be reported under the provisions of 2 U.S.C. 434(b)(2)(4) and (7). Specifically, full information as to the source of all funds transferred to a reporting political committee, as well as the amounts and dates of all individual contributions included in the transfer, must be reported. The Commission agrees that Mr. Coleman may presume that the surplus transferred to his Federal campaign committee is comprised of those individual contributions last received before the State election. The Commission contemplates future regulations that will provide more specific guidance as to the proper reporting of transfers of this type.

The Commission also concludes that the funds to be transferred to the Federal campaign committee may not include any contributions by national banks or corporations, labor organizations, Government contractors, or agents of foreign principals. See 18 U.S.C. 610, 611, and 613. Furthermore, no contributions which exceed $1,000 from any one person and were made after January 1, 1975, may be transferred to the Federal campaign committee. Finally, any funds that were under Mr. Coleman's personal dominion and control, although contributed to a State campaign committee, may be transferred to the Federal campaign committee only to the extent permitted under 18 U.S.C. 608(a).

C. *Request of the Circle Club.* The question presented is whether a pre-existing political committee with residual funds may obtain consent from the original contributors of these funds to "earmark" their contributions for a specific Federal candidate, and transfer said earmarked contributions to the principal campaign committee of the candidate designated by the contributor.

Under 18 U.S.C. 608(b) persons (other than qualified multicandidate political committees) may not lawfully make contributions to any Federal candidate in excess of $1,000 with respect to any election. Subsection (b)(2) allows certain political committees to make $5,000 contributions to any Federal candidate with respect to each separate election.

In the event that contributions are earmarked by the donor (or on the donor's behalf), or otherwise directed through an intermediary or conduit to a particular candidate, they are treated as contributions to that candidate from the original donor and are, therefore, subject to applicable limits under section 608(b). Section 608(b)(6) would not apply to situations where donors relinquish complete control over their contributions and do not at a later time regain such control either by actual return of their contribution or, as in this instance, by request of the recipient committee for authorization to earmark a contribution originally given without such restriction. Since in this case the committee will be asserting some control over the earmarking by reason of the fact that it will actively seek to obtain consent from the donors to earmark funds for a specific Federal candidate, it follows that the committee, as well as the original donor, should be regarded as having made the contribution.

Hence, both aspects of the transaction are subject to limitation under 18 U.S.C. 608(b)(1). The committee must regard its involvement in procuring the authorization to earmark as tantamount to its own contribution and, therefore, subject to the $5,000 limit in 18 U.S.C. 608(b)(2), if it is otherwise qualified to make contributions in that amount. Further, such designated contributions must be reported to the Commission and the intended recipient by the political committee as provided in 18 U.S.C. 608(b)(6). Until issuance of final regulations, this may be accomplished by complying with the reporting provisions of 2 U.S.C. 434(b) and the earmarking regulations issued by the previous supervisory officers and adopted by the Commission on an interim basis on June 2, 1975, 40 FR 23833.

D. *Request of Senator James Buckley.* The Friends of Jim Buckley Committee has established an internal method of allocating political expenditures from "non-political" expenditures for constituent services. The Committee has solicited funds for both political and non-political purposes through its fundraising appeals. Senator Buckley requests an opinion as to:

(1) Whether the Commission will recognize the functional distinction between the two types of expenditures;

(2) Whether it will be necessary to establish another committee to handle funds expended for constituent services; and

(3) If a separate committee is established, whether a separate committee for constituent services will be able to receive funds from the political committee.

The matter of constituent service accounts is controlled by the provisions of 2 U.S.C. 439a and such rules as may be necessary to carry out the provisions of section 439a. The Commission has formally proposed such rules which treat contributions to and expenditures by constituent service funds as transactions of a political committee. See Notice 1975-18, August 5, 1975 (40 FR 32951).

Furthermore, in Advisory Opinion 1975-14, decided August 7, 1975, the Commission held that contributions to constituent service accounts are subject to 18 U.S.C. 608, 610, 611, 613, 614, and 615. Accordingly, the Commission has no objection to transfers of funds from the existing political committee to another one newly organized, but recognizes no functional distinctions between the two types of expenditures described in the request. Finally, the Commission concludes that all expenditures made by either the existing political committee or a new constituent service committee are subject to the spending limits applicable to a candidate under 18 U.S.C. 608(c).

Dated: August 21, 1975.

THOMAS B. CURTIS,
Chairman for the Federal Election Commission.

[FR Doc.75-22658 Filed 9-2-75;8:45 am]

[Notice 1975-37, AOR 1975-38—AOR 1975-57]

ADVISORY OPINION REQUESTS

In accordance with the procedures set forth in the Commission's Notice 1975-4, published on June 24, 1975 (40 FR 26660), Advisory Opinion Requests 1975-38 through 1975-57 are published today. Some of the Requests consist of similar inquiries from several sources which have been consolidated in cases where appropriate.

Interested persons wishing to comment on the subject matter of any Advisory Opinion Request may submit written views with respect to such requests within 10 calendar days of the date of the publication of the request in the FEDERAL REGISTER. Such submission should be sent to the Federal Election Commission, Office of General Counsel, Advisory Opinion Section, 1325 K Street, NW., Washington, D.C. 20463. Persons requiring additional time in which to respond to any Advisory Opinion Request will normally be granted such time upon written request to the Commission. All timely comments received by the Commission will be considered by the Commission before it issues an advisory opinion. The Commission recommends that comments on pending Advisory Opinion Requests refer to specific AOR number of the Request commented upon, and that statutory references be to the United States Code citations, rather than to the Public Law Citations.

AOR 1975-38: Use of Excess Campaign Funds for Office Expenses and Federal Preemption (Request Edited by the Commission).

GENTLEMEN: I am writing to request advisory opinions on the following questions, with regard to the Federal Election Laws.

(1) If I, as a Member of Congress, elect to use left-over campaign funds for

legitimate office expenses, will these expenditures be counted in determining whether I, or my Campaign Committee, have reached any of the spending limits set forth under the new law?

(2) If I elect to use campaign funds for legitimate office expenses, will it still be necessary for me or my Campaign Committee to file periodic reports with the Clerk of the House up to and until I again announce myself as a Candidate, or may I close out my accounts until that time?

(3) Does the new Federal Election Law supercede state campaign regulations, or must state laws be adhered to separately?

SILVIO O. CONTE,
Member of Congress.

Source: Representative Silvio O. Conte, House of Representatives, 239 Cannon House Office Building, Washington, D.C. 20515. (July 15, 1975.)

AOR 1975—39: Settlement of Campaign Debts Owed to Corporations (Request Edited by the Commission).

GENTLEMEN: Your recent Advisory Opinions 1975–5 and 1975–6 prompt us to ask on behalf of the Metzenbaum Post-Campaign Committee:

> May a candidate's committee, which incurred debts during the 1974 senatorial campaign, settle those debts with corporate or non-corporate creditors, if the committee has made a serious effort to bring down the amount of said debts since the date of the election and has little likelihood of raising additional funds sufficient to pay all debts in full?

After the election, we found ourselves indebted to the extent of about $113,000.00. A number of fund-raising events and personal solicitations have been made to the point that the committee has now been successful in decreasing that debt to under $79,000.00. The committee has a cash balance of a little over $5,000.00 at the present time. Some of the creditors, both individuals and corporations, have indicated a willingness to settle the amounts due them if we will offer a cash settlement. We believe it may be possible for us to solicit a modest amount of additional money. However, the last sentence of Advisory Opinion 1975–6 issued by the Commission on July 23, 1975 makes reference to the problem possibly faced by corporate creditors that acceptance of such settlements could be construed as violations of the Federal Election Campaign Act.

* * * * *

MELVIN S. SCHWARZWALD,
Counsel for the Metzenbaum Post-Campaign Committee.

Source: Metzenbaum Post-Campaign Committee by Counsel, Melvin S. Schwarzwald, Metzenbaum, Gaines & Stern, 1700 Investment Plaza, 1801 East 9th Street, Cleveland, Ohio 44114. (August 1, 1975.)

AOR 1975—40: Reporting Contributions from Political Action Committees (Request Edited by the Commission).

* * * The Federal Election law appears to be ambiguous on the question of the requirement of campaign committees to report contributions by political action committees when such funds are used to purchase tickets to a reception. * * *

It is my understanding * * * that campaign committees *are not* required to report individual contributions of $100 or less by political action committees when such contributions are made for the purpose of purchasing tickets to a reception. * * *

[T]his Committee requests a formal, written [advisory opinion] on whether a campaign committee is required to disclose publicly contributions of $100 or less by political action committees when such contributions are made for the purpose of purchasing tickets to a reception.

I would also like to know the rules covering reporting by donor organizations. I understand they must report their contributions, regardless of the amount.

WALLY JOHANSON,
Treasurer.

Source: Wally Johanson, Treasurer, Oberstar for Congress, Volunteer Committee, P.O. Box 465, Duluth, Minnesota 55802. (July 17, 1975.)

AOR 1975—41: Investment or Savings Deposits of Contributions or Other Receipts (Request edited by the Commission).

DEAR MR. CURTIS: Our Committee * * * formally makes his request of the Commission for an Advisory Opinion as to when, if ever, receipts from contributions, sales, collections, loans and/or transfers may be deposited in an interest-bearing savings account in a state and/or national bank, or invested in government treasury notes.

(Mrs.) ANN M. EPPARD,
Assistant Treasurer.

Source: (Mrs.). Ann M. Eppard, Assistant Treasurer, Shuster for Congress Committee, Star Route 5, Everett, Pennsylvania 15537. (July 24, 1975.)

AOR 1975—42: Application of Spending limits to Candidate Purchase of Advertising in Directories and Yearbooks (Request Edited by the Commission).

DEAR MR. CHAIRMAN: I have been invited by the editors of Hawaii's annual "Labor Director" to purchase a ⅛ page advertisment in the Directory. My photograph will appear with the words "Aloha to Labor from Sparky" superimposed. I have also been invited to purchase a quarter-page advertisement in the Hawaii State Little League Baseball "Souvenir Yearbook," which is published annually at the end of the Little League Baseball season. My photograph will appear with the words "Aloha and Best Wishes. (s) Spark Matsunaga, Member of Congress."

I would appreciate receiving the Commission's opinion as to whether this expenditure must be recorded as a "campaign expenditure" under the provisions of the Federal Elections Campaign Act, as amended. If so, would the cost of the advertisement be credited toward the Primary Election campaign expenditure ceiling established in 1974?

If the proposed advertisement is not a "campaign expenditure" under the provisions of the Federal Elections Campaign Act, could funds from my congressional Communications Fund be used for its purchase? A report of receipts and expenditures under my Communications Fund has been filed with the Clerk of the U.S. House of Representatives and the Lieutenant Governor of the State of Hawaii.

SPARK MATSUNAGA,
Member of Congress.

Source: Representative Spark Matsunaga, 422 Cannon House Office Building, Washington, D.C. 20515. (Two letters dated July 22, 1975.)

AOR 1975—43: Establishment by Corporation of Voluntary Employee Political Donation Program (Request Edited by the Commission).

GENTLEMEN: On behalf of TRW, I would like to respectfully request your advice on the following situation:

TRW operates a Good Government Program whereby employees who desire to participate are permitted to have a certain amount of their paycheck withheld and sent to a designated candidate or party. [The Commission notes that the TRW Good Government Program registered as a political committee on August 7, 1975]

All contributions made by our employees to the designated candidates or committees are fully disclosed to the intended recipient. Each recipient receives a check in the total amount of all contributions designated for such recipient and in addition receives a list of every employee who designated a contribution to such candidate or committee together with the amount contributed by such employee. TRW simply acts as an agent of the employee in forwarding the designated contribution much as a bank operates as an agent of a depositor when a check is written and the bank honors that check upon presentment.

However, it would appear possible to argue that TRW is an "intermediary or conduit" within the meaning of Title 18 608(b)(6) of the United States Code. TRW does not believe that our program is within the spirit of this section. However, since the point is arguable we would like to request the Commission's position on this point.

Should the Commission rule that TRW is an "intermediary or conduit" rather than a simple agent of its employees, we would like to be informed of the Commission's requirements for our fund particularly in the following respects:

(1) How frequently should we report or file with the Commission?

In some cases, our payroll departments issue checks biweekly in other cases payroll periods are semi-monthly, monthly or weekly. In some cases the amounts to be withheld pursuant to

the employees direction are withheld in each paycheck and others the deduction is made only once a year. I am sure that neither TRW nor the Commission desires to be inundated with paperwork for this program. Accordingly, if the Commission feels a report is necessary at all, TRW respectfully suggests that such report be provided to the Commission annually.

(2) What form should we use for the report?

We are not aware of any form which can be appropriately used for purposes of § 608(b)(6). Accordingly, if the Commission desires TRW to report its program under this section we respectfully request that the Commission adopt some form on which we may make the report or at least inform us of the various items which the report should contain.

* * * * *

WILLIAM A. HANCOCK.
Senior Counsel.

Source: TRW Good Government Program by Counsel, William A. Hancock, TRW, Inc., 23555 Euclid Avenue, Cleveland, Ohio 44117. (July 28, 1975.)

AOR 1975—44: Request of Socialist Workers 1976 National Campaign Committee (Request Edited by the Commission).

DEAR COMMISSIONERS:

* * * * *

We seek advisory opinions under 2 U.S.C. 437f from the Commission on several questions regarding the Act and the 1974 Amendments.

1. In our letter of January 31, 1975 we requested clarification on the $1,000 limitation on contributions. Does this limit apply separately to primary, runoff (if any), and general elections? Section 608(b)(5) indicates that the limitation is $2,000 for presidential candidates but fails to give any time limitation. Is it for instance, $1,000 before the primary and an additional $1,000 between the primary and the general election? If the limitation does apply separately for candidates contending in primary and run-off elections, does it also apply separately for candidates contesting only the general election?

2. Regarding the limitation of $100.00 on petty cash purchases and transactions (18 U.S.C. 615), does this mean that no check to the order of "cash" can be made for over $100.00? What does a campaign committee do in a situation where a candidate or representative of a candidate is out of town and requires emergency funds in excess of $100.00? What does a committee do in the case where its checks are unacceptable as a means of payment for a certain vendor, for example, the U.S. Postal Service?

* * * * *

4. When candidates are not contesting special, primary, or run-off elections, what are the reporting requirements regarding the 10-day preelection and 30-day postelection reports?.

* * * * *

6. What constitutes a "debt" or "obligations" itemizable under parts 11 and 12 of the reports? Does this refer to long-term debts and obligations of say, 60 days, or something else?

7. Do the non-principal campaign committees have to be authorized in writing by the candidates?

8. What constitutes "affiliation" and "relationship" of committees?

* * * * *

ANDREA MORELL,
Treasurer, Socialist Workers 1976 National Campaign Committee.

Source: Andrea Morell, Treasurer, Socialist Workers 1976 National Campaign Committee, 14 Charles Lane, New York, New York 10014. (July 10, 1975.)

AOR 1975—45: Legality of the Establishment and Administration of "Independent Autonomous" Multicandidate Political Committees (Request Edited by the Commission).

DEAR SIR: We represent the Agricultural & Dairy Educational Political Trust ("ADEPT").

* * * * *

ADEPT submits this advisory opinion request, by counsel, pursuant to the provisions of 2 U.S.C. 437f(a).

The pertinent facts are that ADEPT is considering the establishment in several states of the Union of independent and autonomous political committees which, like ADEPT, would be multiple candidate committees and which, like ADEPT, would be political committees * * *. Each such committee would operate solely within the state in which it was organized; would be governed by committee members at least one of whom would be resident in such state; would make political contributions as defined by the provisions of 2 U.S.C. 431(e) and 18 U.S.C. 591(e); would exercise its independent judgment as to the beneficiaries and amounts of its contributions; would report to the Federal Election Commission pursuant to the provisions of 2 U.S.C. 434(a); and, except to the extent it might receive unanticipated and unsolicited donations, would depend solely for its funds upon transfers from ADEPT (which transfers would be reported by ADEPT as contributions by ADEPT); and which might receive the benefit of accounting, clerical, legal or similar services in kind from ADEPT (which services also would be reported by ADEPT as contributions from ADEPT).

The basic question is whether such committees may be established.

If the basic question be answered in the affirmative, ADEPT would propound the following questions.

1. May the Treasurer of ADEPT also serve as the treasurer of one or more of the state committees?

2. Would the limitations upon the quantum of contributions set forth in 18 U.S.C. 608(b)(2) be applicable (1) separately to ADEPT and to each such committee or (2) in the aggregate to ADEPT and each and every such committee?

3. May one or more members of the ADEPT committee also hold membership on one or more state committees?

4. May each state committee be funded by transfers of funds from ADEPT? In this connection ADEPT envisions that upon being notified by a particular state committee that the funds thereof were depleted to the sum of $1,000.00 or some other relatively small sum, ADEPT would transfer to that particular state committee a substantial sum, as for example, $25,000.00. No part of the transfer would be earmarked for a particular contribution. The state committee would be free to spend the money as it deemed appropriate. The state committee then would be expected to advise ADEPT when at some subsequent date its funds available for contribution again dropped to $1,000.00.

* * * * *

MARION EDWYN HARRISON.

Source: Marion Edwyn Harrison, Harrison, Lucey, Sagle & Solter, 1701 Pennsylvania Avenue, NW., Washington, D.C. 20006. (July 15, 1975.)

AOR 1975—46: Fee for the Televised Appearance of A Member of Congress (Request Edited by the Commission).

DEAR MR. CURTIS: I am writing on behalf of United States Representative Barbara Jordan, 18th District of Texas to request advisory opinions regarding section 616 of the "Federal Election Campaign Act Amendments of 1975." As you know, that section deals with the "Acceptance of Excessive Honorariums."

Miss Jordan has been asked to provide editorial comment once a month which is recorded on video tape, for presentation on the C.B.S. television Morning News Show. She is paid One Hundred and Fifty Dollars for each taping.

It is our position that this payment is salary for services for which a fee is traditionally required, and therefore, should not be included when computing her acceptance of honorariums for the calendar year. * * *

RUFUS (BUD) MYERS.

Source: Representative Barbara Jordan by Rufus Myers, Administrative Assistant, 1534 Longworth House Office Building, Washington, D.C. 20515. (July 3, 1975.)

AOR 1975—47: Expenditures of Corporate Funds by Host Committees for the Benefit of National Political Party (Request Edited by the Commission).

DEAR COMMISSIONERS:

* * * * *

On behalf of the Democratic National Committee, a supplementary advisory opinion is requested in this regard.

Specifically, Advisory Opinion 1975–1 provided, in part, that local corporations which are engaged in certain retail businesses may contribute funds to a local civic association, or other similar type of business association ("Host Committee"), which payment, under certain conditions, would not constitute a pro-

hibited corporate contribution within the provisions of 18 U.S.C. 610. The Opinion did not cover the purposes for which a Host Committee could expend its funds, including funds derived by it from local retail corporations referred to above.

An Opinion is respectfully requested that a Host Committee may offer to the National Committee any of the services, benefits, or uses of property described in paragraphs (1) through (7), inclusive, of Advisory Opinion 1975–1, without violating 18 U.S.C. 610, and that such transactions do not involve "expenditures" under 26 U.S.C. 9008(d).

STUART E. SEIGEL.

Source: Stuart E. Seigel, Cohen and Uretz, 1775 K Street, NW., Washington, D.C. 20006. (August 4, 1975.)

AOR 1975—48: Attribution of Contribution to Political Party to Candidate Receiving Funds from that Party (Request edited by Commission).

DEAR COMMISSIONER: * * * We request that the Federal Election Commission issue an Advisory Opinion in answer to this question:

Because the 1974 Act imposes a $1,000 limit on contributions by an individual to a candidate for election to Federal office, if a contributor makes a contribution of less than $1,000 to a candidate's campaign committee and thereafter is asked to contribute to one or more state and local party committees, some portion of whose receipts from contributions will be contributed by that committee to or expended for the election of that same candidate, but where the portion of the individual's contribution has not been earmarked for that candidate either by the contributor or the party committee, can the contributor make that contribution to the state or local party committee without being considered to have exceeded the $1,000 limitation?

If the answer to the foregoing question is no, what steps must the state or local party committee or the contributor take in order to insure that his total contributions to the Federal candidate do not exceed the $1,000 limit?

RICHARD C. FRAME,
State Chairman.

Source: Richard C. Frame, State Chairman, Republican State Committee of Pennsylvania, P.O. Box 1624, Harrisburg, Pa. 17105. (August 5, 1975.)

AOR 1975—50: Application of 1974 Amendments to Debt Transaction Incident to Special Election in 1975 (Request edited by Commission).

DEAR MR. CURTIS: After studying the latest Federal Election Commission Advisory Opinion (1975–76) there remain specific questions to be answered concerning campaign debts owed by this Committee.

Jeff LaCaze was a candidate for the U.S. House of Representatives from The Sixth District of Louisiana. The results of the general election of November 5, 1974 was disputed and after litigation the state courts ordered a new election for January 7, 1975.

* * * * *

* * * [C]ontributions in excess of $1,000 were received by this Committee during 1975 and used for an election held in 1975 * * *.

Please clarify this [question], i.e. were contributions received subsequent to December 31, 1974 and prior to January 8, 1975 subject to the 1971 Act * * * or subject to provisions of the 1974 Act as indicated in Advisory Opinion 1975–6?

Additionally, please consider the following for an [advisory opinion]:

1. Promissory notes made in 1974.

a. Are accrued interest payments made in 1975 on these notes, "debt" incurred during 1974 and therefore, payable with contributions as outlined in Advisory Opinion 1975–6?

b. Can makers of these notes (i.e. co-guarantors, etc.) pay interest accumulated on these notes without having these contributions being subject to the 1974 Act?

2. Corporate debts owed by a Candidate or Committee.

a. Can debts owed by a candidate or committee to a corporation be forgiven or settled for sums less than those previously billed without such forgiveness of debt being considered an "illegal contribution" as outlined under 18 U.S.C. 610–611?

b. Can a corporation write off as bad debts, any debts owed by a candidate or committee for which payment cannot be made?

TED E. DOVE,
Treasurer.

Source: Ted E. Dove, Treasurer, The Jeff Lacaze Committee, P.O. Box 14649, Baton Rouge, Louisiana 70808. (August 5, 1975.)

AOR 1975—51: Use of Excess Campaign Funds to Purchase Congressional Office Equipment (Request edited by the Commission).

DEAR MR. CURTIS: * * * This is a request for an advisory opinion on the use of campaign funds to defray Congressional office expenses above the usual electrical equipment and clerk-hire allotments.

Our office plans to install a computer terminal to meet the demands of constituent mail. The cost of the terminal will exceed our office allotment and, therefore, we would like to use excess campaign funds to establish a separate Oberstar Office Equipment account.

In checking with the Office of the Clerk of the House, Mr. Moss recommended this separate account and suggested the account be set up in a manner allowing a staff member to make disbursement, rather than require the Member's signature.

Mr. Moss assured me that the use of campaign funds in the manner prescribed is legal and preferred (reference Section 439(a) of the 1974 Federal Election law). However, he felt a letter to your office asking for an advisory opinion would be wise. * * *

JAMES L. OBERSTAR,
Member of Congress.

Source: Congressman James L. Oberstar, Room 323, Cannon House Office Building, Washington, D.C. 20515. (July 8, 1975.)

AOR 1975—52: Assistance by Multi-candidate Committee to Pay Off a Candidate's Past Campaign Debt (Request Edited by the Commission).

GENTLEMEN: I am writing to inquire as to whether or not in your opinion a State Committee may assist a successful candidate for the Congress to pay off his 1974 election debt without impairing the limitations on the amount of money it may give to said Congressman under the new law should he be a candidate for re-election in 1976?

JOHN R. LINNELL.

Source: John R. Linnell, Maine Republican State Committee, 187 State Street, Augusta, Maine 04330. (July 14, 1975.)

AOR 1975—53: Application of Limitations on Contributions and Expenditures to Nomination by Petition Effort (Request edited by the Commission).

DEAR MR. CURTIS: A group of interested citizens in the State of Maryland have formed a political committee of which I am Chairman to explore the possibility of promoting the independent candidacy of Bruce Bradley for the office of United States Senator in 1976.

In the process of gathering preparatory information, we find that under Maryland law, an independent candidate may qualify by petition to have his name placed on the ballot for the general election.

In reviewing the provisions of the Federal Election Campaign Act of 1971 [as amended in 1974] * * * we find the language of 18 U.S.C. 608(c)(1) * * * sufficiently vague as to request a formal advisory opinion from you on the following specific issues:

1. * * * Under Maryland law an independent candidate for United States Senator must qualify for election by petition, a method which, while involving the expenditure of funds for political purposes, is not an expenditure of political funds for nomination by election in a primary election sponsored by an organized political party. We would like an opinion as to whether or not nomination by petition in this case is considered legally equivalent to any other primary election contemplated under [18 U.S.C. 608(c)(1)(C)] * * *. We would interpret an affirmative ruling in this case to mean that an independent candidate for nomination for election to the office of U.S. Senator from the State of Maryland attempting to qualify as a candidate for the general election by petition would be eligible to raise funds and

spend them as if he were any other candidate attempting to obtain nomination for election through the political primary process. Further, such an interpretation would mean that the limitations of [18 U.S.C. 608 (c)(1)(C)] * * * would apply to all political activities of an independent candidate up until such time as he is legally certified as a candidate for the general election by competent state authority.

2. Assuming that the above ruling is in the affirmative, and that an independent candidate is considered for purposes of the spending limitations as any other candidate for nomination by primary, would there be any restrictions on funds used to qualify by petition other than those imposed by the Federal Election Campaign Act of 1971, as amended? We would interpret a no restriction ruling as permitting the expenditure of funds raised to qualify for election by petition for the same types of activities and services as would be procured under the law by any other candidate seeking nomination by primary, i.e. payment of staff salaries, media advertisements, airplane or car rentals, and publications of a promotional nature.

3. If, in fact, qualification by petition constitutes a primary for purposes of [18 U.S.C. 608(c)(1)(C)] * * * and a surplus remains at the time the candidate's petition is certified and he is, in fact, qualified for election under State law, can the surplus be carried over for use in the general election campaign without regard to the limitations imposed under [18 U.S.C. 608(c)(1)(D)]? * * *

JOHN F. FALCONER.

Source: John F. Falconer, Chairman, Bradley for Senate Committee, 10600 Seneca Ridge Drive, Gaithersburg, Maryland 20760. (June 30, 1975.)

AOR 1975—54: Application of Contribution and Expenditure Limitations to Each Election Held in a State (Request edited by the Commission).

GENTLEMEN: * * * Utah has a somewhat unique nomination process. At the respective State Nominating Conventions, attended by delegates elected at precinct mass meetings, primary contenders are reduced to two. If, however, one candidate receives 70 percent of the vote, he becomes the nominee, without a primary. Both Senator Jake Garn (R-Utah), and his opponent, former Congressman Wayne Owens (D-Utah) in 1974 received a 70 percent convention nomination.

Were there, in Utah, to be 3 phases of a Federal campaign (i.e., convention, primary and general) would the campaign limitation apply to each phase, with no carry-over from one time frame to another? Under the prior law the Secretary of the Senate answered this question affirmatively, denoting, accurately, no difference between primary run-offs and the Utah system.

Your advisory opinion on the question raised is sought.

KENT SHEARER,
Legal Counsel.

Source: Kent Shearer, Legal Counsel, Utah Republican Central Committee, c/o Mock, Shearer and Carling, 1000 Continental Bank Building, Salt Lake City, Utah 84101. (June 28, 1975.)

AOR 1975—55: Organizational Contributions to Charity in Lieu of Honorarium To Federal Office-Holders or Scholarship Fund (Request Edited by the Commission).

DEAR MR. CHAIRMAN: I write to request a clarification and interpretation of the requirements and limitations under Section 616 of Title 18 of the U.S. Code with respect to honorariums received by a Member of Congress.

Would it be proper, assuming no self-dealing or self-serving implications of any kind, for private organizations to make contributions to legitimate charities, either in lieu of or in addition to honorariums that I might otherwise receive? Would such contributions in any way count with respect to the limitations imposed under Section 616?

In addition, a special situation would be the possible establishment of a scholarship fund, properly set up with no self-dealing and an unrelated board of directors. If a private organization were asked in lieu of an honorarium, to make such a contribution only if they wished, and not as a condition for my appearance, would this be proper?

AL ULLMAN,
Member of Congress.

Source: Representative Al Ullman, House of Representatives, Washington, D.C. 20515. (August 11, 1975.)

AOR 1975—56: Office Account Expenditures Chargeable to Primary or General Election Campaign.

DEAR SIR: I hereby request an advisory opinion in regard to the following:

Are expenditures by an office account to be counted against the expenditure limitations applicable to a campaign for election (general) or should they be counted against the campaign for nomination for election (primary).

STEPHEN J. SOLARZ,
Member of Congress.

Source: Representative Stephen J. Solarz, House of Representatives, 1228 Longworth House Office Building, Washington, D.C. 20515. (August 12, 1975.)

AOR 1975—57: Application of Limits to Post-election Contributions to Single Candidate Committee (Request Edited by the Commission).

DEAR SIR: We would appreciate a ruling from you regarding certain points of law regarding candidates/campaigns for Federal Office (U.S. Senate), Title III of Public Law 92-225, the Federal Election Campaign Act.

Please give us a ruling on the following:

(1) Is there any limitation as to time that contributions can be accepted *subsequent* to the election?

(2) Is it permissible to accept funds raised from Testimonials, Dinners, etc. (given for the benefit of the candidate) subsequent to the election?

(3) If post election contributions are acceptable, is it in any way contrary to the law to repay the candidate for funds loaned to his own campaign fund, which has been used to defray campaign expenses?

A. R. GRIGSBY,
Treasurer,
John L. Grady Campaign Fund.

Source: A. R. Grigsby, Treasurer, John L. Grady Campaign Fund, Belle Glade, Florida 33430. (August 1, 1975.)

Dated: August 25, 1975.

THOMAS B. CURTIS,
Chairman for the
Federal Election Commission.

[FR Doc.75-22942 Filed 9-2-75;8:45 am]

federal register

WEDNESDAY, SEPTEMBER 3, 1975

PART III:

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

■

ADMINISTRATIVE PRACTICES AND PROCEDURES

NOTE: For another document from the Food and Drug Administration on this matter see 40 FR 40520, in this issue.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Parts 1, 2, 5, 6, 8, 10, 11, 80, 90, 100, 102, 121, 202, 310, 312, 314, 328, 330, 429, 430, 431, 433, 511, 514, 601, 701, 1003, 1004, 1210]

[Docket No. 75N-0001]

ADMINISTRATIVE PRACTICES AND PROCEDURES

Notice of Proposed Rule Making

The Commissioner of Food and Drugs is proposing rules governing the administrative practices and procedures of the Food and Drug Administration. The regulations proposed herein were the subject of a notice of rule making, published in the FEDERAL REGISTER of May 27, 1975 (40 FR 22950), which the Commissioner is revoking elsewhere in this issue of the FEDERAL REGISTER.

The May 27th order specified that the regulations would become effective on July 28, 1975, except for two provisions that were to become effective on November 24, 1975, and invited public comment on the regulations on or before July 28, 1975, for the purpose of making subsequent modifications as appropriate. In a notice published in the FEDERAL REGISTER of June 20, 1975 (40 FR 26027), the Commissioner extended the comment period to August 27, 1975.

On July 23, 1975, the American College of Neuropsychopharmacology brought suit in the United States District Court for the District of Columbia to enjoin the effectiveness of the regulations, contending that section 553 of the Administrative Procedure Act (5 U.S.C. 553) requires that they be proposed for comment prior to publication in the FEDERAL REGISTER as a final rule. Pursuant to request of the Court, the Food and Drug Administration agreed to delay the effectiveness of the regulations pending a decision on the plaintiff's motion for a preliminary injunction. This action was announced in a notice published in the FEDERAL REGISTER of July 28, 1975 (40 FR 31605), staying the effectiveness of the regulations until August 4, 1975.

On July 31, 1975, the District Court issued an Order permanently enjoining the Commissioner from issuing the regulations "without complying, as a condition precedent, with the requirements of section 553 of the Administrative Procedure Act, 5 U.S.C. 553." *American College of Neuropsychopharmacology* v. *Weinberger, et al.*, Civil Action No. 75-1187. Accordingly, in a notice published in the FEDERAL REGISTER of August 4, 1975 (40 FR 32750), the Commissioner stayed the effectiveness of the regulations until further notice. Pursuant to the Court's Order, the Commissioner had the Court's Findings of Fact, Conclusions of Law, and Order published in the FEDERAL REGISTER of August 6, 1975 (40 FR 33063).

The Commissioner is of the opinion that the Court's action is in error. The legal basis and justification for issuing the rules governing Food and Drug Administration administrative practices and procedures as final regulations were set forth in the preamble to the regulation of May 27 and in the Memorandum of Points and Authorities in Opposition to Plaintiff's Motion for a Preliminary Injunction filed in the court proceeding. Nevertheless, the Commissioner has concluded that the regulations should immediately be issued as proposed rules with additional opportunity for comment. The delays and uncertainties involved in attempting to obtain reversal of the decision of the District Court make it impractical to pursue any other course.

The Order of the District Court enjoins the promulgation of the regulations "as final," subject to compliance with the rule making provisions of the Administrative Procedure Act. The regulations incorporate many practices and procedures that were being followed within the Food and Drug Administration prior to May 27; many that are unavoidable in the Commissioner's discharge of the various statutory responsibilities vested in him; and many that apply exclusively to the internal processes of the agency. The Commissioner does not interpret the Court's Order as foreclosing observance of a particular practice or procedure simply because it is codified in the regulations, e.g., the requirement in § 2.22 (21 CFR 2.22) that certain agency officials maintain public calendars. Were the Order to be given that effect, the agency would be literally incapable of operating. Rather, the Commissioner views the Order as preserving the status quo, and as therefore permitting the agency to follow the procedures that it had previously observed, or could have observed, in carrying out its activities without the regulations. The Commissioner has no intention of taking any action in contravention of the Court's Order. Necessarily, the decision whether a particular procedure may be followed will require the exercise of judgment of those agency officials immediately involved.

The regulations proposed herein retain §§ 2.23(b) and 2.330(b)(2)(ii), which were indefinitely stayed, for reasons unrelated to the action of the District Court, in an order published in the FEDERAL REGISTER of July 25, 1975 (40 FR 31234). The Commissioner recognizes that these provisions are controversial and could, if implemented, pose problems for, respectively, associations desiring to participate in agency proceedings and individuals invited to serve as liaison members of advisory committees. Their retention in the proposed regulations does not reflect a commitment to adopt them in final form. The Commissioner desires to receive additional comment on both provisions, and particularly encourages the submission of other possible regulations that would address the problems that those provisions attempt to solve.

To avoid controversy about the manner in which this rule making is conducted, the Commissioner has concluded that the contents of the May 27th notice of rule making should be republished, including the bulk of the preamble. The introductory statement and the discussion under the heading "Effective Date" in the preamble are omitted to prevent confusion. Other references in the preamble that were originally phrased to indicate action already taken have been changed to refer to action proposed. The paragraph describing the nature of the action announced in the document and the authority under which it is taken has been modified to reflect that the rules that follow are proposed and not final. The final paragraph of the May 27th regulation, relating to the effective date, is omitted.

Several minor changes are also incorporated in this republished document to correct typographical errors, inadvertent omissions, and incorrect cross-references.

The Commissioner has concluded that 30 days should be allowed for public comment on these proposed regulations. Their full text has been publicly available in the FEDERAL REGISTER since May 27, 1975. It is widely known that individuals and groups concerned with Food and Drug Administration activities have been actively preparing written comments for submission by August 27, the last day of the extended comment period. Any interested individuals or groups that did not originally plan to submit comments must necessarily have been acquainting themselves with the regulations during the more than 2 months since their initial publication in order to be in a position to comply with, or take advantage of, the regulations as of the original effective date of July 28. Any such individuals and groups will have 30 additional days in which to record and submit any comments on the proposed regulation which they may now wish to make. Comments submitted in response to the invitation of May 27 will be deemed comments on this proposal, and need not be submitted.

When issued as a final rule, the proposed regulations will have an effective date of 30 days after publication in the FEDERAL REGISTER. Although the regulations are proposed in a single, comprehensive document, the Commissioner may issue them as final regulations either as one document or as several documents published at different times. The latter course will permit regulations about which there is little controversy, or that are essential to the efficient functioning of the agency, to be put into effect without unnecessary delay.

This notice proposes administrative practices and procedures governing activities of the Food and Drug Administration. It includes the procedures under which citizen petitions would be submitted to and considered by the agency, the justification for and conduct of formal evidentiary public hearings, public hearings before a Public Board of Inquiry, public hearings before a public advisory committee, public hearings before the Commissioner, regulatory hearings before the Food and Drug Administration, and standards of conduct and conflicts of interest. It would amend existing agency regulations to conform them to the proposed regulations governing practices and procedures.

The present administrative practices and procedures of the Food and Drug

Administration are largely uncodified and, to the extent that they are included in existing regulations, are spread throughout numerous sections in the Code of Federal Regulations and in agency manuals. Many of these practices and procedures have been developed over the years on an ad hoc basis, to meet immediate needs, without systematically integrating them into the agency's overall practices and procedures. Many of the agency's practices and procedures have not been written down in any manual or regulation. Accordingly, the Commissioner of Food and Drugs has concluded that a thorough review of agency practices and procedures should be undertaken, and that comprehensive regulations should be adopted to codify existing requirements, establish new requirements where none currently exist, and conform present regulations so that practices and procedures will be applied consistently throughout the agency. This notice of proposed rule making reflects the continuing efforts of the Food and Drug Administration on this project for more than a year.

The Commissioner notes that this notice proposes regulations dealing with administrative practices and procedures exclusive of regulatory enforcement activities. The Food and Drug Administration is presently at work codifying the agency's enforcement practices and procedures, which will include regulations relating to imports, criminal prosecution (including both the use of citations under section 305 and the criteria for recommending criminal prosecution), recall and detention of products, publicity, regulatory letters, and related matters. These regulations will be published in the FEDERAL REGISTER in the future.

ADMINISTRATIVE PRACTICES AND PROCEDURES (PART 2)

The Commissioner has concluded that Part 2 of Title 21 of the Code of Federal Regulations should be set aside to contain all regulations governing Food and Drug Administration administrative practices and procedures. Accordingly, under this proposal, the existing provisions in Subparts H and M of Part 2, relating to delegations of authority and organization of the Food and Drug Administration, would be transferred to a new Part 5. The provisions relating to formal evidentiary public hearings in present Subpart F of Part 2 are substantially out of date, and would be revoked and superseded by the new regulations in Subpart B of Part 2.

GENERAL (SUBPART A)

Subpart A of proposed Part 2 would encompass all of the general provisions relating to the agency's practices and procedures. The Commissioner anticipates that, as additional agency policy is established with regard to general practices and procedures, it would be added in the form of new sections in this subpart.

SCOPE (§ 2.1)

Subpart A of proposed Part 2 deals with a number of provisions that have general applicability throughout the agency. It contains, for example, uniform requirements with respect to all information filed with the Hearing Clerk, and a standard form for petitions to be filed with the Hearing Clerk. The Commissioner recognizes, however, that specific provisions in other subparts of Part 2, or in other sections of Title 21 of the Code of Federal Regulations, state different requirements applicable to a particular matter. Thus, the form for a new drug application (NDA) in § 314.1(c)(2) would of course remain applicable, as would all of the other specific forms and formats specified throughout present agency regulations. NDA's would continue to be submitted to the Bureau of Drugs as provided in § 314.1(c), a food additive petition would continue to be submitted to the Bureau of Foods as provided in § 121.51(c), and other forms would be submitted as provided in current agency regulations. In summary, all information submitted to the Hearing Clerk would have to comply with the requirements specified in new § 2.5, except to the extent that other specific sections in existing regulations contained different requirements that are inconsistent with the provisions of new § 2.5. Thus, new general requirements would be established that would apply consistently and uniformly throughout the agency, except to the extent that they are explicitly overridden by specific provisions in other sections.

DEFINITIONS (§ 2.3)

Proposed § 2.3 contains uniform definitions for use throughout all of Part 2. Some of the more important definitions are as follows:

The proposed definitions clearly distinguish between a "party" to and a "participant" in a formal evidentiary public hearing or a Board of Inquiry. A "party" is any person who has exercised the right to request a hearing and as a result of whose action a hearing has been granted. A "participant" means any person who wishes to participate in any proceeding, including the parties and other interested persons. The bureau of the Food and Drug Administration responsible for the matter involved is always a party in any hearing.

The terms "interested person" and "any person who will be adversely affected" are defined very broadly to mean any person who wishes to participate in any proceeding of the Food and Drug Administration. There is no requirement that such person exhibit any particular interest, or show any specific economic or other harm or other indicia of "standing." Since Food and Drug Administration activities directly affect all members of the public, all members of the public who wish to participate are "interested persons" and "adversely affected" by definition. The courts have ruled that all citizens who wish to challenge agency actions affecting food and drugs are "adversely affected" and thus may properly submit objections and otherwise participate in administrative proceedings where the statute requires such a showing. See Reade v. Ewing, 205 F. 2d 630 (2d Cir. 1953).

The term "petition" is defined broadly to include any form of formal request for agency action, including petitions, applications, or other similar documents. It does not include routine correspondence which does not purport to meet the requirements for a petition proposed in § 2.6(a) of the regulations.

The proposed definitions distinguish between a "regulation" and an "order," for purposes of application of the requirements of the Administrative Procedure Act. Regulations are agency rules of general or particular applicability and future effect that are issued in the FEDERAL REGISTER and codified in the Code of Federal Regulations. A regulation may state either a legal requirement or a recommendation of the Food and Drug Administration. Orders mean final agency disposition of an administrative proceeding other than by the issuance of a regulation, including the issuance or revocation of product licenses.

A "meeting" is defined to include any oral discussion, whether by telephone or in person.

"Administrative action" includes every form and kind of act, including the refusal or failure to act, involved in the implementation of the laws administered by the Commissioner. The referral of apparent violations to United States attorneys for the institution of criminal and civil proceedings, including any enforcement activity in preparation for or incidental to such referral, is specifically excluded from this definition, however, since such enforcement action is solely within the discretion of the Commissioner and is not subject to petitions or other action by interested persons outside the agency. Thus, such compliance activity as factory inspection, requests for samples, section 305 citations, and similar matters related to the agency's law enforcement role are not included in this definition.

SUMMARY OF PROCEDURES (§ 2.4)

Many interested persons have complained that it is difficult to know and understand all of the administrative procedures utilized by the Food and Drug Administration. The Commissioner recognizes that public understanding of agency procedures is essential to encourage and facilitate public participation in all agency activities. Accordingly, § 2.4 of the regulations would require preparation and broad dissemination of summaries of agency procedures, perhaps in pamphlet form, in terms that will be readily understood and usable by the lay public.

SUBMISSION OF DOCUMENTS TO HEARING CLERK; COMPUTATION OF TIME; AVAILABILITY FOR PUBLIC DISCLOSURE (§ 2.54)

Proposed § 2.5 contains new uniform requirements for submission of all documents to the Hearing Clerk, except where

other provisions in agency regulations specify different requirements.

Under proposed § 2.5, submissions would have to be filed in quintuplicate, except for comments filed by individuals, and would have to include all data and information referred to or in any way relied upon unless the material has been previously submitted as part of the administrative file in the same proceeding, e.g., a petition for reconsideration may refer to the previously established administrative record without reproducing any portion of it. All such documents would be considered as submitted on the date on which they are postmarked or delivered in person during regular business hours, unless an applicable regulation or FEDERAL REGISTER notice specifies otherwise. Actual copies of all documents to which reference is made are needed because of the Commissioner's experience that they are frequently hard to locate. Documents in a foreign language would have to be translated to avoid substantial agency resources being devoted to such translation and delay necessitated by obtaining translation.

Submission would have to be signed by the person making the submission or by an attorney or other authorized representative. An attorney or other authorized representative could, of course, submit comments or other documents in his own name, without revealing that he is acting on behalf of a client. If a submission revealed that an attorney or representative were not acting on his own behalf, there would have to be documentation verifying his authority to act in a representative capacity.

The Commissioner advises that the Food and Drug Administration will require rigid adherence to these proposed requirements. Failure to comply with the requirements of § 2.5, or any other applicable requirements for format and content in these proposed regulations, e.g., § 2.112 relating to objections and requests for hearing, would result in rejection of the submission for filing or, if it has been filed, in exclusion from consideration of any portion of the submission which fails to comply. The courts have held that administrative agencies may properly reject a filing when it is deficient in form. See, e.g., Municipal Light Boards v. Federal Power Comm'n., 450 F. 2d 1341, 1345–1346 (D.C. Cir. 1971), cert. denied, 405 U.S. 989 (1972).

The Commissioner recognizes that it will be difficult for the Hearing Clerk to determine compliance by the hundreds of thousands of submissions made yearly to the Food and Drug Administration with all of the technical requirements of these proposed regulations. The appropriate bureau, the Chief Counsel, and the Associate Commissioner for Compliance could be called upon by the Hearing Clerk to advise as to whether a particular submission should be filed. It is anticipated that some submissions which did not comply might erroneously be filed. Accordingly, the proposed regulations provide that acceptance for filing does not mean or imply that a document in fact meets all applicable requirements of the regulations.

Under some Food and Drug Administration regulations, acceptance for filing means that the agency has determined that a petition contains reasonable grounds for the action requested and that the action requested is in accordance with the law. In view of the fact that the Hearing Clerk is not in a position to make these determinations, the proposed regulations would explicitly provide that acceptance for filing of any document by the Hearing Clerk does not mean or imply anything with respect to the merits of the request.

Because the office of the Hearing Clerk is located in Rockville, MD, it is sometimes inconvenient to deliver a submission which is required to be received by the Hearing Clerk on a specific date. Accordingly, any document delivered to Rm. 6819 of the Food and Drug Administration downtown headquarters building at 200 C Street, SW., Washington, DC, would be considered as having been received by the Hearing Clerk on the date on which it is logged in at that office. The Commissioner emphasizes that this provision would apply only to documents that are required to be received by the Hearing Clerk by a specific date, and not to documents that are required to be mailed to the Hearing Clerk by a specific date.

All submissions to the Hearing Clerk constitute a representation that, to the knowledge and belief of the person making the submission, the statements made are true and accurate. The False Reports to the Government Act, 18 U.S.C. 1001, provides that a willfully false statement in any submission of this type is a felony. All submissions would be required to be signed by the person making the submission, and that individual would therefore be subject to this provision of the law.

Proposed § 2.5(j) governs the availability for public examination and copying of all submissions to the Hearing Clerk. Thus, it would apply to such matters as petitions and comments on petitions, and also to all evidence and pleadings submitted to the Hearing Clerk in the course of a formal evidentiary public hearing pursuant to Subpart B of Part 2, a public hearing before a Public Board of Inquiry pursuant to Subpart C, a public hearing before the Commissioner pursuant to Subpart E, or any alternative form of public hearing used pursuant to § 2.117 in lieu of a formal evidentiary public hearing. It would not apply to a public hearing before a public advisory committee pursuant to Subpart D except when it is being used pursuant to § 2.117 or to a regulatory hearing before the Food and Drug Administration pursuant to Subpart F, however, because those two subparts would not provide for submission of material to the Hearing Clerk. Accordingly, separate provisions in §§ 2.316 and 2.514 would govern examination of the administrative record of a public hearing before a public advisory committee and a regulatory hearing before the Food and Drug Administration.

Proposed § 2.5(j) would divide submissions to the Hearing Clerk into three categories: those that may be seen and copied by the public, those that may be seen but not copied by the public, and those that may be neither seen nor copied by the public.

The Commissioner concludes that all petitions and comments thereon submitted to the Hearing Clerk should be available for public review and copying. These involve public procedures, and any action to be taken must be justified by the Commissioner to the public. For example, the Commissioner must publicly explain his action in accepting or rejecting any comment on a proposed regulation. Accordingly, under the proposed regulations, material which any person did not wish to become available to the public should not be submitted to the Hearing Clerk with a petition or comment. Of course, since NDA's, NADA's, and applications for biologics licenses are submitted directly to the bureaus and not to the Hearing Clerk, their availability for public disclosure would be governed by the provisions on public information in Part 4 and the regulations referenced therein, and not by the provisions of § 2.5(j).

The Commissioner is of the opinion that the type of issue which is likely to be considered at a public hearing before the Commissioner pursuant to Subpart E of Part 2 would be very similar to the type of issue likely to be considered in petitions and comments. Such a hearing would involve policy issues, not technical issues of the kind that will require submission and detailed consideration of trade secret material. For example, any valuable safety and effectiveness data relevant to such a hearing could be discussed in summary form without submitting the full reports in a way that would destroy their commercial value. Accordingly, all material submitted by any person at a public hearing before the Commissioner pursuant to Subpart E would also be fully available to the public.

The only exception to this would be when a public hearing before the Commissioner were being used pursuant to § 2.117 in lieu of a formal evidentiary public hearing. In that situation the same rules on examination and copying of the administrative record would apply as would apply if it were held pursuant to Subpart B, i.e., § 2.5(j) (2) and (3) would be applicable. The Commissioner concludes that the same disclosure rules should apply to all alternative forms of public hearing used under § 2.117.

Objections and requests for hearing filed pursuant to Subpart B, and material submitted at either a formal evidentiary public hearing or a public hearing before a Public Board of Inquiry, would also be fully available to the public except to the extent prohibited by the provisions in § 2.5(j) (2) and (3), discussed below, which limit public access to particular types of material. The Commissioner is of the opinion that public proceedings of any type should be held on the basis of publicly available data and information wherever possible. Unless this is true, participants in the proceeding may not be in a position to review and evaluate all relevant information, and thus to participate in such proceedings in a mean-

ingful way. Accordingly, the Commissioner proposes that all data and information submitted to the Hearing Clerk relating to such proceedings should be available for examination and copying by the public, with only very limited exceptions.

The exceptions to the general rule for public disclosure of material submitted to the Hearing Clerk are proposed in § 2.5 (j) (2) and (3), and relate solely to data and information which constitute trade secrets or which represent a clearly unwarranted invasion of personal privacy.

With respect to data and information involving personal privacy, the Commissioner has previously stated in paragraph 127 of the preamble to the public information regulations promulgated in the FEDERAL REGISTER of December 24, 1974 (39 FR 44602) that the right to privacy is a fundamental principle of law and ethics. Accordingly, §§ 4.63 and 4.82 would prohibit discretionary release of any information that falls within the personal privacy exemption to the Freedom of Information Act. That policy is fully reflected in § 2.5(j) (3), which would similarly prohibit public disclosure of material submitted to the Hearing Clerk which contains data and information of a privacy nature, e.g., names of medical patients. The Commissioner anticipates that the prohibition against submission of such material to the Hearing Clerk in § 2.5(c) (4) would prevent its submission. If it is submitted and filed, however, it would not be available for public disclosure.

With respect to data and information which constitute trade secrets and confidential commercial or financial information, the agency's public information regulations published on December 24, 1974 reflect detailed consideration of the application of the provisions of 21 U.S.C. 331(j) and 18 U.S.C. 1905, which need not be repeated here. Those regulations clearly distinguish between material which provides a competitive advantage because it is needed for submission to the Food and Drug Administration by each person who wishes to obtain approval for marketing of a particular product (safety and effectiveness data) and material which, if known to any competitor, could be put to use directly by that competitor in his business activity (manufacturing and quality control procedures, production and sales data, quantitative and semiquantitative formulas, and design and construction information). The former have an indirect competitive effect, and the latter have a direct competitive effect. Accordingly, slightly different rules were adopted in the provisions of Part 4 and the regulations referenced therein with respect to these two different categories of material.

The Commissioner is of the opinion that the same distinction should be reflected in the provisions of proposed § 2.5(j) (2) and (3) with respect to public disclosure of material filed with the Hearing Clerk. Data and information relating to safety and effectiveness, which of course necessarily reveal the protocols involved, would be placed on public display in the office of the Hearing Clerk but would not be available for copying. In contrast, data and information relating to such trade secrets as manufacturing processes and quantitative formulas would not be available either for examination or for copying by the public. Of course, any data and information which are available for public disclosure pursuant to Part 4 and the regulations referenced therein would be available for public examination and copying pursuant to proposed § 2.5(j) (1) and would not be subject to the limitations set out in proposed § 2.5(j) (2) or (3).

Thus, the provisions in proposed § 2.5 (j) (2) relating to limited availability of safety and effectiveness information would apply only to new drugs and new animal drugs. Safety and effectiveness data relating to food additives, antibiotics, and biologics would be available for public disclosure pursuant to the public information regulations promulgated on December 24, 1974.

In accordance with the provisions of Part 4 and the regulations referenced therein, a summary of secret safety and effectiveness data is itself not secret, because no NDA or NADA can properly be approved on the basis of such a summary. Moreover, the public information regulations promulgated on December 24, 1974, provide that the Food and Drug Administration will release, for every NDA or NADA, a summary of the safety and effectiveness data on the basis of which the approval was made. Accordingly, any hearing which concerns the safety or effectiveness of a new drug or new animal drug would permit full public participation, since any participant would be able to obtain a copy of the summary of all of the relevant data and information and would then be able to check that summary against the full reports of the data and information contained in the office of the Hearing Clerk.

At the same time, providing the full reports only in the office of the Hearing Clerk, and prohibiting their copying or, if they should be copied, subsequent submission to the Food and Drug Administration in support of any petition or application, would protect their commercial value to the maximum extent that is consistent with a public hearing. The Commissioner notes that the trade secret status of this type of data and information consists not in actual knowledge of the content of the reports, but in their availability for submission to the agency to support an NDA or NADA. By precluding such submission, the commercial value of this material would be preserved.

The Commissioner is unaware of any formal evidentiary public hearing on an NDA or NADA conducted by the Food and Drug Administration since 1938 in which manufacturing processes and similar information were relevant. All such hearings have related to issues of safety and effectiveness. Under the provisions of proposed Subpart B, only the relevant portions of the NDA or NADA would be submitted to the Hearing Clerk, and the irrelevant portions would not become a part of the administrative record. Accordingly, it is highly probable that, in practice, all participants in virtually all future hearings would have access to all of the data and information needed for meaningful participation. It would only be the rare instance where, in order to protect valid trade secrets, relevant information could not be made available to all participants.

In order to reduce the possibility of damage to commercial interests, proposed § 2.5(j) (2) provides that safety and effectiveness data and information which constitute trade secrets would be available for public examination only as long as is necessary for participation in a hearing and any subsequent judicial review.

The Commissioner notes that the provisions of proposed § 2.5(j) (2) represent a compromise between the need for public availability of information relevant to a public hearing, and the need for protection of trade secrets. Greater access to the data and information involved would be provided than is the situation where no public hearing is held, but less access would be provided than for data and information which do not constitute trade secrets. The Commissioner concludes that this resolution of the matter is consistent with applicable statutes and is in the public interest.

The Commissioner realizes that, in some instances, it would be a hardship to require that a participant in a proceeding, who is located elsewhere in the country, come to the Hearing Clerk's office in Rockville, MD, to review data and information that are available for examination in the Hearing Clerk's office but not for copying. Where this would occur, the Commissioner would entertain a petition requesting that the data and information involved be sent to the nearest Food and Drug Administration District Office, where they might be examined by the participant.

The Commissioner emphasizes that the provisions in proposed § 2.5(j) will be strictly followed. If a person submitted comments on a regulation and marked some of the attachments as "confidential," those attachments would be placed on public display in accordance with the provisions of proposed §§ 2.5(j) (1) and 4.27 without consultation with the person who submitted the information.

In some proceedings, the proposed regulations would require the Food and Drug Administration to file the prior administrative record, which would include the relevant portions of an NDA or NADA. In performing this function, the Food and Drug Administration could either request that the holder of the NDA or NADA review and make an initial designation of those portions for which full public access is not warranted, pursuant to proposed § 2.5(j) (2) or (3), after which the agency could make its final determination on the matter; or the agency could itself make a determination and then consult with the holder of the NDA or NADA on any close questions pursuant to the provisions of § 4.45.

INITIATION OF ADMINISTRATIVE PROCEEDINGS (§ 2.6)

Proposed § 2.6 would recognize that an administrative proceeding may be initiated in any of three ways: On the initiative of an interested person outside the agency, on the agency's initiative, or at the request of a court.

The Supreme Court has held, in the four decisions it handed down on June 18, 1973, relating to the agency's regulation of new drugs, that the Food and Drug Administration has primary jurisdiction to make the initial administrative determination on issues within its statutory mandate: "A decision that FDA lacks authority to determine in its own proceedings the coverage of the Act it administers, subject of course to judicial review, would seriously impair FDA's ability to discharge the responsibility placed on it by Congress." Ciba Corp. v. Weinberger, 412 U.S. 640, 643 (1973). Accordingly, proposed § 2.6(b) would provide that the agency will request a court to dismiss, or to hold in abeyance its determination of, or to refer to the agency for administrative determination, any issue within the agency's jurisdiction which has not previously been determined by the agency or which, if it has previously been so determined, the agency concludes should be reconsidered and subject to a new administrative determination.

CITIZEN PETITION (§ 2.7)

The Administrative Procedure Act, 5 U.S.C. 553(d), provides that every agency shall accord any interested person the right to petition for the issuance, amendment, or repeal of a rule. Even more fundamental, the First Amendment to the Constitution explicitly recognizes the right of the people to petition the government for a redress of grievances. Accordingly, proposed § 2.7 provides that any person may submit to the agency a citizen petition requesting the Commissioner to issue, amend, or revoke a regulation or order to take or refrain from taking any other form of administrative action.

Under proposed § 2.7 the citizen petition is intended to cover every form of agency administrative activity, including a refusal to act. It may relate to factual, policy, or legal issues. The proposed regulation does not set out all of the possible activities involved because it is intended to be all-inclusive and any such list would necessarily be incomplete. It would not cover, however, referral of matters to United States attorneys for enforcement action in the courts and related regulatory activity.

In the past, there has been no form or other procedural requirements relating to a citizen petition. This has resulted in confusion and uncertainty on the part of those who wish to petition the agency on a particular matter, as well as on the part of those in the agency who have received various forms of requests and have been unable to determine how they should be handled.

The provisions of proposed § 2.7 would not apply to routine correspondence. Where members of the public address letters to the Food and Drug Administration making informal requests or suggestions, they would be handled in the same way as other correspondence rather than as petitions under proposed § 2.7. For example, anyone could send a letter to the agency suggesting particular action which, if the agency then pursued the matter on its own initiative, would obviate filing a petition pursuant to proposed § 2.7. Denial of an informal request or suggestion encompassed in routine correspondence would not be sufficient, however, to constitute final agency action and to invoke the right to judicial review of administrative action as set out in proposed § 2.11. Only those matters specifically raised in a formal petition submitted pursuant to proposed § 2.7 would require a formal response by the Commissioner which constituted final agency action subject to such court review.

Proposed § 2.7 would therefore in no way impede the normal flow of informal and routine correspondence by the agency, on the basis of which most of its daily work is accomplished. Rather, § 2.7 would be reserved for those specific matters where, perhaps after informal discussion and correspondence, a member of the public concludes that a formal proceeding should be initiated to resolve a particular matter. Thus, the agency would easily be able to distinguish between informal discussion and formal petitions in a way that has not previously been possible.

The petition would have to include the action requested, a statement of grounds, and the environmental impact, if any, of the action requested. In addition to including all data, information, and views on which the petition relies, it would also have to include representative data and information known to the petitioner that are unfavorable to the petition. The Commissioner has found, in reviewing petitions submitted in the past, that adverse or unfavorable information is omitted and ignored, thus resulting in a very unbalanced and misleading presentation. It is for this reason that, in recent regulations, the Commissioner has required submission of representative unfavorable information in order to provide a more balanced and reasonable presentation, e.g., § 328.30(c) 18 relating to submission of data and information on in vitro diagnostic products in connection with the development of a standard. Without such a requirement, a person submitting a petition could present only one side of the story and thus mislead both the Food and Drug Administration and the public as to the true situation. This provision would prevent, for example, a manufacturer from submitting only data showing the safety and utility of an ingredient or product, or a consumer advocate from submitting data showing only the hazards from an ingredient or product. In both instances, a balanced presentation, showing representative data on both sides of an issue, would be required. The failure to include such data and information would constitute a violation of the False Reports to the Government Act, 18 U.S.C. 1001.

Any petition which appears to meet the requirements set out in this proposed regulation would be filed by the Hearing Clerk and handled in accordance with the provisions of this regulation. A docket number would be assigned to each petition (or to related petitions) which would be used to identify the administrative file established by the Hearing Clerk for all submissions relating to that petition.

The Commissioner on occasion receives petitions on which others wish to comment before the Commissioner takes action. The proposed regulation would provide that such comments may be submitted to the Hearing Clerk and would be included as part of the administrative file.

The Commissioner would review and rule upon every petition as soon as possible, taking into consideration the agency resources, the priority assigned to the matter, and time requirements established by statute. Perhaps the greatest problem facing the Food and Drug Administration today is the scarcity of resources to deal with petitions and other similar requests. Quite frequently, a lack of resources, and the high priority necessarily given to health-related matters, requires that important but lower priority matters be deferred for a substantial period of time. It is evident that not all petitions can be handled in a short period of time, simply because of the lack of resources available. Thus the Commissioner anticipates that, in a significant number of instances, petitions with a relatively low priority would not be acted upon promptly.

An apparent delay in responding to a petition might also result from the fact that the agency is in the process of taking action of the type sought in the petition, but has not reached the point of implementation. To grant the relief sought in the petition in such instances would be premature; to deny the petition would constitute final administrative action possibly triggering the unnecessary initiation of judicial review by the petitioner. A delay in ruling on the petition would be prudent in such instances.

A determination with respect to the priority to be assigned to any particular petition or other matter must of necessity be within the discretion of the Commissioner, who is charged with the responsibility for implementing all provisions of the laws subject to his jurisdiction.

A petitioner could supplement or amend his petition at any time, and could withdraw it without agency approval at any time before the Commissioner rules on it.

The decision of the Commissioner on a petition would have to be in writing and would have to be sent to the petitioner as well as placed in the public administrative file in the office of the Hearing Clerk. The Commissioner has inherent discretionary power to set any reasonable effective date relating to any decision resulting from a citizen petition.

In reviewing the matter and making his decision, the Commissioner could, in his discretion, utilize any of a wide variety of optional procedures specified in the proposed regulation.

The record of the administrative proceeding would be specified in proposed § 2.7(i). Under proposed § 2.7(j), that administrative record would constitute the exclusive basis for the Commissioner's decision. Accordingly, any subsequent judicial review would be based solely upon that administrative record and the Commissioner's decision. If the Commissioner or any interested person wished to rely upon other data or information not included in the administrative record, the new information would have to be submitted with a new petition seeking to modify the decision.

The Hearing Clerk would be required to maintain a chronological list of all petitions filed pursuant to this section, including all requests for advisory opinions pursuant to proposed § 2.19, showing the docket number, the date of filing, the name of the petitioner, and the subject matter involved. This list would exclude petitions submitted elsewhere in the agency pursuant to proposed § 2.6(a)(1). Those other petitions would be listed in the list of regulations prepared pursuant to proposed § 2.10(i) or in other lists, e.g., the list of approved NDA's available pursuant to § 4.117(a)(1) of the newly-promulgated public information regulations published in the FEDERAL REGISTER of December 24, 1974 (39 FR 44602).

ADMINISTRATIVE RECONSIDERATION OF ACTION (§ 2.8)

Proposed § 2.8(a) would recognize the inherent right of any administrative official to reopen and reconsider any matter, at any time, on his own initiative or on the petition of any interested person, for any reason whatever. This principle has long been recognized by the courts. See, e.g., United States v. Pierce Auto Freight Lines, Inc., 327 U.S. 515, 534–535 (1946); Interstate Commerce Comm'n. v. Jersey City, 322 U.S. 503, 517–518 (1944); American Chain & Cable Co. v. F.T.C., 142 F. 2d 909, 911 (4th Cir. 1944); and Cia Mexicana De Gas v. Federal Power Comm'n., 167 F. 2d 804, 806–807 (5th Cir. 1948).

Proposed § 2.8(b) contains a specific form for use by any interested person who wishes to request reconsideration by the Commissioner of any part or all of a decision rendered on the basis of a petition submitted pursuant to proposed § 2.6(a), i.e., either in the form specified in proposed § 2.7(b) or in a form specified in any other applicable section in Food and Drug Administration regulations. A petition for reconsideration would be limited to the administrative record on which the Commissioner made his decision, and would have to be filed within 30 days after the date of the decision involved and before legal action is brought in the courts to review such action. A petition for reconsideration submitted later than 30 days after the date of decision would have to be denied as untimely. The Commissioner proposes that a strict time limit of 30 days should be established for such a petition, as well as for a petition for an administrative stay of action pursuant to proposed § 2.9, in order to make certain that such matters are settled promptly. Although filing such petitions would not operate to delay any administrative action, the uncertainty that would be generated by permitting such petitions at any point in time would undermine effective implementation of the act.

A petition for reconsideration would be limited to those situations involving reconsideration of a matter arising out of a petition submitted pursuant to proposed § 2.6(a). The Commissioner is of the opinion that, although he could, and in many instances would, reconsider other matters on his own initiative or at the request of an interested person, a formal petition for reconsideration should be limited to those situations in which a well-defined administrative record delineates the data and information on which a decision is reached, and where the decision is in writing. In the future, this would cover all matters where interested persons have formally requested action of the Commissioner, since all such formal requests would have to be the subject of a petition filed pursuant to § 2.6(a). Formal reconsideration of any other action would have to be initiated in the form of a petition pursuant to § 2.7, so that an appropriate administrative record could be delineated and considered. This procedure would be utilized, for example, where the Commissioner took action on his own initiative rather than pursuant to a petition, and thus the formal administrative record of the type specified in proposed § 2.7 could not yet be designated and ready for reconsideration.

The Commissioner has broad discretion in determining whether he should reconsider a matter as a result of a petition for reconsideration. If he concluded that a matter should be reconsidered, he would be required promptly to review the merits of the matter and reaffirm, modify, or overrule his prior decision. His decision on reconsideration, like his initial decision, would be made in writing, sent to the petitioner, and filed with the Hearing Clerk. In the event that reconsideration is undertaken, all pertinent records would become part of the administrative record of the proceeding.

ADMINISTRATIVE STAY OF ACTION (§ 2.9)

As proposed, § 2.9(a) would recognize the inherent authority of an administrative official to set and to stay or postpone the effective date of any administrative action on his own initiative, or on the petition of any interested person, for good cause. See, e.g., 5 U.S.C. 705 and N.L.R.B. v. Pool Mfg. Co., 339 U.S. 557, 580–582 (1950); Moog Industries, Inc. v. Federal Trade Comm'n., 355 U.S. 411 (1948); Niagara Mohawk Power Corp. v. Federal Power Comm'n., 379 F.2d 153, 158–159 (D.C. Cir. 1967); 1 Davis, Administrative Law Treatise § 6.07 (1958 ed.).

In contrast to the provisions governing reconsideration of action, which would be limited to matters arising from petitions submitted pursuant to § 2.6(a), proposed § 2.9(b) would provide that an administrative stay of action may be requested with respect to any decision of the Commissioner. Such request for stay would have to be in the form specified in the regulations, and be submitted within 30 days after the date of the decision involved. For any decision published in the FEDERAL REGISTER, the date of decision would be the date of such publication. A request for postponement or extension of the effective date of any regulation would have to be made by submitting a petition for a stay pursuant to this regulation. The record of the administrative proceeding with respect to any requested stay would become part of the total administrative proceeding relating to that matter.

For the same reasons that court enforcement action would be excluded from the definition of administrative action and thus could not be the proper subject of a petition, it also could not be a proper subject of a petition for an administrative stay of action.

The proposed regulations would point out that the mere filing of a petition for a stay of action pursuant to this section would not, in itself, operate to stay or otherwise delay any administrative action by the Commissioner, including enforcement action of any kind, unless the Commissioner, in his discretion, determined that a stay or delay is in the public interest, or a statutory provision required a stay, or a court ordered a stay. Similarly, other procedural actions taken by an interested person in accordance with the proposed regulations, e.g., the filing of a petition or a request for advisory opinion or any other related action, would not stay or delay any administrative action to which it may relate. The Commissioner is charged with enforcement of important regulatory statutes vitally affecting the public health, and a determination as to when enforcement or other administrative action is appropriate must be subject to his discretionary determination, subject of course to judicial review.

The Commissioner could grant a stay or an extension of time for as short or as long a period of time as is justified under the circumstances. Such a stay could be for a specific time period, which can later be extended, or for an indefinite time period.

The Commissioner advises that adoption of a regulation itself would constitute a finding by the Commissioner that the regulation is in the public interest, and requires a substantial showing to justify a stay.

PROMULGATION OF REGULATIONS FOR THE EFFICIENT ENFORCEMENT OF THE LAW (§ 2.10)

The Commissioner's general authority under section 701(a) of the Federal Food, Drug, and Cosmetic Act to promulgate regulations for the efficient enforcement of the act permits the establishment of

any regulations which are "reasonably related to the purposes of the enabling legislation." See Mourning v. Family Publications Services, Inc., 411 U.S. 356, 369 (1973), and Thorpe v. Housing Authority of the City of Durham, 393 U.S. 268, 280–281 (1969). All such regulations are subject to the procedural requirements and exemptions for informal rule making set out in the Administrative Procedure Act, 5 U.S.C. 553.

In addition to the general rule making authority under section 701(a) of the act, section 701(e) and certain other sections of the act specify particular provisions of the law with respect to which Congress concluded that more detailed and formal procedural requirements should be established. Those particular provisions, which are specified in proposed § 2.12(c) (1) through (15), require rule making "on a record" and thus are subject to a formal evidentiary public hearing pursuant to the requirements of 5 U.S.C. 556 and 557, as spelled out in the provisions contained in Subpart B of Part 2 of the proposed regulations. As proposed, the provisions of § 2.10 would therefore apply only to regulations not subject to the provisions of § 2.12 except insofar as § 2.12 and Subpart B incorporate by reference some of the general requirements of § 2.10.

Proposed § 2.10(b) spells out the procedure for the promulgation of regulations to implement the laws administered by the Commissioner.

Each notice of proposed rule making would have to contain in the first or second paragraph a general statement describing the substance of the document in broad and simple terms, similar to the first paragraph of this notice proposing these new regulations. The Commissioner has received numerous requests that the agency include such a paragraph in all notices so that it can be reproduced and used by interested publications to describe, in terms readily understood by the public, the scope an intended impact of the proposal.

Each proposed regulation would also contain a proposed effective date. Most proposals published in the past have not specified the proposed effective date, and thus interested persons who have submitted comments have not had an opportunity to express their views on this aspect of the matter.

Ordinarily, 60 days would be provided for comment on a proposal, although the Commissioner could reduce or extend this time period for good cause. Approximately 3 years ago, the normal period for comment was extended from 30 days to 60 days in order to provide sufficient time for comment on most proposals, and to avoid the constant requests for additional time for comment that were then prevalent. Unfortunately, the Commissioner has found that many people do not take the stated time for comment seriously, and instead wait until the last minute before beginning work on their submission, with the belief that any request for extension will usually be granted. In the future, therefore, the Commissioner would deny requests for time extension without an extremely persuasive showing of good cause. Extensions of time to comment would not routinely or ordinarily be granted.

Two types of time extension could be utilized, where justified. First, a short period of time, of less than 30 days, could be granted to one or more persons by letter or memorandum filed with the Hearing Clerk without the necessity of a published notice in the FEDERAL REGISTER. Second, any extension of time for comment of 30 days or longer would have to be the subject of a notice published in the FEDERAL REGISTER and would be applicable to all interested persons.

Ordinarily, in accordance with proposed § 2.5, all comments would have to be submitted to the Hearing Clerk in quintuplicate. The Commissioner recognizes, however, that this would be a burden upon individual members of the public who usually submit comments by letter, without enclosing any copies. Accordingly, individuals would have to submit only one copy of their comments.

Any interested person could of course petition for the establishment of a regulation in accordance with proposed § 2.6 (a). In the past, there have been no explicit criteria for determining when the Commissioner will issue a proposal to be published in the FEDERAL REGISTER on the petition of an interested person. The proposed regulation spells out the criteria for making this discretionary determination.

The Commissioner could, in his discretion, issue for publication two or more alternative proposals on the same subject to obtain comment on the different alternatives. Where the Commissioner did not have sufficient information to make a determination whether a proposal should be published, he could instead issue a notice stating that the petition has been filed and requesting additional comment and information to determine whether a proposal is justified.

After the time for comment on a proposed regulation had expired, the Commissioner would review the comments and terminate the proceeding, issue a new proposal, or promulgate a final regulation. Once again, the time within which this can be accomplished would be determined according to the priority of the matter in relation to other matters pending before the agency and the resources available to the agency for this type of work at that moment. No specific time period could be established with respect to this process because of the uncertainties involved.

The proposed regulations point out that the Commissioner's decision must be based on the entire administrative record, and that the quality and persuasiveness of the comments, rather than the number or length of comments, will determine the Commissioner's conclusions on them. In the past, many persons have erroneously believed that the number of comments is in some way relevant to the Commissioner's decision. As a result, on several occasions the Commissioner has been flooded with thouands of form letters, each making the identical point, and often in identical words. The Commissioner advises that such repetitive comments would be given no more weight than a single comment, and indeed that a single well-reasoned comment, relying upon sound data and information, would be given far greater weight than a large number of form letters which simply support or oppose a proposal in conclusory terms.

The Commissioner notes that agency experience shows that most comments filed in response to a proposal oppose the proposal in whole or in part. Indeed, in many instances all comments will oppose the proposal. This is true because persons opposing a proposal are far more likely to respond to the invitation for comment than are persons who support it. It is therefore apparent that the number of comments supporting or opposing a proposal must be regarded as immaterial to the Commissioner's ultimate decison.

Under the Administrative Procedure Act, 5 U.S.C. 706, a final regulation will be upheld by a court unless it is found, in light of the administrative record before the Commissioner at the time he made his decision, to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. Accordingly, the Commissioner's determination with respect to the final regulation would have to rest upon all of the information in the administrative record, including both the data and information submitted with the comments and the data and information identified by the Commissioner as relevant to the matter. It is this administrative record, and only this record, on which the Commissioner would make his decision.

The Administrative Procedure Act, 5 U.S.C. 553(c), requires that the agency incorporate in each regulation it promulgates "a concise general statement" of the basis and purpose of the regulation. The courts have held that, although the agency is not required to develop specific and detailed findings and conclusions of the kind customarily associated with formal proceedings, it does require a sufficiently reasoned articulation of the administrative decision to permit meaningful judicial review. See, e.g., Federal Trade Comm'n. v. Sperry & Hutchison Co., 405 U.S. 233, 245–250 (1972); Securities & Exchange Comm'n. v. Chenery Corp., 318 U.S. 80, 87–95 (1943); National Nutritional Foods Ass'n. v. Weinberger, F.2d (2d Cir. 1975); Consumers Union v. Consumer Product Safety Comm'n., 491 F.2d 810, 812 (2d Cir. 1974); Kennecott Copper Corp. v. Environmental Protection Agency, 462 F.2d 846, 850 (D.C. Cir. 1972); Environmental Defense Fund v. Ruckelshaus, 439 F.2d 584, 597–598 (D.C. Cir. 1971); and Automotive Parts & Accessories Ass'n. v. Boyd, 407 F.2d 330, 338 (D.C. Cir. 1968). The proposed regulations therefore would require that the preamble to the final regulation summarize each type of comment received, state the Commissioner's conclusions with respect to it, and contain a thorough and comprehensible articula-

tion for the Commissioner's decision on each issue so raised.

The Administrative Procedure Act, 5 U.S.C. 553(b), provides that regulations that are interpretive, or that relate to agency practices and procedures, may be published as final regulations without time for comment. Nevertheless, as a matter of policy, the Commissioner has concluded that ordinarily such regulations should be published with time for comment before they are adopted, with the exceptions discussed below. Thus, they would be handled in the same way as any other regulations. This is in accordance with recent recommendations of the Administrative Conference of the United States, and codifies the practice of the Commissioner for the past 3 years.

On occasion, the Commissioner issues for publication in the FEDERAL REGISTER informational notices of interest to the regulated industry or the public, statements of legal interpretation, and matters involving agency organization and delegations of authority. In accordance with the Administrative Procedure Act, these would be published without time for comment, since they are intended solely for informational purposes and are not the type of material on which public comment is relevant.

In accordance with the provisions of the Administrative Procedure Act, 5 U.S.C. 553(b), the Commissioner could dispense with the requirements of notice and public procedure when he determines for good cause that they are impracticable, unnecessary, or contrary to the public interest. However, the proposed regulations provide that, whenever this procedure is used, the notice promulgating the regulation would have to provide an opportunity for submission of comments to determine whether the regulation should subsequently be modified or repealed.

This procedure would assure both that regulations could be promulgated in final form where that is essential, and that even under those circumstances the policy of the Administrative Procedure Act and these proposed regulations of providing time for public comment would nonetheless be implemented. Moreover, in the event that a court should determine that the regulation must first be published for comment, this defect would already have been cured by explicitly inviting comments and, by expediting consideration of those comments, the agency would be in a position to assure prompt promulgation of a final regulation.

The requirement that a regulation first be published as a proposal for comment would also be inapplicable to food additive and color additive petitions and to new animal drug regulations. Food additive and color additive petitions are subject to a notice of filing rather than to a proposal, as provided in sections 409(b)(5) and 706(d)(1) of the act, and new animal drug regulations are promulgated by notice pursuant to section 512(i) of the act.

The proposed regulations would provide for a number of alternative optional procedures that the Commissioner could, in his discretion, use in reviewing any proposed or final regulations. All of these procedures have been used by the agency on occasion in the past, and this provision simply recognizes current practice.

The proposed regulations would specify the data and information which are included in the record of the administrative proceeding, and on which the Commissioner must base his decision and any reviewing court must base its review. Any interested person who subsequently requested that new information be considered by the Commissioner would have to submit it with a new petition to modify the final regulation.

The Hearing Clerk would be required to maintain a chronological list of all regulations proposed and promulgated pursuant to the provisions of this section and proposed § 2.12, which deals with regulations promulgated after an opportunity for a formal evidentiary hearing. The list would have to show the docket number, the name of the petitioner, if any, and the subject matter involved. This list would exclude those regulations resulting from petitions filed and assigned a docket number pursuant to proposed § 2.7, which would appear separately on the list of petitions required to be maintained pursuant to proposed § 2.7(1).

Thus, proposed § 2.10 sets out a comprehensive procedure for issuance of the vast majority of the regulations promulgated by the Food and Drug Administration. For the most part, it would simply codify and unify current practice. In the future, all employees of the agency and all interested persons outside the agency would have available a consistent and fair procedure, in writing, for handling these matters.

COURT REVIEW OF FINAL ADMINISTRATIVE ACTION; EXHAUSTION OF ADMINISTRATIVE REMEDIES (§ 2.11)

Once the Commissioner had promulgated a final regulation pursuant to § 2.10, it would be subject to judicial review in accordance with the Administrative Procedure Act, 5 U.S.C. 701 et seq., and, in many instances, the Declaratory Judgment Act, 28 U.S.C. 2201. All other forms of final administrative action taken by the Commissioner would also be subject to court review in this way, except for those that are solely within the Commissioner's discretion. Proposed § 2.11 would establish the practices and procedures governing such judicial review of most actions. Actions subject to the provisions of proposed § 2.12 and Subpart B of Part 2 would, however, be governed by the provisions in Subpart B and not by § 2.11, since unique statutory requirements apply to them.

As already noted, § 2.7 would establish a procedure by which any interested person could formally request action from the Commissioner. Accordingly, § 2.11(b) would provide that this administrative procedure must be exhausted before any person may properly seek relief in court with respect to a particular matter. If any person filed suit in court before exhausting his administrative remedies, the Commissioner would object to such court action and request its dismissal or referral to the agency on the grounds of a failure to exhaust administrative remedies, the lack of final agency action, and the lack of an actual controversy.

An existing Food and Drug Administration regulation is subject to judicial review under the Administrative Procedure Act, 5 U.S.C. 701 et seq., at any time by any interested person. If the regulation was promulgated some years ago, however, any person who concludes to challenge its legality might wish first to petition the Commissioner pursuant to proposed § 2.7 to amend or revoke the regulation. The Commissioner's decision on that petition, as well as the regulation itself, would then be subject to judicial review in accordance with proposed § 2.11.

A request that the Commissioner stay any form of administrative action would first have to be directed to the Commissioner in accordance with the provisions of proposed § 2.9 before any request were made that a court stay such action. Pursuant to § 2.9 (b) and (f), such administrative relief would have to be requested within 30 days after the action involved were taken. If no such request were made within 30 days, any right to request such relief would be deemed to have been waived, and the Commissioner would object to any subsequent request for a judicial stay on the ground of a failure to exhaust administrative remedies.

The Commissioner recognizes the right of any interested person to seek judicial review of any final agency administrative action, in accordance with Abbott Laboratories v. Gardner, 387 U.S. 136 (1967). Once a final agency decision has been made, it is the policy of the Food and Drug Administration not to interpose technical objections, such as a lack of standing, to the right of any interested person to seek court review. Of course a decision of the Commissioner to institute or not to institute civil or criminal enforcement action in the courts on a particular matter is not subject to judicial review because it is committed by the law solely to his discretion.

The matters handled by the Food and Drug Administration, governing the safety, effectiveness, functionality, and labeling of consumer products that represent over 25 percent of the consumer dollar spent daily in this country, vitally and directly affect the interests of every citizen. Accordingly, applying the standards established in Sierra Club v. Morton, 405 U.S. 727 (1972), it is the opinion of the Commissioner that every citizen has standing in the courts to contest any action of the agency, and that no objection relating to such standing will be interposed by the agency in such cases. The Commissioner has followed this policy for the past 3 years.

The Commissioner is also of the opinion that current judicial decisions require any court review of final administrative action taken by the Food and Drug Administration to be based solely on the administrative record of the pro-

ceeding identified in these regulations, on the basis of which the Commissioner made his decision. No additional data, information, or views may properly be presented to a reviewing court without first presenting them to the Commissioner by a petition pursuant to proposed § 2.6(a), with a request that the action be modified or revoked on the basis of such new information. In short, both the Commissioner and any other person who is interested in any matter pending before the Food and Drug Administration are obligated to submit and identify all relevant data and information at the administrative stage of the proceeding. It is improper for either to wait until the matter is pending before the courts and then to identify new information, or to present new arguments, to support a position. See e.g., Camp v. Pitts, 411 U.S. 138 (1973), Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 419–420 (1971), and Bradley v. Weinberger, 483 F.2d 410, 414–415 (1st Cir. 1973).

Accordingly, all cases involving review of Food and Drug Administration action in the future should properly be decided solely on motions to dismiss or for summary judgment. A trial de novo or the submission of additional written or oral testimony or other evidence would not be proper. Pursuant to recent court decisions, it is apparent that judicial review of administrative action pursuant to the Administrative Procedure Act must proceed on the basis solely of the administrative record involved in the decision in the same way that administrative review of action taken after a formal evidentiary public hearing proceeds on the basis of the established administrative record. New information cannot be introduced at the judicial level, only at the administrative level.

The Commissioner recognizes that, on occasion, the administrative record relating to a particular matter may be found, upon judicial review, to be unclear or incomplete. Under these circumstances, the Commissioner would request that the court remand the matter for further administrative proceedings, prior to a final judicial ruling on the matter. See, e.g., Securities & Exchange Comm'n. v. Chenery Corp., 318 U.S. 80, 93–94 (1943). The Commissioner views this procedure as preferable to a court decision based on an inadequate record, after which the Food and Drug Administration could in any event reopen the matter at the administrative level and correct the deficiencies in the administrative record, thereby requiring further judicial review on the basis of the new record.

Similarly, on occasion the administrative record relating to a particular matter might be found, upon judicial review, to be clear and complete, but the court could require further elucidation of the rationale for the administrative action. Under these circumstances, the Commissioner could either request that such further explanation be provided in writing directly to the court without further administrative proceedings, or that the matter be remanded to the agency for further administrative proceedings in order to provide the requested explanation. This choice will depend upon the facts of the specific situation. In neither event, however, would it be necessary or proper for a court to conduct its own evidentiary hearing on the matter. "A failure of the agency adequately to explain its actions is not a warrant to the district court to conduct a *de novo* evidentiary hearing," but rather justifies a remand to the agency for a more complete articulation of its reasoning or a court hearing limited to that purpose. See, e.g., National Nutritional Foods Ass'n. v. Weinberger, 512 F. 2d 688, 701 (2d Cir. 1975).

Depending upon the nature of the specific matter involved, it might well be appropriate for a regulation or other administrative action to remain in effect pending remand to the agency or further court proceedings under these circumstances. Where this is in the public interest, the Commissioner will request that the court not stay the matter pending such remand. See, e.g., Twin City Milk Producers Ass'n. v. McNutt, 122 F. 2d 564, 568 (8th Cir. 1941).

The Commissioner is of the opinion that the requirement that his decision, and subsequent court review, be based solely on the administrative record will in no way diminish justifiable reliance upon the experience and expertise of the agency with respect to the matters involved. The Federal Trade Commission has for many years exercised its expertise in similar matters through written opinions, and reviewing courts have properly deferred to such expertise where it has been exercised in a reasonable manner and articulated through the written opinion. The requirement that a decision be based upon the record does not mean that such expertise and judgment must in some way be encapsulated in documentary evidence or "proved" as a "fact," but simply that it be referred to and explained in the comprehensive written statement of the basis for the Commissioner's decision on a particular matter, so that it is a matter of record. For example, the courts have uniformly deferred to the expertise of the Federal Trade Commission in determining that advertising is misleading to the public without the need for specific evidence that particular persons have been so misled, and the Commissioner anticipates that the expertise, experience, and judgment of the Food and Drug Administration in such matters would be similarly recognized. See, e.g., United States v. An Article of Drug . . . Bacto-Unidisk, 394 U.S. 784, 791–792 (1969) and Federal Trade Comm'n. v. Colgate-Palmolive Co., 380 U.S. 374, 384–392 (1965).

Thus, § 2.11 would establish a consistent administrative policy with respect to judicial review. First, it would strongly encourage any person who believes that the agency is acting improperly to participate in the proceeding at the administrative level, and to advance all information and arguments at that point rather than wait until the matter has proceeded to the courts. Second, it would require the Food and Drug Administration to identify the data and information on which it bases a decision, and to articulate the reasons for that decision. Third, it would encourage any person who believes that the agency has acted improperly to seek judicial review, and guarantees that the Food and Drug Administration will not interpose technical procedural issues but rather will meet the substantive issue on its merits. Fourth, it would guarantee to the courts that there will be a specific and designated administrative record and a thorough explanation of the decision on the basis of which an informed judicial review can be conducted, and would guarantee to the Commissioner that the court in conducting its review will consider only the data and information reviewed by the Commissioner rather than new information which the Commissioner has had no opportunity to review. In the opinion of the Commissioner, this procedure would establish an extremely fair and reasonable method of proceeding for all interested persons.

The Commissioner is aware of the possibility of a multiplicity of suits in various jurisdictions challenging a particular matter. The Supreme Court pointed out in Abbott Laboratories v. Gardner, 387 U.S. 136, 154–155 (1967), that:

> * * * the courts are well equipped to deal with such eventualities. The venue transfer provision, 28 U.S.C. § 1404(a), may be invoked by the Government to consolidate separate actions. Or, actions in all but one jurisdiction might be stayed pending the conclusion of one proceeding. * * * A court may even in its discretion dismiss a declaratory judgment or injunctive suit if the same issue is pending in litigation elsewhere. * * * In at least one suit for a declaratory judgment, relief was denied with the suggestion that the plaintiff intervene in a pending action elsewhere * * *
>
> Further, the declaratory judgment and injunctive remedies are equitable in nature, and other equitable defenses may be interposed. If a multiplicity of suits are undertaken in order to harass the Government or to delay enforcement, relief can be denied on this ground alone. * * * The defense of laches could be asserted if the Government is prejudiced by a delay. * * * And courts may even refuse declaratory relief for the nonjoinder of interested parties who are not, technically speaking, indispensable.

Accordingly, if suit is brought in more than one jurisdiction on the same matter, the Commissioner will recommend one or more of the procedural mechanisms suggested by the Supreme Court to deal with the matter.

PROMULGATION OF REGULATIONS AND ORDERS AFTER AN OPPORTUNITY FOR A FORMAL EVIDENTIARY PUBLIC HEARING (§ 2.12)

In contrast to the regulations issued under section 701(a) of the act and 5 U.S.C. 553, some regulations and orders are designated in the act as requiring an opportunity for development "on the record," i.e., for a formal evidentiary trial-type public hearing conducted in accordance with the Administrative Procedure Act, 5 U.S.C. 556 and 557. In enacting the present act, Congress desig-

nated a limited number of provisions subject to this formal requirement. Proposed § 2.12(c) (1) through (18) specifies those provisions of the law, some of which are listed in section 701(e) of the act and others of which are designated elsewhere in the act or other laws, and provides that they are subject to the special provisions established in Subpart B of Part 2. Those proceedings designated in § 2.12(c) (1) through (15) relate to rule making. Those designated in § 2.12(c) (16) through (18) relate to adjudication. The different procedures that would apply to each category are set out in proposed Subpart B.

The Commissioner has carefully considered whether the wording of section 701(e) of the act and the related provisions in the other sections of the act listed in proposed § 2.12(c) require development of a formal record pursuant to the Administrative Procedure Act, 5 U.S.C. 556 and 557. This matter has never directly been adjudicated in the courts. In a recent decision, however, the Supreme Court used section 701(e) of the act as an example of a statutory provision which requires a hearing "on the record" and thus a formal evidentiary public hearing. See United States v. Florida East Coast Railway Co., 410 U.S. 224, 237–238 (1973). Although this was dictum, and not a holding, the Commissioner concludes that it represents the Supreme Court's current thinking on the matter and thus should be followed without further litigation. Accordingly, the proposed regulations require an opportunity for a formal evidentiary public hearing for all regulations and orders listed in section 701(e) and related provisions of the act and the Fair Packaging and Labeling Act.

A similar question arises with respect to the biological licensing provisions contained in section 351(a) of the Public Health Service Act, 42 U.S.C. 362(a). This legal issue has never become a matter of contention, and has never been addressed by the courts. The provisions of 5 U.S.C. 558 relating to licensing do not change the requirement in 5 U.S.C. 554(a) that a formal evidentiary public hearing pursuant to 5 U.S.C. 556 and 557 is required only where the applicable statute specifically provides for an opportunity for a hearing "on the record." See, e.g., Lincoln Transit Co. v. United States, 256 F. Supp. 990, 993–994 (S.D. NY. 1966). Section 351(a) of the Public Health Service Act does not require a hearing "on the record." Nevertheless, the Commissioner is of the opinion that an opportunity for a formal evidentiary public hearing should be available with respect to the licensing of biologics to the same extent that it is available for nonbiological drugs, i.e., new drugs and antibiotics. Presently, § 310.4 exempts biological drugs licensed pursuant to section 351(a) from the new drug requirements of section 505 of the act. In promulgating the review procedures for determining the safety, effectiveness, and proper labeling of biological drugs in § 601.25 of the regulations, however, the Commissioner announced in the FEDERAL REGISTER of August 18, 1972 (37 FR 16679) that this exemption would be superseded and revoked as the results of the biologics review become available. Accordingly, upon completion of the biologics review, § 310.4 will be totally revoked, and all biologics will be subject to the new drug provisions of the act as well as to the licensing requirements of section 351(a) of the Public Health Service Act. This means that the same procedural requirements will be applicable to biologics as are applicable to other new drugs, including an opportunity for a formal evidentiary public hearing. If these procedures are to be changed, as the Commissioner and the Administrative Conference of the United States believe they should, this is properly done by Congress. Accordingly, the proposed regulations provide that denial or revocation of a license pursuant to section 351(a) of the Public Health Service Act shall be subject to an opportunity for a formal evidentiary public hearing.

In contrast to the licensing provisions of section 351(a) of the Public Health Service Act, the standards authorized by section 351(d) are properly issued in regulations promulgated pursuant to the general rule making provisions of the Administrative Procedure Act, 5 U.S.C. 553, because they are not required to be based "on the record," and thus are subject to the general rule making provisions in proposed § 2.10 rather than to the formal evidentiary hearing provisions in proposed § 2.12 and Subpart B. The same is true of performance standards for electronic products promulgated pursuant to section 358 of the Public Health Service Act, 42 U.S.C. 263f, for which a hearing "on the record" also is not required by the statute. See United States v. Allegheny-Ludlum Steel Corp., 406 U.S. 742, 756–757 (1972).

SEPARATION OF FUNCTIONS; EX PARTE COMMUNICATIONS (§ 2.13)

In the FEDERAL REGISTER of March 24, 1972 (37 FR 6107), the Commissioner issued a proposed regulation to revise former § 2.104, dealing with separation of functions and ex parte communications before and during formal evidentiary public hearings. Former § 2.104 would be revoked and replaced by these proposed regulations. The preamble to that proposal stated that, although present law does not require separation of functions in formal rule making proceedings and does not prohibit ex parte communications during formal hearings of any kind, as long as they are made a matter of record, the Commissioner had concluded that strict separation of functions and an outright prohibition of ex parte communications should be adopted in both formal rule making and adjudication proceedings to avoid even the appearance of unfairness.

Two comments were received on this proposal, one from a law student and the other from a trade association. The law student generally favored the proposal, although he enclosed an excerpt from Davis, Administrative Law Text, sec. 13.05 (1972), which strongly opposes formal hearings or separation of functions with regard to any Food and Drug Administration rule making. The trade association also generally approved the thrust of the proposal, although it suggested a number of clarifying changes and requested republication for further comment. The Commissioner concluded to defer final action on this proposal until a complete revision of all of the agency's procedural regulations could be undertaken.

Under the 1972 proposal, separation of functions would have occurred as of the moment of publication of a regulation or order on which there is an opportunity for a formal evidentiary public hearing. In the intervening 3 years, the Commissioner has as a matter of policy imposed separation of functions in the following way.

With respect to all rule making except the revocation of antibiotic monographs, separation of functions has been imposed as of the date of publication of a notice of hearing, rather than as of the date of publication of the final regulation which preceded the notice of hearing. This has allowed customary negotiations and attempts at settlement after the regulation is published and requests for hearing are made, and before it is finally concluded that a hearing must be held. Once it is determined that a hearing is necessary, and a notice of hearing has been published, strict separation of functions has been imposed.

With respect to all adjudication and revocation of antibiotic monographs, the Commissioner has imposed separation of functions as of the date of publication of the notice of opportunity for hearing or, in the case of an antibiotic monograph, the date of the request for hearing. This approach to separation of functions was promulgated in the FEDERAL REGISTER of March 13, 1974 (39 FR 9750), for new drugs and antibiotics. It would be adopted by cross-reference for biologics in these proposed regulations and would be adopted for new animal drugs in proposed amendments to § 514.200 to be published in the FEDERAL REGISTER in the near future.

The Commissioner concludes that the practice developed during the past 3 years should be adopted in proposed § 2.13. It has worked effectively and efficiently. It has assured all parties to a rule making proceeding that, once it is determined that a formal evidentiary public hearing must be held, all reasonable steps will be taken to make certain that no party to the proceedings improperly or unduly influences either the presiding officer or the Commissioner. It has similarly assured all parties to an adjudication (and to the related proceeding for revocation of an antibiotic monograph) that, once a formal evidentiary public hearing is requested, both the decision about whether a matter is properly subject to summary judgment or requires a hearing, and the decision resulting from any hearing, will be independently considered and resolved by the office of the Commissioner without ex parte communications from the bureau.

Accordingly, proposed § 2.13 provides that, in any matter which is subject by statute to an opportunity for a formal

evidentiary public hearing, the rules on separation of functions and ex parte communications would become operable for rule making (except antibiotic monographs) as of the date of publication in the FEDERAL REGISTER of the notice of hearing, and for adjudication and antibiotic monographs at the time of the notice of opportunity for hearing and request for hearing. After that time, for either a rule making or an adjudication proceeding, the bureau of the Food and Drug Administration which is a party to the proceeding and the other parties to the proceeding would be precluded from ex parte communications or any other form of participation with the presiding officer or the Commissioner, except in the way that all parties openly participate in the proceeding. Under the current regulations governing adjudicatory proceedings such as withdrawal of approval of an NDA, the bureau involved in the matter submits to the office of the Commissioner a proposed final order granting or denying a hearing, without making this document available to the NDA holder or others, but there may be no ex parte communications between the bureau and the office of the Commissioner about that matter. In the event ex parte communications did take place, they would have to be the subject of a written memorandum, and any person involved in such communications would be made available for appropriate cross-examination and rebuttal testimony.

REFERRAL BY COURT (§ 2.14)

As a result of the Food and Drug Administration's primary jurisdiction over the matters within its statutory mandate, any Federal, State, or local court may hold in abeyance, or refer to the Commissioner, any matter for an initial administrative determination. In such circumstances, the Commissioner should promptly agree or decline to accept any such referral. The Commissioner would make every reasonable effort to accept such referrals and to institute proceedings to determine the matters so referred, but would reserve the right to decline a referral in light of other agency priorities and the resources available to the agency. In handling such a matter, the Commissioner could, in his discretion, utilize any of the various procedures established in the proposed regulations.

The Commissioner would encourage the judiciary to utilize the provisions of this proposed section. Referral of complex and technical issues falling within the jurisdiction of the Food and Drug Administration to the agency for an initial administrative determination will promote consistent and fair interpretation and application of the law. See Weinberger v. Hynson, Westcott and Dunning, Inc., 412 U.S. 609, 624, 627 (1973), Ciba Corp. v. Weinberger, 412 U.S. 640, 643–644 (1973), Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S. 645, 652–654 (1973); National Ethical Pharmaceutical Ass'n. v. Weinberger, 365 F. Supp. 735 (D.S.C. 1973), aff'd. per curiam, 503 F. 2d 1051 (4th Cir. 1974); Purdue Frederick Co. v. Acme United Corp., CCH F.D. Cosm. L. Rep., Para. 38,002 (D. Conn., January 30, 1975).

MEETINGS AND CORRESPONDENCE (§ 2.15)

In addition to formal proceedings, such as public hearings, the Commissioner recognizes that informal procedures are properly utilized to handle administrative determinations. Indeed, without them, the entire administrative process would bog down in stifling formality.

Such informal procedures include meetings and correspondence. Section 2.15 of the proposed regulations sets out the rules governing use of these procedures.

Proposed § 2.15(b) relates to the use of an open public meeting to discuss any matter pending before the agency. Public notice of any such meeting would be given through the agency's public calendar, and could, depending upon the time involved, also be published in the FEDERAL REGISTER. Any interested person could attend and participate although no transcript and recording would be required, one could be taken and in any event a written summary would be prepared and retained in any relevant administrative file.

The Commissioner notes that this procedure has usefully been employed in the recent past on a number of occasions. See e.g., the notices on microwave ovens published in the FEDERAL REGISTER of December 5, 1973 (38 FR 33510), on digoxin published in the FEDERAL REGISTER of March 8, 1974 (39 FR 9219), and on high intensity mercury vapor discharge lamps published in the FEDERAL REGISTER of January 29, 1975 (40 FR 4328). Such meetings would be conducted informally, very much like a town meeting, and are not to be structured. Unlike a public hearing before the Commissioner, as proposed in Subpart E of Part 2 of the proposal, there would be no fixed order in which persons may participate nor any advance notice required of those who intend to attend and participate. The Commissioner would anticipate increased use of these public meetings to explore pending matters in the future.

Under proposed § 2.15(c), any meeting between an employee of the Food and Drug Administration and any person outside the Department of Health, Education, and Welfare relating to a pending case or other regulatory action or decision would have to be recorded in a written memorandum, and filed in the administrative file on the matter, unless it involved only a brief description of the matter provided for informational purposes. This would assure that an adequate administrative record would be maintained of all contacts outside the Department on any regulatory matter, to avoid the possibility or appearance of improper influence.

Thus, if a person in another government agency outside the Department, or in Congress, were to telephone any person in the Food and Drug Administration to make any suggestion about a pending regulatory decision, a memorandum would be prepared summarizing the discussion. Other meetings with persons within the Federal government, however, which do not involve a pending regulatory matter, would not be subject to this requirement. Preparation of memoranda of meetings with representatives of Congress would be subject to additional rules proposed in paragraph (g) of § 2.15, discussed below.

Proposed § 2.15(d) deals with any private meeting between a person and a representative of the Food and Drug Administration in the agency offices. The Commissioner is of the opinion that it is a fundamental right of every citizen to meet with his government in private. The Federal government is created by the people, and absent explicit statutory authority, the government has no right to impose upon any citizen who requests an opportunity for a private meeting with a representative of the government a requirement that others outside of the government be present. Accordingly, § 2.15 (d)(1) would provide that neither the Food and Drug Administration nor any other person may require the attendance of any person who is not a Federal government employee or consultant without the agreement of the person requesting such a private meeting.

At the same time, by statute, the Food and Drug Administration is responsible for matters that affect all members of the public. Accordingly, whenever a private meeting involved a matter covered by paragraph (c) or any other important matter, a decision on an issue, or statements or advice or conclusions to which future reference may be required as part of the administrative record, a written memorandum summarizing the substance of any private meeting would be prepared by a representative of the agency. This would assure that any matter which should be documented as part of the public record is in fact so recorded. The availability of such memoranda for public disclosure would be determined by the provisions of the agency's public information regulations in Part 4 and the regulations referenced therein. The Commissioner believes that this will adequately protect the public interest, without infringing upon the citizen's right to a private meeting.

Somewhat different rules would apply where the Food and Drug Administration was requested to send a representative to a meeting to be held outside agency offices. The Commissioner recognizes that agency employees have a responsibility to meet with all segments of the public in order to promote the objectives of the act and the agency. Accordingly, proposed § 2.15(e) states that, where an agency representative is invited to attend an outside meeting, he may do so where he concludes that it is in the public interest and will promote the objectives of the act and the agency. He could, of course, request that such meeting be an open meeting when he concludes that this would be in the public interest. He could agree or decline to participate in any such meeting which is held as a private meeting, depending upon which action he concludes would best serve the public interest. In no event, however,

could an agency representative knowingly participate in any meeting which is closed on the basis of sex, race, or religion. All outside meetings would be subject to the requirements relating to preparation of memoranda summarizing the substance of the meeting.

In addition to meetings initiated by outside persons, Food and Drug Administration representatives could also initiate meetings with any person. Any such meetings with one or two people, e.g., relating to a pending petition, could be held as a private meeting. Any such meeting with a large number of people, however, would have to be held as an open public meeting pursuant to proposed § 2.15(b), and thus would be publicly announced so that any person could attend and participate. Again, all such meetings would be subject to the rules for preparation of a memorandum summarizing the substance of the matter, whether they are private or open.

The Commissioner recognizes that the content of summaries of oral discussions, whether by telephone or in person, could differ depending upon the person who prepares the summary. Accordingly, proposed § 2.15(g) provides that, in addition to the agency summary, any outside person participating in such a meeting may prepare and submit to the agency for inclusion in the administrative record his own written memorandum recording the substance of the meeting. Pursuant to § 4.104(c) of the public information regulations, this summary would be released along with the agency summary whenever public request is made for them.

All memoranda of meetings and correspondence would be filed in any appropriate public administrative file and made a part of the administrative record of the relevant proceeding.

Any meeting between a Food and Drug Administration employee and a representative of Congress, e.g., a committee staff member, relating to any pending or potential investigation, inquiry, or hearing would be recorded in a written memorandum which would be forwarded to the agency's Office of Legislative Services. This provision would not restrict the right of any agency employee to participate in any such meeting, but would guarantee that the agency would be aware of any congressional concern about agency activities and thus be in a position to respond in an adequate way.

DOCUMENTATION OF SIGNIFICANT DECISIONS IN ADMINISTRATIVE FILES (§ 2.16)

Section 2.16 would require all Food and Drug Administration employees to document, in an appropriate manner, every significant agency decision.

The agency employees responsible for handling any matter would be responsible for assuring that the agency has a complete administrative file on it. The file would contain appropriate documentation, including the recommendations and decisions of responsible employees. It would have to reveal any significant controversies or differences of opinion and their resolution. Any agency employee working on a matter would have the opportunity to record his views on that matter, for inclusion in the file. Once a written, signed, and dated memorandum were placed in the file, it could not be altered, added to, or removed. Rather than permit changes to be made in a document by a person other than the person who prepared that document, such changes would be reflected by preparing a new memorandum. This would provide a complete record of the development of the matter within the agency.

Memoranda and other documents prepared by agency employees not contained in the administrative file would have no status or effect. Thus, the file would contain all pertinent material, and would represent the definitive record of the administrative handling of the matter.

Memoranda placed in the administrative file would relate to the issues under consideration, and would be sent to other appropriate agency employees. Such memoranda would be required to avoid defamatory language, intemperate remarks, undocumented charges, or irrelevant matters, e.g., personnel complaints. To the extent that a memorandum records the views of any agency employee in addition to the author, it would be furnished to such other employee who would, pursuant to the new regulations, have an opportunity to respond in any way that they believed appropriate.

All agency employees working on a matter would have access to the administrative file on that matter, as appropriate for the conduct of their work. Reasonable restrictions could be placed upon access by employees to such files in order to make certain that the files do not become dismantled, lost, or unavailable to others who need them for their work.

The Commissioner is of the opinion that these rules would guarantee full participation of all agency employees in the matters on which they were working and adequate documentation of the manner in which, and the reasons for which, decisions are made within the agency, without at the same time entangling the agency in endless red tape and producing pointless paperwork.

INTERNAL AGENCY REVIEW OF DECISIONS (§ 2.17)

Many Food and Drug Administration decisions vitally affect interested persons and groups outside the agency. Inquiries are constantly received, throughout the agency, from individual consumers, manufacturers, and affected professionals, as well as organizations representing these interests. Few people outside the agency understand where their questions and complaints should be directed.

Section 2.17 of the proposed regulations provides for an orderly process of administrative review of decisions within the agency, and thus advises those outside the agency of how they should pursue matters which interest and concern them. Any decision of an agency employee would be subject to review by that employee's supervisor at the request of the employee himself, on the initiative of the supervisor, at the request of any interested person outside the agency, or as required by duly promulgated delegations of authority. Such review ordinarily would follow the established agency channels of supervision or review for the specific matter involved. Where a person outside the agency requested internal agency review of any decision, it would be done only through established agency channels. Review would take place to resolve issues, to review policy matters, in unusual situations requiring immediate review in the public interest, and as required by the delegations of authority.

Thus, where a matter had not yet been reviewed by a bureau director, any request from outside the agency that he review it would be denied until the matter was first reviewed at lower levels. Similarly, any request for intervention or review by the office of the Commissioner would be denied until the matter had been fully considered within the bureau and forwarded to the office of the Commissioner. It is, of course, entirely within the Commissioner's discretion to grant or deny a request to review any matter.

Any internal agency review of a decision would have to be based solely upon the data and information available in the administrative file. If any interested person presented new data or information not previously considered, the matter would be returned to the appropriate lower level within the agency for a reevaluation before it is again subjected to internal review at a higher level. Thus, bureau directors and the office of the Commissioner would act in basically the same way as a reviewing court. Division personnel could be assured that higher agency officials would not intervene before a matter is fully considered at the lower level, and would not review any issue on the basis of information not available at that level.

DISSEMINATION OF DRAFT FEDERAL REGISTER NOTICES AND REGULATIONS (§ 2.18)

Until relatively recently, there has been no Food and Drug Administration policy or regulations governing the dissemination of draft FEDERAL REGISTER notices and regulations. As a result, such documents have at times been given to some persons and not to others, in a way that raised public concern about agency activities.

Proposed § 2.18 would codify the policy that has been followed by the Food and Drug Administration on this matter during the past 2 years.

The Food and Drug Administration welcomes assistance from anyone in developing its policy and regulations. General concepts could be discussed by agency employees with any interested person. Details of a document, or a draft of a document, could not be furnished to any interested person outside the Executive Branch of the Federal Government unless and until it was made available to all interested persons by a notice published in the FEDERAL REGISTER. See, e.g., the notices with respect to the availability of the GMP regulations for low-acid canned foods published in the FEDERAL

REGISTER of November 14, 1972 (37 FR 24117), and the various regulations for shellfish control published in the FEDERAL REGISTER of December 13, 1973 (38 FR 34353) and January 14, 1975 (40 FR 2607).

In some instances, detailed discussion of a draft document would be necessary for proper development of administrative policy. This could be especially true where a specific industry which is the subject of a particular regulation had detailed technical knowledge not otherwise available to the Food and Drug Administration, and which was critical in developing an effective regulation. Where this occurred, the draft document would be made available to all interested persons through an announcement in the FEDERAL REGISTER, and any other appropriate protective procedures would be undertaken to make sure that a full and impartial administrative record would be established. Thus, public regulations would not be negotiated in private.

In certain limited instances, it has long been agency policy that a draft of a final regulation relating to a particular ingredient or product, e.g., a regulation relating to a food additive, new animal drug, or antibiotic drug, may be furnished to the petitioner for comment on the technical accuracy of such regulation. The proposed regulations would continue this long-standing practice. In these situations, where only technical accuracy rather than any policy issue is involved, publication of the availability of the draft regulation in the FEDERAL REGISTER would be unnecessary in order to protect the public interest.

The provisions of the Radiation Control for Health and Safety Act of 1968, 42 U.S.C. 263f, explicitly require the Commissioner to consult with interested persons in the development of performance standards. Accordingly, the Commissioner would publish in the FEDERAL REGISTER an announcement that a performance standard is being considered, and thereafter a draft of a proposed or final performance standard, including any amendment thereof, would be furnished to any interested person upon request and could be discussed by agency employees in detail with any interested person at any time through final consideration of such a document.

All such documents would be continuously available to the public after publication of the notice in the FEDERAL REGISTER, and it would therefore be unnecessary to publish in the FEDERAL REGISTER a specific notice of the availability of each draft of the document.

The regulations recognize that the restrictions on discussion and disclosure of draft FEDERAL REGISTER notices and regulations proposed in this paragraph would not apply to those situations in which internal agency documents were properly disclosed under §§ 4.83 through 4.89 of the agency's public information regulations. Such situations include disclosure to consultants, other Federal departments and agencies, Congress, State and local government officials, and foreign government officials, as well as disclosure required by court order and in administrative or court proceedings. Thus, it would be entirely proper to provide a draft regulation to an advisory committee without making it publicly available to all interested persons. If it should become available to some members of the general public, however, the agency would make it available for public disclosure to all interested persons pursuant to § 4.21, as was done with a draft of revised drug GMP regulations by a notice published in the FEDERAL REGISTER of March 19, 1975 (40 FR 12535).

ADVISORY OPINIONS (§ 2.19)

Throughout its history, the Food and Drug Administration has issued advisory opinions in various forms. Early advisory opinions, between 1938 and 1946, were issued as trade correspondence (TC's). More recently, advisory opinions have been codified in the agency's Compliance Policy Guides manual, which is available from the Public Records and Documents Center, in other documents designated as "advisory opinions," and in preambles to FEDERAL REGISTER documents. The proposed regulations recognize the continuing status of these prior documents as advisory opinions except to the extent that they are revoked. Some of these advisory opinions, particularly those in the form of trade correspondence, have been revoked, e.g., the notice published in the FEDERAL REGISTER of May 20, 1969 (34 FR 7922).

Prior Food and Drug Administration policy has not distinguished between formal advisory opinions and informal oral advice and correspondence. As a result, confusion and uncertainty has been engendered both within the agency and outside as to whether opinions expressed in correspondence or orally carry the weight of the agency or only of the individual agency employee involved.

Absent specific regulations to the contrary, the statements of a government employee do not bind the government. See, e.g., Bentex Pharmaceuticals, Inc. v. Richardson, 463 F.2d 363, 368 n.17 (4th Cir. 1972), rev'd on other grounds, 412 U.S. 645 (1973); Udall v. Oelschlaeger, 389 F.2d 974, 977 (D.C. Cir. 1968), cert. denied, 392 U.S. 909 (1968); AMP Inc. v. Gardner, 275 F. Supp, 410, 412 n.1 (S.D.N.Y. 1967), aff'd, 389 F.2d 825 (2d Cir. 1968); and United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes, 178 F. Supp. 847, 853–854 (D.N.J. 1959). Accordingly, because of the lack of any agency regulations on this matter, none of the correspondence or oral advice previously issued by the agency has had any binding legal effect.

In many instances, important agency correspondence relating to the legal status of ingredients and products has not been compiled or reviewed in any comprehensive or systematic way, with the result that few in the agency have known about the existence of such correspondence nor has the fact that such correspondence has no legal status been understood by the public. For this reason, on recent occasions the agency has been forced to issue regulations formally withdrawing prior opinion letters relating to the food additive and new drug status of products. See 21 CFR 121.11 and 310.100.

The Commissioner would resolve the present uncertainty by the proposal of regulations that would clearly and explicitly recognize the difference between the informal opinion of an individual in the agency, which represents his best information and advice, and the formal opinion of the agency, which represents a position of the Food and Drug Administration that is binding and commits the agency to the views expressed until they are formally modified or revoked. Section 2.19 of the proposed regulations would establish such a system.

Under § 2.19, a request for a formal advisory opinion would be made pursuant to a specified form. The resulting advisory opinion would have to be followed by the agency until it is amended or revoked. Amendment or revocation of an advisory opinion would be required to be made with the same degree of public dissemination as adoption of the original advisory opinion, or by publishing notice of such revocation in the FEDERAL REGISTER, which by statute constitutes adequate public notice. See 44 U.S.C. 1508; North American Pharmacal, Inc. v. Department of HEW, 491 F.2d 546 (8th Cir. 1973). An advisory opinion, would, however, have to be explicitly revoked, and could not be revoked by implication as a result of publication of other advisory opinions or regulations.

The Commissioner advises that a request for an advisory opinion would be granted whenever feasible. The fact that a course of action was already being followed by the person requesting the advisory opinion, or that an investigation or regulatory action was already pending with respect to the matter, would not operate to preclude an advisory opinion.

On the other hand, the Commissioner recognizes that there are some circumstances where an advisory opinion might not be feasible. For example, where there was insufficient information on which to base an informed opinion, e.g., further investigation was necessary before such opinion could be given, or where the subject matter was so complex that any opinion would be too qualified and indefinite to be helpful, a request for an advisory opinion could be denied. An advisory opinion would ordinarily concern policy matters or issues of broad applicability. Thus, advisory opinions ordinarily would not be given with respect to a particular product or label, unless a policy issue of broad applicability were involved. Similarly, a request for an advisory opinion on the legality of a product marketed by a competitor, or on any similar matter, would also ordinarily be denied, although the Food and Drug Administration would investigate complaints about the legality of products or practices when filed by any interested person.

All statements or advice given by a Food and Drug Administration employee orally or in writing, but which did not constitute an advisory opinion, would represent informal communications that

contain the best information and opinion available to that employee at that time, but would not have the same binding effect as an advisory opinion. Accordingly, such informal communications would in no way obligate or commit the agency to the views expressed.

On occasion, the Food and Drug Administration receives oral or written requests which require resolution of important issues that have broad applicability, but which do not specifically request an advisory opinion. Under the proposed regulations, the Commissioner could, in his discretion, handle such inquiries as a request for an advisory opinion in order to provide a definitive agency position on the matter and to give it wide dissemination.

Ordinarily, an advisory opinion would commit the Food and Drug Administration to the position stated in the opinion, until it is amended or revoked. In unusual situations involving an immediate and significant danger to health, however, the Commissioner could take appropriate civil enforcement action contrary to an advisory opinion prior to amending or revoking it. Thus, although an advisory opinion would in virtually all instances be binding upon the agency until amended or revoked, the regulations would provide for sufficient flexibility to permit immediate action where essential to public protection.

The Commissioner has carefully considered whether advisory opinions should be published in the FEDERAL REGISTER. In view of the potentially large number of advisory opinions and the resources that would be necessary to accomplish this, the Commissioner has concluded that it would not be feasible. Such advisory opinions may be compiled as part of the agency's Compliance Policy Guides manual, or in a separate compilation of advisory opinions. The substance of these advisory opinions would undoubtedly be disseminated widely by the agency trade associations, and the trade press.

One particular issue has frequently arisen within the Food and Drug Administration within the past few years. Companies have often requested the agency for so-called "certificates of free sale," i.e., a statement from the Food and Drug Administration that a particular ingredient or product may lawfully be sold in this country. Such "certificates" are often required by foreign governments before a product may be imported into that country.

In the opinion of the Commissioner, an unrestricted "certificate" of this kind cannot be given because the Food and Drug Administration cannot guarantee the legality of any particular product at all times. Nor would a formal advisory opinion be appropriate, since it would involve a particular product and the agency's resources are insufficient to provide this service for all products. The agency would, however, provide an informal letter stating specific information with respect to a product, e.g., that it is the subject of an approved NDA or food additive regulation, or that the agency does not presently object to the product's labeling, if sufficient information had been submitted to make such a determination and if there were sufficient agency resources to provide this service. Such "certificates" would thus not constitute a formal advisory opinion on the status of a product, but would provide informal written views which state the current views of the agency employee who signs the letter.

FOOD AND DRUG ADMINISTRATION REGULATIONS, GUIDELINES, RECOMMENDATIONS, AND AGREEMENTS (§ 2.20)

The Commissioner is aware that there is uncertainty about the status of some of the various types of documents adopted by the Food and Drug Administration. In general, these documents fall into the following four categories: Regulations, guidelines, recommendations, and agreements. Proposed § 2.20 would clarify the status and legal effect of these different types of documents.

Proposed § 2.20(a) would provide that all agency regulations having general applicability and legal effect shall be promulgated in the FEDERAL REGISTER pursuant to proposed § 2.10 or § 2.12. This is in accordance with the requirements of the Administrative Procedure Act and current case law. Any document, other than a statute, which the Food and Drug Administration intended to enforce as a legal requirement, would have to be published as a regulation in the FEDERAL REGISTER.

Of course, the agency is not required to issue regulations implementing the law before it takes legal action to enforce specific statutory provisions against persons or products in violation of the law. Thus, the agency could continue to seize a food product containing a poisonous or deleterious substance, or a new drug which is being marketed illegally without an approved NDA, regardless whether it has first issued a regulation designating that substance as poisonous or deleterious or that drug as a new drug. On the other hand, if the agency chose to bring such action, it could not rely upon any guidelines it may have issued as establishing substantive legal requirements.

In addition to provisions which would be enforced as legal requirements, regulations could contain provisions which were intended only as guidelines and recommendations. The specific language of each provision in a regulation would state its intended application. For example, provisions which stated that a person "shall" take certain action would establish a legal requirement, whereas provisions which stated that a person "should" or "may" take certain action would establish guidelines and recommendations which would not be legal requirements. Thus, the fact that a provision was published in the FEDERAL REGISTER as a regulation would not be determinative of whether it established a legal requirement or guidelines and recommendations.

Proposed § 2.20(b) would govern the establishment and use of Food and Drug Administration guidelines, which would not be published in the FEDERAL REGISTER as regulations. The Commissioner recognizes that such guidelines, which do not have the legal status of regulations, are increasingly important in providing assistance both to the regulated industry and to agency employees who are charged with consistent and fair administration of the law. In many instances, such guidelines would be available on an informal basis before comparable regulations could be promulgated. For example, the Commissioner might wish to issue guidelines for acceptable premarket substantiation for safety of cosmetics, as required by § 740.10(a), published in the FEDERAL REGISTER of March 3, 1975 (40 FR 8912), in order to obtain experience with such guidelines before publishing them in a proposed regulation. Moreover, not all guidelines would be appropriate for publication in the FEDERAL REGISTER as regulations. Some would be intended as no more than informal suggestions. Others would be so voluminous and complex as not to be appropriate for FEDERAL REGISTER dissemination.

Still others would be subject to such frequent change as to make their publication for comment virtually impossible. Under these circumstances, the development and use of guidelines that represented acceptable conduct from the standpoint of the agency, but which would not be published in the form of regulations are imperative for efficient administrative implementation of the law.

As the use of guidelines in the agency has increased, their methods of development, their availability, notice of any changes, and an opportunity to participate in their development and modification, have become more important. These proposed regulations would regularize these matters, and in the judgment of the Commissioner would provide for adequate notice and opportunity to participate for all interested persons.

Proposed § 2.20(b)(1) defines "guidelines" broadly to include all technical or policy criteria relating to any matter subject to the jurisdiction of the Commissioner. Guidelines state procedures or standards of general applicability which are not legal requirements but which are acceptable to the agency with respect to a particular subject matter. Although analytical methods are clearly guidelines, they would be excepted from the provisions of this regulation because of their large number, their length and complexity, and the volume and frequency of amendments involved. Such analytical methods are, of course, available for public disclosure pursuant to the public information regulations contained or cross-referenced in 21 CFR Part 4.

Although a person may rely upon an agency guideline with assurance that it is acceptable to the Food and Drug Administration, he is also free to use any different procedure or standard even though it is not provided for in a guideline. When a person chooses to differ from a guideline, he may, but is not required to, discuss the matter further with

the agency to prevent the expenditure of money and effort on work that may later be determined to be unacceptable. The Commissioner is concerned that innovation not be stifled by the adoption of guidelines. Nor does the Commissioner believe that, in all instances, a person who deviates from a guideline should feel obligated to consult with the agency first. Where such consultation is requested, however, the agency is obligated to provide the best answer available to it at that moment.

The Commissioner emphasizes that following a testing guideline does not in any way guarantee that the ingredient or product so tested will receive agency approval. Approval must depend, of course, upon all of the available information relating to the matter. The results may indicate that the ingredient or product should be disapproved, or that additional testing must be undertaken. Similarly, poor quality testing will not be acceptable even if the protocol complies with a guideline.

Guidelines would be issued by filing them in the public file established by the Hearing Clerk for this purpose, and publishing a notice of availability of the guideline in the FEDERAL REGISTER. Amendments to a guideline would be issued in the same way. Any interested person could, of course, petition the agency pursuant to proposed § 2.7 to issue a guideline relating to any matter.

When a guideline was amended or revoked, just as where an advisory opinion was amended or revoked, the question would inevitably arise as to whether work undertaken or completed in good faith reliance on the prior version of the guideline would remain acceptable to the Food and Drug Administration. The Commissioner believes that such work should remain acceptable unless substantial public interest considerations preclude continued acceptance. This determination would be made on the basis of all of the surrounding facts. Where the guideline consisted of a protocol for an animal study which was simply being revised to reflect the latest knowledge about appropriate scientific procedures rather than because of any concern about the scientific validity of prior results under the former protocol, the old work would undoubtedly remain acceptable. Where the guideline or advisory opinion consisted of labeling standards, however, labels meeting the old guideline ordinarily would no longer remain acceptable after an appropriate transition period. Whenever possible, the notice of an amended guideline would state when it has been determined that work previously undertaken or completed on the basis of the prior guideline no longer remains acceptable.

For the same reasons that FEDERAL REGISTER notices and regulations must be available to all members of the public on an equal basis, all draft guidelines must similarly be accessible to all interested persons on the same basis. Accordingly, the dissemination of draft guidelines would be subject to the requirements of proposed § 2.18. Similarly, to guarantee an opportunity for interested persons to comment on guidelines and to suggest modifications, the notice of availability of a guideline would state the individual or office responsible for each guideline so that written comments could be filed. Such comments could then be used by the agency in considering further modifications.

The Commissioner advises that guidelines would have the same legal status as an advisory opinion. Until modified or revoked, they would represent the formal position of the agency and bind the agency to that position. Other informal communications relating to acceptable procedures or standards would represent the best information and opinion available to a particular employee at a particular time, but would not constitute a guideline or advisory opinion and thus would not obligate the agency to follow the views expressed.

The Commissioner emphasizes that only those guidelines which were issued by the Food and Drug Administration pursuant to proposed § 2.20(b) would have any official status. Other written documents would, until issued as guidelines, stand on the same legal footing as any informal communication by an agency employee. Accordingly, it would be important for all such written documents relied upon throughout the agency to be reviewed and a decision made whether they should be issued as guidelines pursuant to these provisions or should no longer be used by the agency. To complete this process, § 2.20 (b) would not become effective for 180 days. Those internal written documents which had not been issued as guidelines by that time would no longer be regarded as having official agency approval as representing acceptable procedures or standards and would have no status other than as representing the views of a particular employee.

Proposed § 2.20(c) deals with agency recommendations which are not published in the FEDERAL REGISTER as regulations. In addition to guidelines, which relate to regulatory matters that fall within the laws administered by the Commissioner, the Food and Drug Administration also formulates and disseminates recommendations about matters which are authorized by, but do not involve direct regulatory action under those laws. Examples are model State and local ordinances, recommendations for physicians and technicians in the proper use of machines and products, and other similar matters.

The Commissioner is of the opinion that recommendations of this nature should be handled pursuant to the procedures for guidelines, except that they should be included in a separate public file established by the Hearing Clerk. Thus, recommendations could be made public in the same systematic and comprehensive way. Of course, recommendations could also be incorporated in agency regulations.

Finally, proposed §2.20(d) deals with agency agreements. The Food and Drug Administration enters into agreements, memoranda of understanding, and other similar formal written documents with government agencies, foreign governments, companies subject to the agency's regulatory jurisdiction, and other persons. All of these would be required to be published in the FEDERAL REGISTER and included in the public file on agreements established by the Public Records and Documents Center pursuant to § 4.108. Any such document not included in that public file would be deemed to be rescinded and would have no force or effect whatever.

PARTICIPATION IN OUTSIDE STANDARD-SETTING ACTIVITIES (§ 2.21)

As the Food and Drug Administration has increased its reliance upon regulations to establish standards to regulate the practices and products of those subject to the laws administered by the Commissioner, questions about the activities of agency employees in outside standard-setting activities have arisen. It is the Commissioner's opinion that agency policy on this matter should be reflected in proposed § 2.21.

"Standard-setting activities" is defined broadly to include all of the same technical and policy criteria that are properly the subject of agency regulations and guidelines. In general, the Food and Drug Administration encourages employee participation in outside standard-setting activities that are in the public interest.

Proposed § 2.21 divides outside standard-setting activities into three categories: Those conducted by other Federal government agencies; those conducted by State and local government agencies and by United Nations organizations and other international organizations and foreign governments pursuant to treaty; and those conducted by private groups and organizations.

With respect to all three categories of standard-setting activities, any agency employee could participate after the approval by the relevant bureau director or the Commissioner of Form PHS3763 ("Request for approval of appointment as liaison representative") covering the activity involved. This form and all pertinent background material describing the activities would have to be included in the public file on standard-setting activities established for this purpose by the Public Records and Documents Center. The Food and Drug Administration employee who participated in these activities would refer all requests for information about or participation in such activities to the group or organization responsible. Where, as often occurs, the agency employee could invite members of the public to accompany him at any meeting relating to such activities, such invitation would have to be extended to a representative sampling of the public and not just to one interest group.

Special additional requirements would apply with respect to standard-setting activities by private groups and organizations. The Food and Drug Administration employee could participate either as a voting or as a nonvoting liaison

representative, but participation by the individual would not connote Food and Drug Administration agreement with, or endorsement of, any decisions reached. Should the matter come before the agency at a later date, that employee could not serve as the deciding official on the matter involved. Nor would the fact of that employee's participation, per se, be relevant in any subsequent agency determination with respect to that matter.

In addition, the proposed regulation would establish minimum standards that would apply to all outside private standard-setting activities in which Food and Drug Administration employees participated. The activities would have to be based upon sound scientific and technological information, and be designed to protect the public against unsafe, ineffective, or deceptive products or practices. The activities could not be designed for economic benefit of any company, group, or organization, or involve violation of the antitrust laws. Perhaps most important, the group or organization responsible for the standard-setting activities would be required to have a procedure through which any interested person would have an opportunity to provide information and views on the activities involved, without the payment of fees. The exact manner in which this was accomplished, including whether such presentation was in person or in writing, would be at the discretion of the group or organization responsible for the activities.

In some situations involving private standard-setting activities, the Food and Drug Administration has a particular regulatory interest which justifies direct participation as an agency activity. Examples of such activities include the development of uniform State and local laws and regulations that will implement the same policies that are expressed in the laws administered by the Commissioner, and development of analytical methods used for regulatory purposes. In these situations, the Commissioner may determine that agency participation would be an official activity that does connote agreement with or endorsement of the decisions reached, and that participation by the individual would not in any way disqualify him from consideration of the matter, if it arose within the agency. Any such determination would be included in the public file on the matter.

Many Food and Drug Administration employees have close daily contact with associations of State and local government officials who have parallel responsibilities at the local level. Many agency employees are members of these associations, and participate in their activities. The Commissioner concludes that the standard-setting activities of these associations, of which 11 are listed in the new regulations, should not be subject to the requirements of this section. Instead, a list of all committees and other groups of these associations would be included in the public file on standard-setting activities so that agency participation in these matters would be a matter of public record.

PUBLIC CALENDARS (§ 2.22)

Proposed § 2.22 would provide for two types of public calendars to be disseminated weekly: A prospective calendar of public proceedings that would contain all public meetings and similar events for the following 4 weeks, and a retrospective calendar of private meetings of top agency officials for the previous week with persons outside the Federal government.

The prospective calendar would contain public meetings, conferences, hearings, advisory committee meetings, seminars, and other public proceedings of the Food and Drug Administration, as well as significant public events involving the agency, such as congressional hearings and court cases. It would not contain future private meetings or similar nonpublic events, or public events of organizations other than the Food and Drug Administration in which agency employees participated. It is the opinion of the Commissioner that inclusion of such meetings and events would necessarily be incomplete and inaccurate because of the need to schedule or cancel meetings or agenda items on short notice, and would serve no useful purpose because others would not be entitled to attend private meetings and would in any event be able to obtain memoranda of meetings shown on the retrospective calendar to the extent permitted by the public information regulations contained in 21 CFR Part 4 and the regulations referenced therein.

The retrospective public calendar would contain, for the preceding week, all of the meetings with persons outside the Federal government and other significant events involving designated top officials of the Food and Drug Administration. The agency officials subject to this requirement are set forth in proposed § 2.22(b)(3).

The Commissioner has concluded that the retrospective public calendar should include all personal meetings, but might or might not include oral discussions by telephone at the option of the official making the report. Any meeting with an onsite contractor, e.g., at the National Center for Toxicological Research, would not have to be included because of the impracticalities involved. Meetings with other persons in the Federal government, e.g., with an official of another government agency or a member of Congress, would not be shown on the retrospective public calendar regardless of whether those other persons had also invited to the meeting persons from outside the Federal government.

The regulation would provide that meetings with the working press also would not be included in the retrospective calendar at this time. This issue was closely debated within the Food and Drug Administration, and there is a contrariety of views on it. Some agency officials believe that, because of the unique status of the press in this country, such discussions should not be required to be made a matter of public record. Other agency officials strongly believe that the same principles should apply to the working press as to any other member of the public, with respect to meetings and discussions. The Commissioner proposes that, for purposes of these regulations, the working press be exempt on an interim basis. The Commissioner particularly invites comment on this aspect of the regulations so that a determination can be made on the matter.

Finally, the Commissioner recognizes that meetings which would prejudice law enforcement activities, or would invade privacy, are properly excluded from the retrospective public calendar, and the regulations would so provide.

REPRESENTATION BY AN ORGANIZATION (§2.23)

It is common practice for organizations to represent their members by filing petitions, comments, objections, and otherwise participating in any administrative proceeding of the Food and Drug Administration. The Commissioner believes that this is an entirely proper function and that it serves very useful purposes.

At the same time, the Commissioner believes that, when a trade association participates in the administrative process in this way, such representation is properly interpreted as expressing the viewpoint of all of the members of the trade association except those specifically excluded by name in any submission. Accordingly, proposed § 2.23(b) would require that every submission either attach a list of the members of the trade association or refer to such a list that is placed on permanent file with the Hearing Clerk and is kept current by the trade association. In this way, the representation of the trade association would be made a matter of public record.

When a trade association filed an objection or request for hearing in a proceeding that permits an opportunity for a formal evidentiary public hearing, all subsequent action by the association with respect to such matters would bind each member except to the extent that that member independently filed its own objection or request for hearing or was otherwise specifically excluded from representation by the trade association in the matter, in which case its rights would be entirely separate and distinct.

It has been common practice for trade associations and other organizations to file declaratory judgment actions or other judicial review proceedings on behalf of their members to determine the legality of Food and Drug Administration action. Again, the Commissioner believes that such activity is entirely proper and serves a useful public purpose. In the opinion of the Commissioner, a trade association or other membership organization has standing in the courts to represent its membership in such matters, and the Food and Drug Administration would not interpose procedural objections to such standing.

In the past, however, after a trade association has obtained an adverse judicial interpretation with respect to a particular issue, its members have continued to litigate the matter in separate judicial proceedings. For example, after the Pharmaceutical Manufacturers Association unsuccessfully challenged agency regulations governing adequate and well-controlled clinical investigations in Pharmaceutical Manufacturers Ass'n v. Richardson, 318 F. Supp. 301 (D. Del. 1970), and did not appeal that adverse determination, individual PMA members continued to litigate the same issues in courts throughout the country, and ultimately in the Supreme Court. Thus, the benefit of the initial representative legal action by the trade association to settle an issue on behalf of its members has been wholly destroyed, and litigation has proliferated, wasting public resources without the benefit of a definitive decision. The Commissioner believes that such proliferation is contrary to the public interest and to the purpose of such litigation, and that a determination in any suit involving a trade association properly binds all members of the association and precludes further litigation of the same issues by any association member.

In the future, the Commissioner intends to take two independent steps to assure that representative actions brought by trade associations or other organizations on behalf of their members settle issues and preclude further litigation by the membership. First, the Commissioner will take appropriate legal measures in such cases to have the case brought or considered as a class action or otherwise as binding upon all members of the association or organization except those explicitly excluded by name. Second, regardless whether the case is brought or considered as a class action or as otherwise binding upon all members, the Commissioner will take the position in any subsequent suit involving the same issues and any member of the association or organization not explicitly excluded by name from the prior suit that such issues are precluded from further litigation by such member pursuant to the doctrines of collateral estoppel or res judicata. Accordingly, proposed § 2.23 (c) gives adequate notice to all trade associations or organizations and their membership that future litigation by the association or organization will have this legal effect. See, e.g., Abbott Laboratories v. Gardner, 387 U.S. 136, 154–156 (1967), National Automatic Laundry and Cleaning Council v. Schultz, 443 F. 2d 689, 704 (D.C. Cir. 1971), and Acree v. Air Line Pilots Ass'n., 390 F. 2d 199, 202 (5th Cir. 1968).

SETTLEMENT PROPOSALS (§ 2.24)

The Commissioner wishes to encourage settlement of issues without hearings and litigation wherever this is feasible. Accordingly, proposed § 2.24 would provide that settlement proposals and related matters could be raised by any person at any point in any administrative proceeding, and that unaccepted proposals of this nature would not be admissible in evidence in any Food and Drug Administration proceeding. The Food and Drug Administration would oppose admission of such proposals in any other administrative or court proceeding. Thus, settlement could be proposed without fear that it would later be used against the individual to imply that he did not have confidence in his case or was willing to concede the incorrectness of part of his position. The Commissioner recognizes that all settlement involves compromise on the part of all persons involved, and unless this protection is granted the possibility of settlement would be severely diminished.

On the other hand, where a compromise is accepted, it may well be necessary to submit the various settlement proposals and related matters in evidence in an administrative or court proceeding in order adequately to explain the compromise reached. Proposed § 2.24 therefore would apply only to unaccepted proposals for settlement.

WAIVER, SUSPENSION, OR MODIFICATION OF PROCEDURAL REQUIREMENTS (§ 2.25)

The Commissioner is of the opinion that it is important to establish detailed procedural rules for the various public hearings conducted by the agency. Without such rules, which are set forth in proposed Subparts B through F, neither the presiding officers nor the participants would have sound guidance on how to proceed, and the uncertainty and confusion that would prevail would substantially hinder the progress of these hearings.

By providing such detailed regulations, on the other hand, there is the danger that, on occasion, variations will be necessary. The Commissioner recognizes that the procedural requirements for these hearings must have sufficient flexibility to be workable in a wide variety of situations. It is simply not possible to take account of all reasonable variations and exceptions that have occurred in the past and will occur in the future. Accordingly, § 2.25 would provide that the Commissioner or the presiding officer in any such hearing could modify any procedural requirement with respect to a particular hearing to assure a fair and efficient hearing, where this would serve the interests of justice and not prejudice any participant.

FORMAL EVIDENTIARY PUBLIC HEARINGS (SUBPART B)

Proposed Subpart B would establish the requirements applicable to those situations where there is a statutory right to an opportunity for a hearing "on a record," i.e., a formal evidentiary trial-type public hearing, usually before an administrative law judge, or where the Commissioner concludes, in his discretion, that such an opportunity should be provided. The statutory provisions under which such an opportunity would be granted are listed in § 2.12(c) (1) through (18). Proposed Subpart B would replace former Subpart F of Part 2 and the provisions in other parts of the regulations relating to such specific matters as food additives and new drugs, which now govern formal agency hearings.

Section 701(e) of the act originally required a formal evidentiary public hearing for every regulation promulgated pursuant to that section, regardless whether any controversy existed on the matter. Because this inflexible requirement was obviously unworkable, it was amended to require a hearing only upon receipt of objections and a request for a hearing. See Pub. L. No. 83–335, 68 Stat. 55 (1954) and Pub. L. No. 84–905, 70 Stat. 919 (1956). The courts have since narrowed the requirement for a hearing still further, as reflected in the provisions of proposed § 2.113(b), discussed below.

One commentator has pointed out that "some of this country's gravest administrative deficiencies stem from lawyer-induced overreliance on courtroom methods to cope with problems for which they are unsuited." Gellhorn, Administrative Procedure Reform; Hardy Perennial, 48 Am. Bar Ass'n. Journal 243 (March 1962). Largely as a result of lengthy trial-type hearings on the regulations for special dietary foods and peanut butter, there has been virtually unanimous criticism of the way in which section 701(e) has been utilized. See, e.g., Byerley, Rx for Administrative Ills: Simplification, Association of Food & Drug Officials of the United States Quarterly Bulletin, Vol. 34, No. 1, p. 17 (January 1970); Note, FDA Rule-making Hearings: A Way Out of the Peanut Butter Quagmire, 40 Geo. Wash. L. Rev. 726 (1972). In 1971, the Administrative Conference of the United States released a report on the agency's use of formal hearings in which a number of recommendations for improvement were made. See Hamilton, Rulemaking on a Record by the Food and Drug Administration, 50 Tex. L. Rev. 1132 (1972). Subsequently, the Administrative Conference has also issued a report and recommendations suggesting modification of the present statutory requirements for formal hearings. See Hamilton, Procedures for the Adoption of Rules of General Applicability: The Need for Procedural Innovation in Administrative Rulemaking, 60 Cal. Law R. 1276 (1972) and Crampton, Causes and Cures of Administrative Delay, 58 American Bar Ass'n. Journal 937 (September 1972).

At about the same time, the American Bar Association appointed a special committee to consider the agency's hearing procedures, which also issued a report and recommendations. See Pendergast, The Diagnosis and Treatment of FDA Hearings, Association of Food & Drug Officials of the United States Quarterly Bulletin, Vol. 34, No. 1, p. 23 (January 1970). These various reports and recommendations have been widely discussed. See, e.g., Hamilton, Rulemaking on a Record, 26 Food Drug Cosmetic Law Journal 627 (December 1971); Goodrich, A Reply to Professor Hamilton's Comments and Recommendations for Procedural Reform, 26 Food Drug Cosmetic Law Journal 639 (December 1971).

The Commissioner has carefully considered all of the comments and sugges-

tions made in the course of these reports and discussions. Many are incorporated into these proposed regulations.

During the same period, the courts have realized that the use of a formal evidentiary public hearing is not always appropriate for agency decisionmaking. In American Airlines, Inc. v. Civil Aeronautics Board, 359 F. 2d 624, 629 (D.C. Cir. 1965), cert. denied, 385 U.S. 843 (1966), the court noted that "rulemaking is not to be shackled, in the absence of clear and specific congressional requirement, by importation of formalities developed for the adjudicatory process and basically unsuited for policy rulemaking." In Marine Space Enclosures, Inc. v. Federal Maritime Commission, 420 F. 2d 577, 589–590 (D.C. Cir. 1969), it was suggested that, in appropriate situations, a formal evidentiary public hearing "may usefully approach the legislative rather than the adjudicatory model." In Walter Holm & Co. v. Hardin, 449 F. 2d 1009, 1016 (D.C. Cir. 1971), the court stated that "This requirement of hearing is not shackled by rigidities of procedure that may stultify the regulatory program." More recently, in Cooper Laboratories, Inc. v. Commissioner, 501 F. 2d 772, 792–793 (D.C. Cir. 1974), it was suggested that the hearing required by the Federal Food, Drug, and Cosmetic Act with respect to withdrawal of approval of an NDA "need not borrow the characteristics of conventional courtroom controversy, burdened with the impedimenta of the kind of arcane questions with which lawyers often bedevil expert witnesses," but rather "can perhaps best be provided by an on-the-record conference-hearing procedure, modeled on conference discussions between lawyers and experts."

Thus, the Commissioner has recognized that, in those situations where complex scientific and medical issues are involved, a searching scientific inquiry conducted by independent experts may well be more appropriate to resolve the matters involved than a formal evidentiary public hearing. Use of a public hearing before a Board of Inquiry pursuant to Subpart C, or a public hearing before a public advisory committee pursuant to Subpart D, would therefore be authorized. Similarly, where a legislative-type public hearing before the Commissioner pursuant to Subpart E would be appropriate to consider broad policy issues, the proposed regulations would provide for this mechanism.

The courts have recently sustained the use of section 701(a) of the act for substantive rule making, in addition to section 701(e), so that the Food and Drug Administration "may follow streamlined procedures designed to avoid the endless delays that have tended to paralyze adjudicatory hearings and render them ineffective as a means of utilizing agency expertise." See National Nutritional Foods Ass'n. v. Weinberger, 512 F. 2d 688, 697 (2d Cir. 1975). As the Court stated in that case, which involved an agency rule making proceeding with respect to the safety of vitamins A and D, "Since the decision did not turn on precise factual issues or on the credibility of witnesses but represented a judgment based upon consideration of relevant medical and scientific data, we doubt that a trial-type adversary hearing would have shed any further light on the question * * *"

There has been substantial concern expressed in recent years about the need for development of more appropriate procedures than trial-type hearing for resolving difficult scientific issues. See, e.g., Hall, A. "* * * Diet Wholesome, But Not Excessive," Food Technology, Vol. 27, No. 7, p. 61 (1973) and Katz, One Profession's Finding of Fact is not Necessarily Another's, 22 National Academy of Sciences News Report, No. 6, pp. 4–5 (June–July 1972). The Commissioner believes that a Public Board of Inquiry or a public advisory committee represents a feasible approach to this problem, combining the features of traditional scientific inquiry with the need of the law to develop a full record on which to base the Commissioner's decision and subsequent judicial review. The Commissioner is hopeful that the flexibility provided by the range of procedures available under the proposed regulations would be fully utilized by the public and the regulated industries to avoid inappropriate use or abuse of formal trial-type hearings.

SCOPE OF SUBPART (§ 2.100)

Proposed Subpart B would be applicable both to adjudicatory and to rule making proceedings subject to the requirements for a formal evidentiary public hearing in the Administrative Procedure Act, 5 U.S.C. 554, 556, and 557. For the most part, the procedures are identical in both situations. In a few instances, however, the proposed regulations would provide different provisions for these two types of hearings.

In addition to formal evidentiary public hearings required by statute, the Commissioner could also, in his discretion, hold such a hearing with respect to any matter where he concluded that it would be in the public interest. Thus, even if a formal evidentiary hearing were requested but not justified pursuant to the proposed regulations, the Commissioner could order that a hearing be held on the matter pursuant to this Subpart if he concluded that there were sound public policy reasons for doing so.

INITIATION OF A FORMAL EVIDENTIARY PUBLIC HEARING INVOLVING THE ISSUANCE, AMENDMENT, OR REVOCATION OF A REGULATION (§ 2.110)

Proposed § 2.110 would govern initiation of a formal evidentiary public hearing involving rule making. The statutory provisions covered by this section are set out in proposed § 2.12(c) (1) through (15).

In general, rule making that would be subject to an opportunity for a formal evidentiary public hearing pursuant to § 2.12(c) (1) through (15) is no different than rule making that is subject only to the notice-and-comment procedures under 5 U.S.C. 553 and § 2.10 of the proposed regulations, up through promulgation of the final regulations. After publication of a final regulation subject to this Subpart, however, any person who would be adversely affected would have 30 days within which to file written objections and a request for a formal evidentiary public hearing.

The Commissioner notes that section 701(e) of the act and the other related statutory provisions explicitly provide 30 days within which objections and requests for hearing may be submitted. The Commissioner has no legal authority to extend this time period. In the past, many persons have requested, and been denied, an extension of this 30-day period. Accordingly, the proposed regulations would explicitly provide that this 30-day period shall not be extended by the Commissioner.

The statutory provisions relating to color additives and food additives are somewhat different from those for other regulations subject to this Subpart. Under sections 409 and 706 of the act, the notice of filing of a petition published in the FEDERAL REGISTER takes the place of the customary proposal, and thereafter the final order is published with time for objections and a request for hearing but no time for additional comment. Under §§ 8.9 and 121.51(h) (21 CFR 8.9 and 121.51(h)), as established in the recently promulgated public information regulations, the Commissioner will make available for public disclosure all safety and functionality data relating to any color additive or food additive at the time of filing of the petition, so that public comment can be prepared meaningfully and submitted prior to publication of the final regulations.

Similarly, the statutory provisions relating to new animal drug regulations explicitly eliminate the need for a proposal before promulgating a final regulation. Under section 512(i) of the act, a new animal drug regulation is promulgated by notice, which upon publication in the FEDERAL REGISTER is effective as a regulation.

For many years, it has been customary to promulgate technical amendments to antibiotic monographs as final regulations rather than as proposals because they usually involve only technical considerations rather than policy issues, are prepared in consultation with the manufacturers who must meet them, and impose new safety requirements in the public interest. The proposed regulations would permit the continuation of this practice under these circumstances. Where controversy or significant policy issues exist, such amendments would be published as proposals unless public health considerations required that they be made effective immediately.

INITIATION OF A FORMAL EVIDENTIARY PUBLIC HEARING INVOLVING ISSUANCE, AMENDMENT, OR REVOCATION OF AN ORDER (§ 2.111)

Proposed § 2.111 would govern the initiation of a formal evidentiary public hearing that is adjudicatory in nature. The statutory provisions involved are set out in proposed § 2.12(c) (16) through (18), and relate to approval or with-

drawal of approval of new drugs, new animal drugs, and biological licenses.

In these circumstances, the Commissioner would issue a notice of opportunity for hearing on any proposal to take adverse action with respect to the particular matter involved. The applicant for or holder of the order in question, and all other persons subject to the notice, e.g., the manufacturer of an identical, related, or similar drug that is covered by the order, would have 30 days after the issuance of the notice within which to request a formal evidentiary public hearing on the matter.

The Commissioner notes that, pursuant to the statutory provisions involved, only specified persons would have the legal right to exercise the opportunity for a hearing on these matters. Unlike the situation involved in public rule making, where every member of the public is entitled to an opportunity for a hearing, the statute explicitly states that only the persons directly affected by the agency action, i.e., those who hold or are covered by the license involved, have an opportunity for a hearing with respect to the matters involved under these three statutory provisions. Thus, for example, a physician has no legal right to a hearing to contest withdrawal or approval of a new drug.

Nonetheless, the Commissioner could, in his discretion, grant a formal evidentiary public hearing, or some other type of public hearing, e.g., a public hearing before the Commissioner pursuant to proposed Subpart E, upon the request of any interested person even though he may not have the statutory right to a hearing. The Commissioner would consider any request for a hearing involving a new drug, new animal drug, or biologics license, even though the person submitting the request had no statutory opportunity for a hearing on the matter involved.

Specific provisions are included in other sections in agency regulations relating to a request for hearing upon adverse action relating to new drugs, new animal drugs, and biological licenses, i.e., §§ 314.200, 514.200, and 601.7(a). The proposed regulations cross-reference these existing provisions.

FILING OBJECTIONS AND REQUESTS FOR A HEARING ON A REGULATION OR ORDER (§ 2.112)

Section 2.112 of the proposed regulations specifies with particularity the form in which objections to agency action and requests for a hearing must be submitted. In general, each objection must be separately numbered and, if a hearing is requested on it, accompanied by a detailed description and analysis of the specified factual information intended to be presented in support of the objection if a hearing is held. Under proposed § 2.113(b)(6), the failure to follow this form, or to file it within the time period specified, would result in denial of a hearing. As discussed in paragraph 16 of the preamble to the hearing regulations for new drugs and antibiotics published in the FEDERAL REGISTER of March 13, 1974 (39 FR 9750), it is not necessary to submit unfavorable data and information in requesting a hearing, but if a hearing is granted such unfavorable data and information would be required to be submitted pursuant to proposed § 2.153(a)(2) and (b).

RULING ON OBJECTIONS AND REQUESTS FOR HEARING (§ 2.113)

Based upon any objections or requests for hearings filed pursuant to proposed §§ 2.111 and 2.112, the Commissioner would have a number of options to pursue. First, he could modify or revoke the regulation or order involved. Second, he could order a formal evidentiary public hearing or an alternative form of hearing on the matter. Third, he could deny any hearing as unjustified and let the regulation or order stand unmodified.

Proposed § 2.113(b) sets out the criteria under which the Commissioner could determine whether a request for hearing has been justified. The Commissioner believes that these criteria accurately reflect the legal standards enunciated by the courts in litigation on these matters during the past few years. See, e.g., Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 620–622 (1973); Cooper Laboratories, Inc. v. Commissioner, 501 F.2d 772, 776–777, 780 n.22 (D.C. Cir. 1974); Hess & Clark v. Food & Drug Administration, 495 F.2d 975, 982–985 (D.C. Cir. 1974); Gulf States Utilities Co. v. Federal Power Comm'n., 411 U.S. 747, 772–775 (1973); Federal Power Comm'n. v. Texaco, 377 U.S. 33, 39–41 (1964); United States v. Storer Broadcasting Co., 351 U.S. 192, 202–205 (1956); Municipal Light Boards v. Federal Power Comm'n., 450 F.2d 1341, 1345–1346 (D.C. Cir. 1971); Citizens for Allegan County, Inc. v. Federal Power Comm'n., 414 F.2d 1125, 1128–1129 (D.C. Cir. 1969); Total Telecable, Inc. v. Federal Communications Comm'n., 411 F.2d 639, 641–642 (9th Cir. 1969); Virginia Electric & Power Co. v. Federal Power Comm'n., 351 F.2d 408, 410 (4th Cir. 1965); and Dyestuffs and Chemicals, Inc. v. Flemming, 271 F.2d 281, 286–287 (8th Cir. 1959), cert. denied, 362 U.S. 911 (1960).

To justify a hearing, there must be a genuine and substantial issue of fact for resolution at the hearing. If there are only policy or legal issues involved, rather than factual issues, there is no requirement that a hearing be held on the matter.

The factual issue must, moreover, be capable of being resolved by available and specifically identified reliable evidence. A request for hearing accompanied only by general allegations or denials or descriptions of contentions would not be sufficient to justify a hearing. Such a request would have to be accompanied by a detailed description and analysis of the specific factual information intended to be presented in the event that a hearing were held, not by general allegations. The failure to identify reliable evidence to be presented at the hearing would result in a decision that the hearing had not been justified.

The specific evidence identified in a request for hearing must be adequate to justify resolution of the factual issue in the way sought by the person submitting the request. If the Commissioner concluded that, even assuming the truth and accuracy of all of the data and information submitted in support of the objection and request for the hearing, they are insufficient to justify the factual determination urged, there would be no issue of fact remaining and thus no point whatever in conducting a hearing on the matter. For example, an allegation that a regulation may have a particular economic impact could be accepted by the Commissioner as factually true, without the need for a hearing, and still not require any change in the regulation involved. Summary disposition of the matter would be clearly warranted at that stage of the proceeding. If, on the other hand, the data and information submitted were on their face sufficient to justify the factual determination urged and the Commissioner would change the regulation or order if such facts were proved to be true, a hearing on the issue would be warranted. Thus, a hearing would be denied only where there was no relevant factual issue in dispute.

Resolution of the factual issue in the way sought by the person must be adequate to justify the relief requested in the objections and requests for hearing. Irrelevant factual contentions that are not determinative or controlling with respect to the relief requested would not justify a hearing. In some instances in the past, the Commissioner has received requests for a hearing on food standards which fail to include a product, but which do not exclude or otherwise affect that product. Under these circumstances, a hearing is not justified. Whenever there is an effect upon a product, however, a hearing may be justified. See, e.g., A. E. Staley Mfg. Co. v. Secretary of Agriculture, 120 F.2d 258 (7th Cir. 1941).

The action requested must not, on its face, be inconsistent with or in violation of any provision of the act or in any agency regulation particularizing the statutory standards. Instead of requesting a hearing under these circumstances, the proper procedure for the person to follow is to request an amendment or waiver from the regulation involved. For example, the Food and Drug Administration is presently engaged in rule making proceedings to establish monographs for OTC drug products and for biological products. Once those monographs are promulgated and made effective, new drug applications and biological licenses which are not in conformity with the monographs will be revoked or required to be amended to be consistent with the monograms. Hearings would not be granted with respect to such revocation or amendment, since the issue would already have been decided in the rule making proceeding. The proper procedure for any aggrieved manufacturer would be to request an amendment of or waiver from the monograph.

In some instances, a request for hearing may present a close question as to

whether a hearing is justified, or the Commissioner may otherwise be uncertain as to whether the public interest justifies a hearing. In such circumstances § 2.113(d) would provide that the Commissioner may serve upon the party involved a proposed order denying a hearing, and the party would have 30 days within which to respond with justification for the hearing.

MODIFICATION OR REVOCATION OF REGULATION OR ORDER (§ 2.114)

Based upon objections or a request for hearing, the Commissioner could modify or revoke the regulation or order involved, in whole or in part. Such modification or revocation would be accomplished through a further FEDERAL REGISTER notice. Thereafter, further objections or requests for hearing would be submitted with respect to such modification or revocation, but not with respect to any other provisions in the regulation or order involved. Such other provisions would become final upon expiration of the original 30 days provided for objections or requests for hearing, and could not thereafter be reopened except upon further notice by the Commissioner specifically reopening them.

DENIAL OF FORMAL EVIDENTIARY PUBLIC HEARING IN WHOLE OR IN PART (§ 2.115)

Where the Commissioner concluded that a formal evidentiary public hearing, or the alternative form of hearing requested, was not justified, proposed § 2.115 would require that he issue a notice of such determination in the FEDERAL REGISTER. In accordance with present procedure and applicable case law, any such determination would specify the reasons therefor.

Proposed § 2.115(b) specifies the record of the administrative proceeding. That administrative record would constitute the exclusive record for the Commissioner's decision, and the record upon which subsequent court review of the denial of a hearing could be obtained.

In some instances, a request for hearing could be granted on some issues and denied on others. Under these circumstances, the denial would constitute final agency action on that matter, and would be subject to judicial review pursuant to the specific statutory provisions relating to that subject matter. The time for filing a petition for judicial review would begin to run on the date of publication in the FEDERAL REGISTER of the Commissioner's determination denying a public hearing on those particular issues. The failure to file such a petition within the time period established by the specific statutory provisions governing the matter would constitute a waiver of the right to judicial review of those particular issues at any later time, regardless whether a hearing had been granted on other issues. In this way, there would be prompt judicial review of any partial denial of a hearing. In the event that a reviewing court concluded such denial to be improper, the issues involved could then be added to the hearing before it was concluded.

JUDICIAL REVIEW AFTER WAIVER OF HEARING ON A REGULATION (§ 2.116)

In the past, it has been assumed that any person who wishes to obtain judicial review of the Commissioner's decision on a final regulation which is subject to an opportunity for a hearing must request a hearing, and go through the entire hearing process, before he may obtain such review in the courts. The Commissioner concludes that this is a wasteful procedure that is not required by the statute. Accordingly, proposed § 2.116 provides a procedure under which judicial review could be obtained on any regulation which is subject to an opportunity for a formal evidentiary public hearing without the necessity of requesting or conducting such a hearing.

Under this procedure, the interested person need submit only an objection to the final regulation involved. After the Commissioner issued a notice in the FEDERAL REGISTER ruling upon any such objection, the person could then appeal the Commissioner's ruling on that objection to a United States Court of Appeals pursuant to the applicable statutory provisions in the act. The record for review would be the administrative record of the proceeding designated in the proposed regulations.

The Commissioner notes that this procedure would not be available where a hearing is in fact requested and justified on the particular matter involved by some other person. Under those circumstances, since the matter would be the subject of a formal evidentiary hearing or an alternative form of hearing, it would be impermissible to have it also subject to immediate court review while the issue is being reviewed in a hearing. If a hearing were requested and justified on an unrelated aspect of the matter, however, immediate court review of an adverse ruling on an objection could, and indeed should, be obtained pursuant to this new procedure. The failure to file a petition for court review within the statutory time period after the Commissioner's determination rejecting the objections would constitute a waiver of judicial review on those objections.

This procedure is quite similar to the procedure used for review of regulations issued by the Commissioner under section 701(a) of the act which are reviewable in the courts under the Administrative Procedure Act, 5 U.S.C. 701 et seq., except that the statutory provisions of the act permit direct review in a United States Court of Appeals rather than in a United States District Court. The record for review upon such appeal would be, however, the same record in both instances, i.e., the administrative record compiled before the Commissioner on the basis of which he made his decision.

The Commissioner concludes that this procedure would substantially expedite matters by eliminating the necessity for a public hearing prior to court review of any matter on which an interested person wishes to institute legal challenge. It would provide a fair and efficient procedure for such challenge, without burdening both the party involved and the Food and Drug Administration in a needless public hearing. The courts would moreover, have a full administrative record to review, even without the public hearing. That record would consist of all of the relevant FEDERAL REGISTER notices, a full articulation of the Commissioner's decision, including the reasons for his rejection of the objections filed to the final regulation, and all of the data and information on which the Commissioner and the other parties to the matter relied. The reviewing court's determination of whether the Commissioner's decision were supported by substantial evidence of record in this instance would therefore be no more difficult, and indeed probably no different, than its determination after a public hearing was held on a matter.

REQUEST FOR ALTERNATIVE FORM OF PUBLIC HEARING (§ 2.117)

For the reasons already noted above, the Commissioner is of the opinion that it is important to establish alternative forms of public hearings in addition to the formal evidentiary public hearing provided in Subpart B of the proposed regulations. Proposed § 2.117 would provide that a person who had a right to an opportunity for a formal evidentiary hearing could waive that opportunity and, in lieu thereof, request a public hearing before a Public Board of Inquiry pursuant to Subpart C, a public hearing before a public advisory committee pursuant to Subpart D, or a public hearing before the Commissioner pursuant to Subpart E. Such a waiver could, but would not have to, be conditioned upon the grant of one of these alternative forms of hearing. Such a request could be on his own initiative or at the suggestion of the Commissioner. The Commissioner anticipates that, in many instances, such a person would request a hearing under Subpart B and then indicate his willingness to waive that right to a hearing, conditioned upon the use of an alternative form of hearing. A request for an alternative form of hearing could be filed by the Hearing Clerk in the same administrative file as any related objections and request for hearing under Subpart B.

It is the opinion of the Commissioner that an alternative form of hearing would be used only where all persons who had a right to a formal evidentiary public hearing, and who had justified such a hearing, agreed to the alternative form. Under recent case law, it is clear that an alternative form of hearing could in many instances be required even without the consent of the parties. The Commissioner believes, however, that it will be unnecessary to resort to this type of requirement, and that parties to a hearing would readily agree to the form of hearing that would resolve the issue most expeditiously. Should this not occur, however, the Commissioner would reconsider this portion of the proposed regulations and might require use of alternative forms of hearings where they were more appropriate under the circumstances involved.

The Commissioner could, of course, determine to hold an alternative form of public hearing even where the formal requirements for justifying a formal evidentiary public hearing had not been fully satisfied. Where close questions arose with respect to justification for a formal evidentiary public hearing, it could well be in the best interests of all parties to agree to the use of an alternative form of hearing rather than to conduct litigation on the question whether a formal evidentiary public hearing had been justified.

If the Commissioner determined that an alternative form of public hearing should be used, a FEDERAL REGISTER notice would be published setting forth all of the pertinent information relating to the hearing, including any provision of the regulation or order which had been stayed, the issues to be considered at the hearing, and similar matters. If the hearing were to be conducted by a Public Board of Inquiry or a public advisory committee, the notice would state whether the findings and conclusions resulting from the hearing would be handled as a recommended decision or as an initial decision.

NOTICE OF HEARING; STAY OF ACTION (§2.118)

If the Commissioner determined that a request for hearing justified a formal evidentiary public hearing, he would have to issue a notice of that determination in the FEDERAL REGISTER, setting forth all relevant information about the hearing, such as a statement as to which parts, if any, of the regulation or order involved are stayed pending the hearing, the parties to the hearing, the issues to be considered at the hearing, whether the presiding officer will prepare a recommended decision or an initial decision, and similar matters. The presiding officer and the time of the prehearing conference could be included in the notice of hearing or be published in a later notice.

The Commissioner notes that the various provisions of the act that would be subject to proposed § 2.12 and Subpart B state different requirements with respect to whether a regulation or order is automatically stayed pending a public hearing. All regulations and orders subject to sections 505 and 701(e) of the act are automatically stayed by the filing of proper objections and requests for a hearing. Under section 409 of the act, the Commissioner has discretion to stay or not to stay a food additive regulation pending a hearing. Neither section 507 of the act nor section 351 of the Public Health Service Act provides for a stay of an antibiotic or biologic regulation or order pending a hearing, and accordingly the Commissioner also has discretion to grant or deny a stay under these provisions. Where the Commissioner has discretion to consider a stay, any request for a stay pending a hearing would have to be submitted pursuant to proposed § 2.9.

The statement of the factual issues raised by the objections or requests for hearings contained in the notice of hearing would determine the scope of the hearing. Although the presiding officer could revise or restate the issues, he could not add other issues or delete any of those issues contained in the notice of hearing.

EFFECTIVE DATE OF A REGULATION (§ 2.119)

If no objections were filed and no hearing requested, the regulation would become effective as specified in the notice promulgating it, and the Commissioner would publish an appropriate notice in the FEDERAL REGISTER confirming the effective date of the regulation involved. Based upon additional information, the Commissioner could also extend the time for compliance with the new regulation.

EFFECTIVE DATE OF AN ORDER (§ 2.120)

If no hearing were requested in response to a notice of opportunity for hearing, the Commissioner would publish a final order withdrawing approval of the NDA, NADA, or biologics license involved. Such withdrawal could, of course, involve the entire approval or only a portion of it, e.g., elimination of a single indication from labeling. The final order would establish the date on which it becomes effective.

Any person subject to the notice of opportunity for hearing, e.g., the manufacturer or distributor of a drug product which is identical, related, or similar to a drug product named in the notice, who did not request a hearing would be bound by the final order as of its effective date. If one person requested a hearing and others did not, the Commissioner could publish a final order covering those who did not request a hearing before he ruled upon the other person's request for hearing, or he could delay any such final order and handle them all at once.

In accordance with section 512(i) of the act, a final order withdrawing or modifying approval of an NADA would require that a corresponding change forthwith be made in the regulation reflecting the action taken.

APPEARANCE AND PRACTICE (§§ 2.130 AND 2.131)

Proposed §§ 2.130 and 2.131 relate to the filing of a notice of appearance in any formal evidentiary public hearing. No person would have to be licensed or otherwise specially qualified to appear on his own behalf or on behalf of any other interested person.

No person could participate in any proceeding without first having filed a written notice of appearance under these provisions. A notice of appearance could be stricken by the presiding officer for good cause, in which case the person involved could no longer participate in the proceeding.

PRESIDING OFFICER (§§ 2.140–2.144)

Proposed §§ 2.140 through 2.144 relate to the authority and functions of the presiding officer. In most instances the presiding officer will be an administrative law judge. In general, the presiding officer will have the authority and duty to conduct a fair and expeditious hearing.

The Food and Drug Administration presently has no subpoena power, and accordingly the presiding officer would have no authority to require witnesses to answer questions. In the event that a person whose direct testimony has been presented then declines to answer any question presented by the presiding officer or by any other participant on cross-examintion, however, the presiding officer could strike all the testimony of that witness. Similarly, where a participant in the hearing fails to abide by the regulations and the orders issued by the presiding officer, all evidence presented by that participant could properly be stricken from the record.

HEARING PRODEDURES (§§ 2.150–2.165)

Proposed §§ 2.150 through 2.165 contain the procedures that would be utilized in the conduct of the formal evidentiary public hearing.

FILING AND SERVICE OF SUBMISSIONS (§ 2.150)

Proposed § 2.150 would require all submissions relating to a formal evidentiary public hearing to be filed with the Hearing Clerk in accordance with proposed § 2.5. Copies of any such submission would be served on all participants in the proceeding except for documentary data and information.

PETITION TO PARTICIPATE IN FORMA PAUPERIS (§ 2.151)

Proposed § 2.151 provides that the Commissioner could grant a participant's petition to proceed in forma pauperis, where the person was indigent and there was a strong public interest justification in his participation, or where such participation was in the public interest because it primarily benefited the general public. Under these circumstances, the participant would have to file only one copy of each submission with the Hearing Clerk, and the Hearing Clerk would then be responsible for serving copies upon all other participants.

ADVISORY OPINIONS (§ 2.152)

Proposed § 2.152 provides for the use of advisory opinions to settle issues during the course of a formal evidentiary public hearing.

DISCLOSURE OF DATA AND INFORMATION BY THE PARTICIPANTS (§ 2.153)

Proposed § 2.153 would require the director of the agency bureau responsible for the matter involved in the hearing to submit to the Hearing Clerk, before publication of the notice of hearing, all relevant portions of the administrative proceeding, all documents in the bureau files containing relevant factual data and information, whether favorable or unfavorable, all other documentary data and information on which the bureau relies for its position, and a narrative statement of his position on the factual issues involved and the type of evidence intended to be introduced in the hearing. Within 60 days after publication of the

notice of hearing, all other participants would have to file with the Hearing Clerk the same information. The failure to comply with this requirement would constitute a waiver of the right to participate further in the hearing and, in the case of a party, a waiver of the right to a hearing.

The Commissioner notes that those portions of the administrative record not relevant to the issues in the hearing would not be included in the documents filed by the bureau director. For example, if the manufacturing and quality control procedures for a new drug were not in issue in a hearing relating to the drug's safety or effectiveness, they would not be a part of the hearing record and, because they are otherwise prohibited from public disclosure pursuant to the provisions of Part 4 and the regulations referenced therein, would not be available for public disclosure.

Such submissions could be supplemented later in the proceeding with the approval of the presiding officer, but the Commissioner emphasizes that good cause would have to be shown as to why such supplemental material was not reasonably known or available, or why its relevance could not reasonably have been foreseen.

No participant would have to file data and information already filed by the Food and Drug Administration or by any other participant. Thus, participants are encouraged to exchange and consolidate lists of documentary evidence to reduce duplicative submissions.

PURPOSE; ORAL AND WRITTEN TESTIMONY; BURDEN OF PROOF (§ 2.154)

Proposed § 2.154 would govern the presentation of evidence and the burden of proof in a formal evidentiary public hearing. The Commissioner is of the opinion that, since the use of oral direct testimony and the use of cross-examination have been the principal causes for delay of Food and Drug Administration hearings in the past, most of the hearing should be developed through the submission of written documentary and testimonial evidence. Oral evidence should be permitted only where necessary for a full and true disclosure of relevant evidentiary facts. See, e.g., Long Island R.R. v. United States, 318 F. Supp. 490 (E.D.N.Y. 1970).

Under the Administrative Procedure Act, 5 U.S.C. 556(d), all direct evidence in a formal evidentiary public hearing involving rule making may be required to be introduced in writing, and a party to an adjudicatory proceeding may introduce direct testimony either orally or in writing. Commentators and the courts have pointed out, however, that it is virtually impossible to draw a clear line between rule making and adjudicatory proceedings, and thus that the true nature of any proceedings and the requirements applicable to them must be considered by reviewing the nature of the issues involved rather than by the use of arbitrary labels. See, e.g., Appalachian Power Co. v. Environmental Protection Agency, 477 F.2d 495, 500–501 (4th Cir. 1973); City of Chicago v. Federal Power Comm'n., 458 F.2d 731, 739 (D.C. Cir. 1971), cert. denied, 405 U.S. 1074 (1972); American Airlines, Inc. v. Civil Aeronautics Board, 359 F.2d 624, 627–632 (D.C. Cir. 1966), cert. denied, 385 U.S. 843 (1966); 1 Davis, Administrative Law Treatise § 5.01; 2 Davis, Administrative Law Treatise § 15.03; and Note, The Judicial Role in Defining Procedural Requirements for Agency Rulemaking, 87 Harv. L. Rev. 782 (1974). This is particularly true with respect to Food and Drug Administration proceedings. Although revocation of an antibiotic monograph and withdrawal of approval of a new drug on grounds of lack of safety or effectiveness involve the identical issue, the former is technically regarded as "rule making" whereas the latter is technically regarded as "adjudication." It is apparent, and the courts have recognized, that this distinction is meaningless and that, under the circumstances, an agency may apply similar procedural requirements depending upon the nature of the issues involved.

Accordingly, the Commissioner believes that the need for oral direct testimony should depend upon whether the type of proceeding involves "adjudicatory" facts or "legislative" facts. Where the issues involved a particular party or product and had no general applicability, e.g., the failure of one manufacturer to use adequate quality control in processing a specific drug product, they would be regarded as adjudicatory in nature. Where the issues had general applicabity, as is true with the safety and effectiveness of a class of drugs produced by a number of companies, they would be regarded as "legislative" or "rule making" in nature. Accordingly, all issues of general applicability would be subject to the requirement for written direct testimony, whereas issues involving specific applicability and particular parties would be considered adjudicatory in nature and each party would determine whether, and the extent to which, he wished to present his direct testimony orally or in writing.

With respect to cross-examination, the Administrative Procedure Act, 5 U.S.C. 556(d), states that the same rules shall apply in both rule making and adjudicatory proceedings. Under the law, cross-examination shall be permitted upon a showing that it is necessary for a full and true disclosure of the facts. The Commissioner therefore would adopt this standard, under which the presiding officer would in all cases determine whether cross-examination has been justified. The burden would be on the party involved to justify cross-examination in each instance in which it is requested. Ordinarily, cross-examination would be justified when it related to witness perception or credibility, but not when it related to a judgment based on scientific, medical, or technical data.

The Commissioner emphasizes that these new regulations would not eliminate either oral direct examination or oral cross-examination. Rather, they would require that any participant in a formal evidentiary public hearing justify the need for such oral presentation. Where the lack of an oral presentation could be shown to prejudice any participant, the proposed regulations would provide that such an oral presentation should be permitted. Accordingly, formal evidentiary public hearings would be far less protracted and legalistic but would preserve the right of each participant to make a full and fair presentation of his case.

It is the Commissioner's opinion that these rules fully meet the requirements of the Administrative Procedure Act, as interpreted by the courts. They would neither hinder the parties in developing the relevant facts, nor unduly prolong the proceeding to the detriment of the public interest. Any diligent party would have full opportunity to present all relevant information for consideration by the presiding officer and the Commissioner.

Pursuant to the Adminstrative Procedure Act, 5 U.S.C. 556(d), the proponent of a regulation or order has the burden of proof in any formal evidentiary public hearing. Except as otherwise provided by statute, this means that, where an interested person submits a petition to the agency but the agency modifies it in any significant way, the agency itself must bear the burden of proof with respect to such modification. Where the matter involves a drug, food additive, or color additive, however, the provisions of the act specifically place the burden of proof on the person contending that the product is safe or effective or both and who is requesting approval or contesting withdrawal of approval. In these situations, the burden of proof remains on any such participants regardless whether the proceeding involves a denial of approval in the fisrt instance, or revocation of prior approval. See, e.g., Environmental Defense Fund v. Finch, 428 F.2d 1083, 1092 n.27 (D.C. Cir. 1970) and Dow Chemical Co. v. Ruckelshaus, 447 F.2d 1317, 1324 (8th Cir. 1973).

PARTICIPATION OF NONPARTIES (§ 2.155)

Proposed § 2.155 provides that a nonparty participant would have basically the same rights as a party to the proceeding, except that he could not submit written interrogatories or conduct cross-examination except to the extent that the presiding officer found that such additional rights should be granted because the participant's interests would not be adequately protected otherwise, or it would be required for a full and true disclosure of relevant evidentiary facts. Any person whose petition was the subject of the hearing would have the same rights as a party, even though he did not meet the definition of a party in proposed § 2.3(a)(10).

CONDUCT AT ORAL HEARINGS OR CONFERENCES (§ 2.156)

Proposed § 2.156 would require dignified and ethical conduct by all participants in a hearing. Failure to observe this requirement would result in exclusion from the proceeding by direction of the

presiding officer. Exclusion of a participant for improper conduct at a hearing has been upheld in the courts. See, e.g., Ubiotica Corp. v. Food and Drug Administration, 427 F.2d 376, 382 (6th Cir. 1970).

TIME AND PLACE OF PREHEARING CONFERENCE (§ 2.157)

Proposed § 2.157 provides for a prehearing conference to be held as scheduled in the notice of hearing or in a subsequent notice.

PREHEARING CONFERENCE PROCEDURE (§ 2.158)

Proposed § 2.158 describes the matters to be determined at a prehearing conference. In general, the purpose of the prehearing conference is to lay out the full course of the hearing to the extent feasible, to identify all issues, to resolve all matters in contention between the participants with respect to the conduct of the hearing, and otherwise to take whatever action is necessary to assure a fair and efficient hearing. At the conclusion of the prehearing conference, the presiding officer must prepare a written prehearing order summarizing all of the decisions made, which would control the subsequent course of the hearing unless later modified for good cause shown. The presiding officer may revise the prehearing order as the evidence develops in the course of the hearing.

SUMMARY DECISIONS (§ 2.159)

Proposed § 2.159 provides that, just as in court proceedings, part or all of a formal evidentiary public hearing would be decided by summary judgment at any point in the proceeding.

RECEIPT OF EVIDENCE (§ 2.160)

Proposed § 2.160 relates to the development of evidence at a formal evidentiary public hearing. All participants will be submitting evidence during the same time period, rather than having it developed in sequence. Separate rules are provided with respect to written and oral evidence.

A written submission to the record would be admissible as evidence unless the document was not authentic or was excluded in order to enforce the procedural requirements of Subpart B. Thus, all of a participant's evidence would be excluded if he failed to comply with the requirements for a hearing.

Written evidence would not be excluded as inadmissible on the ground that it was irrelevant, immaterial, or repetitive. All such evidence would be admitted even though it was of no probative value whatever. The admission of written evidence therefore would not indicate that it was of any weight or value in determining the issues raised at the hearing. The Commissioner believes that it is far preferable to admit all written evidence and then to disregard irrelevant material in reaching a decision, than it would be to spend substantial time in debating the admissibility of such evidence at the hearing. For example, a scientific study or consumer survey would be admissible in evidence without the extensive voir dire that usually precedes it, in full court trials, and the other participants would then submit evidence on any alleged defects in the study or survey in order to support any contentions they might wish to make with respect to the weight that should be given to it. Admitting all written testimony into evidence, without consideration of evidentiary objections, would substantially shorten the time necessary to conduct a hearing.

Oral testimony, whether on direct or on cross-examination, would be admissible as evidence unless it was excluded as irrelevant, immaterial, or repetitive, or to enforce the procedural requirements relating to the hearing. If such evidence was excluded, it would remain a part of the administrative record, as a proffer of proof, in the event that such ruling was later challenged on judicial review. The Commissioner believes that excluding irrelevant, immaterial, and repetitious oral testimony would expedite the hearing by reducing the need for lengthy trial-type proceedings. Accordingly, by encouraging the use of written testimony and limiting oral testimony the proposed regulations woud prevent the type of prolonged and contentious hearings for which the agency has been criticized in the past.

On occasion, oral testimony might be offered relating to matters which constitute trade secrets and which, pursuant to proposed § 2.5(j)(3), would be prohibited from public disclosure. After the presiding officer had assured himself that this was in fact the situation, he would order the portion of the hearing closed which dealt exclusively with oral testimony, whether on direct examination or cross-examination, relating to such matters. Testimony relating to other matters could not be offered during such a closed session. The only persons who could attend and participate in such a closed session would be the witness, his counsel, and Federal Government Executive Branch employees and special government employees.

Any party could at any time in the course of the proceeding move for an order that the submission of oral and written evidence be concluded. It would be within the power of the presiding officer to grant or deny such order. Once the taking of evidence was concluded, no additional evidence could be submitted and considered as part of the record unless the record was reopened for that purpose.

OFFICIAL NOTICE (§ 2.161)

Under proposed § 2.161, the presiding officer could take official notice of specified matters on his own initiative or on the motion of any participant. All participants would have an opportunity to object to any specific matter of which official notice was proposed to be taken.

BRIEFS AND ARGUMENT (§ 2.162)

Proposed § 2.162 would assure all participants of the right to file briefs, together with proposed findings of fact and conclusions of law, at the conclusion of the proceeding. The presiding officer could also permit oral argument in his discretion.

Where a formal evidentiary public hearing involved trade secret matters prohibited from public disclosure pursuant to proposed § 2.5(j)(3), the participants who had access to this information, and particularly Food and Drug Administration representatives, would be expected to make a reasonable effort to avoid disclosing the details of such matters in a way that would reveal the trade secrets involved, in their pleadings and oral arguments. Where such matters were at the very heart of the issue, however and it was essential that they be discussed for the issue to be resolved, whatever presentation is necessary under the circumstances would be permitted.

INTERLOCUTORY APPEAL FROM RULING OF PRESIDING OFFICER (§ 2.163)

Ordinarily, an interlocutory appeal from a ruling of the presiding officer to the Commissioner would not be permitted. Such an appeal pursuant to proposed § 2.163 would be allowed only where specifically provided for with respect to a particular matter in the subpart, or upon certification of the matter by the presiding officer.

OFFICIAL TRANSCRIPT (§ 2.164)

All oral testimony would be transcribed.

MOTIONS (§ 2.165)

Under proposed § 2.165, any participant could make a motion with respect to any matter by filing it with the Hearing Clerk and providing it to the other participants in the proceeding.

ADMINISTRATIVE RECORD (§§ 2.170–2.173)

Proposed §§ 2.170 through 2.173 designate the contents of the adminstrative record, provide for its examination and correction, and state that the record will be the sole basis for decision on the matter involved.

The administrative record begins with the final regulation or order and the objections and requests for hearing thereon, and thus would not include any proposed regulation and comments on it which led to the final regulation. The Commissioner's decision on the matter would have to be based upon the evidence introduced at the hearing, and not upon earlier comments. The original proposal and some or all of the comments on it could, of course, be introduced as evidence by any participant in the hearing who wished to rely upon such material.

The Commissioner has carefully considered the handling of data and information relevant to a formal evidentiary public hearing which would otherwise be prohibited from public disclosure pursuant to 21 U.S.C. 331(j) and 18 U.S.C. 1905, as interpreted and applied in the recently promulgated public information regulations contained in 21 CFR Part 4 and the regulations referenced therein. For the reasons already fully discussed above, § 2.5(j) (2) and (3) would provide that safety and effectiveness data

and information will be available for examination but not for copying, and that manufacturing procedures and related information will not be available for examination or copying. In the Commissioner's experience, this would mean that, in virtually all formal evidentiary public hearings, all of the data and information necessary to full and meaningful participation by members of the public would be accessible.

RECOMMENDED, INITIAL, TENTATIVE, AND FINAL DECISIONS (§§ 2.180–2.185)

Sections 2.180 through 2.185 of the proposed regulations would govern the initial decision of the presiding officer and the final decision of the Commissioner. Food and Drug Administration regulations now provide that the presiding officer in a formal evidentiary public hearing shall never prepare an initial decision on the matters involved, but shall always prepare a report and certify the record to the Commissioner. Thereafter, the Commissioner prepares a tentative order, with time for exceptions by any party, and then a final order after which judicial review can be obtained.

The Commissioner proposes that the new regulations should provide for the full flexibility permitted by the Administrative Procedure Act, 5 U.S.C. 557(b), and thus should state that the Commissioner will in each instance decide, in the notice of hearing, whether the presiding officer will prepare a recommended decision or an initial decision.

Where the notice of hearing states that the presidng officer will prepare a recommended decision, the proposed regulations provide for the same procedure that has been used in the past. That recommended decision would be certified to the Commissioner with the full record, and the Commissioner would then publish tentative and final decisions. This procedure would ordinarily be used where the hearing involved broad policy issues.

Where the notice of hearing stated that the presiding officer will prepare an initial decision, or where the notice of hearing was silent on this matter, the proposed regulations provide that the initial decision shall stand as the final decision unless it is appealed by a party to the Commissioner, or the Commissioner concludes on his own initiative to review it. This procedure would ordinarily be used where the hearing involved narrow technical issues.

The same rule would apply with respect to the handling of trade secret information prohibited from public disclosure pursuant to § 2.5(j)(3) in an initial or recommended decision as would apply under § 2.162(c) for briefs and oral argument by the participants.

If the initial decision was appealed to the Commissioner, or he concluded to review it on his own initiative, the Commissioner would have all the powers he would have had in making the initial decision, and could take whatever action was necessary in the interest of justice, including a remand to the presiding officer for further proceedings. The scope of the issues on appeal would be the same as the scope of the issues at the public hearing unless the Commissioner concluded to limit the issues as permitted by the Adminstrative Procedure Act, 5 U.S.C. 557(b). The Commissioner's decision would, of course, have to be based upon substantial evidence of record, and would be published in the FEDERAL REGISTER. Following his final decision, any participant could petition for reconsideration or a stay of action.

JUDICIAL REVIEW (§§ 2.190 AND 2.191)

Proposed §§ 2.190 and 2.191 provide for judicial review of the Commissioner's final decision, pursuant to the specific statutory provisions governing the matter involved.

PUBLIC HEARING BEFORE A PUBLIC BOARD OF INQUIRY (SUBPART C)

Subpart C of the proposed regulations would establish, as an alternative to a formal evidentiary public hearing, an informal public hearing before a Public Board of Inquiry that would be conducted in the form of a scientific inquiry rather than as a legal trial. The reasons for providing this alternative to a formal evidentiary public hearing have been discussed fully above.

SCOPE OF SUBPART (§ 2.200)

The Commissioner could convene a Public Board of Inquiry whenever he concluded, in his discretion, that it was in the public interest to hold a public hearing before such a Board with respect to any matter pending before the agency. Although no agency regulations currently provide for the right to a public hearing before a Board of Inquiry, the Commissioner may in the future promulgate regulations providing this right. A Public Board of Inquiry could also be requested by any person who had an opportunity for a hearing pursuant to Subpart B, and who waived that opportunity and instead requested pursuant to proposed § 2.117 the establishment of a Board to act as an administrative law tribunal with respect to the matters involved. The Commissioner could, in his discretion, accept or deny such a request.

The Commissioner notes that the only persons who could request a Board of Inquiry pursuant to § 2.117 are those who would, by statute, be entitled to an opportunity for a hearing under Subpart B. For example, an NDA applicant or holder who had received a denial of approval or withdrawal of approval would have a statutory right to request a hearing on the matter, but no other member of the public would have such a right. A physician or other citizen who wished to have a Board inquire into the matter could request the Commissioner to order such a hearing pursuant to his discretionary authority, but he would have no legal right to require either a formal evidentiary public hearing or the establishment of a Board of Inquiry.

NOTICE OF A PUBLIC HEARING BEFORE A PUBLIC BOARD OF INQUIRY (§ 2.201)

Once it was determined that a Board would be established, a notice of hearing would be published pursuant to proposed § 2.201 which would provide the essential information about the hearing. If the hearing was in lieu of a formal evidentiary public hearing the notice of hearing would provide all of the information required by § 2.117(e), and the criteria for granting a stay of the matter pending the hearing would be the same as for a formal evidentiary public hearing.

MEMBERS OF A PUBLIC BOARD OF INQUIRY (§ 2.202)

Proposed § 2.202 would require that the members of a Board have medical, technical, scientific, or other qualifications relevant to the issues to be considered at the hearing. The members would be special government employees and thus subject to the conflict of interest rules applicable to such employees. Although a Board member could be a full-time or part-time Federal government employee or serve on a Food and Drug Administration advisory committee, he could not be a full-time or part-time employee of the agency or otherwise act as a consultant to the agency unless all of the parties to the proceeding agreed.

Within 30 days after the notice of the hearing before the Board was published in the FEDERAL REGISTER, each of the parties to the proceeding and any person whose petition was the subject of the hearing would submit a list of five nominees for members of the Board. Such persons could agree upon a single list of nominees. Following receipt of such lists, such persons could submit comments on the other lists submitted. The Commissioner would then review the lists and comments and select one member of the Board from the lists submitted by the director of the agency bureau involved and any person whose petition was the subject of the hearing, one member from the lists submitted by the other parties, and one member of his own choosing from any source whatever who would serve as the Chairman of the Board. Thus, although the parties would have a right to participate in the selection of the members of the Board, the Commissioner would have the final determination on this matter.

In lieu of the nomination procedure set out above, the parties to such a proceeding and any person whose petition was the subject of the hearing could meet and agree upon any other method of selection that was reasonable, subject to the approval of the Commissioner. For example, any standing advisory committee of the agency could be utilized as the Board for a particular proceeding.

Since the Board would be acting as an adminstrative law tribunal with the consent of the parties involved, it would not meet the definition of an "advisory committee" and thus would not be subject to the requirements of the Federal Advisory Committee Act or Subpart D of these regulations. On the other hand, the procedures established for a Board clearly meet all of the requirements with respect to public notice and participation for an advisory committee. The only difference is that a Board would utilize a public notice of hearing rather than a

charter, and would not be required to be approved by the Office of Management and Budget and the Department.

SEPARATION OF FUNCTIONS; EX PARTE COMMUNICATIONS; ADMINISTRATIVE SUPPORT (§ 2.203)

To assure objectivity and fairness, the proceedings of a Board would be subject to the same provisions with respect to separation of functions and ex parte communications as the proceedings of a formal evidentiary public hearing. Similarly, administrative support for a Board would be provided only by the office of the Commissioner and not by the Bureau which was a party to the proceeding.

SUBMISSIONS TO A PUBLIC BOARD OF INQUIRY (§ 2.204)

All submissions to the Board would be filed with the Hearing Clerk in accordance with the general requirements established in proposed § 2.5. Documentary data and information would have to be filed only with the Hearing Clerk, but all submissions that were generally regarded as "pleadings," such as transmittal letters, summaries, statements of position, and other similar documents, as well as any certification of service required by proposed § 2.204(d), would be sent to each participant so that he would understand the position of all of the participants and would be able to follow the progress of the proceeding. The same provisions with respect to participating in forma pauperis would apply to a public hearing before a Public Board of Inquiry as would apply to a formal evidentiary public hearing.

DISCLOSURE OF DATA AND INFORMATION BY THE PARTICIPANTS (§ 2.205)

Proposed § 2.205 would require that the director of the responsible agency bureau file with the Hearing Clerk, before the notice of hearing was published, the relevant portions of the administrative record of the proceeding up to that time, a list of the persons whose views would be presented orally or in writing at the hearing, all relevant documents in the agency files containing factual data and information, whether favorable or unfavorable, and all other documentary data and information on which he relied. In this way, the full position of the agency with respect to the matters involved would be made public at an early date.

Within 60 days after the notice of hearing, each participant in the proceeding who had submitted a notice of appearance would be required to submit the same information. Because the agency would already have filed its information, no participant would have to submit duplicative documents. This will substantially reduce the amount of paperwork involved.

These submissions could be supplemented later in the proceeding upon a showing of good cause, but no participant could fail to conduct an adequate search and then later supply new information that could reasonably have been found at the time of the initial submission.

The Commissioner believes that it will be important that this section be complied with fully. Accordingly, the failure to comply, e.g., the failure to submit any data and information as required by § 2.205 (a) and (b), would constitute a waiver of the right to participate further in the hearing and, in the case of a party, would constitute a waiver of the right to a hearing.

PROCEEDINGS OF A PUBLIC BOARD OF INQUIRY (§ 2.206)

Proposed § 2.206(a) would make it clear that the purpose of a Board is to review complex technical issues in a reasonably short time by using the informal approach of a scientific inquiry rather than the formal procedures of a legal trial. Accordingly, it is anticipated that there will be little, if any, need for participation by attorneys in the proceeding. The participants will primarily be the scientists and others with technical backgrounds who wish to present data and information relevant to issues raised at the hearing. The agency's Chief Counsel would participate only to the extent that he is requested by the Chairman of the Board to provide legal assistance to the Board.

The Chairman of the Board would determine the order in which the parties and participants make their presentations. Such order of presentation could well be the subject of a prior agreement. Each participant could then proceed with his presentation, which would be made without interruptions and without objection or other legalistic procedures. At the conclusion of a participant's presentation, each of the other participants could briefly state questions or criticism and suggest further questioning with respect to specific matters. The members of the Board could interrupt a participant at any time to ask questions, and could conduct further questioning at the conclusion of the participant's full presentation either on their own initiative or at the suggestion of the other participants. The exact nature of the proceeding would largely be in the discretion of the Chairman, who would be the presiding officer and would have all of the powers necessary to conduct a fair and expeditious hearing.

Following the initial session, each participant would have 30 days within which to submit additional written information. If a second session was requested and justified by any participant, the Chairman would schedule it. Each hearing would be subject to the same procedural requirements.

In addition to hearing the views of the participants, the Board could independently consult with any other person who it concluded may have useful information. All such consultation would have to be at an announced hearing of the Board unless all participants agreed that it could be done in writing.

Moreover, any participant in the proceeding could submit to the Board a request that it consult with specific persons who could have useful information. The Board could accept or deny such a request, in its discretion.

All hearings of a Board would be conducted in open session, and thus could be attended by any interested person, except for presentation of data and information constituting trade secrets prohibited from public disclosure pursuant to proposed § 2.5(j)(3). Presentation of such material would be at a session closed to all persons except those making and participating in the presentation and Federal Government Executive Branch employees and special government employees. The person making the presentation could bring with him only such persons who are employees, consultants, or other persons with whom he had a commercial arrangement within the meaning of § 4.81(a), and thus to whom disclosure could properly be made without destroying the trade secret status of the material.

At the conclusion of all hearings, the Board would permit the participants to submit written statements on their positions, with proposed findings and conclusions. Oral argument could also be permitted, in the discretion of the Board. The Board would then prepare its findings and conclusions on the matter involved.

ADMINISTRATIVE RECORD OF A PUBLIC BOARD OF INQUIRY (§ 2.207)

Proposed § 2.207 specifies the administrative record of a hearing before a Board. The administrative record would be on public display and, except for trade secrets and other confidential information, available for copying.

EXAMINATION OF ADMINISTRATIVE RECORD (§ 2.208)

The same provisions with respect to confidentiality of information submitted in the course of the hearing would apply to the proceedings of a Board as would apply in a formal evidentiary public hearing. In addition, both the lists of nominees for members of a Board and any comments thereon would not be made available for public examination or copying at any time.

RECORD FOR ADMINISTRATIVE DECISION (§ 2.209)

The administrative record of the public hearing would constitute the exclusive record for decision on the matter. If the public hearing was held in lieu of a formal evidentiary public hearing pursuant to proposed § 2.117, the findings and conclusions of the Board would constitute an initial decision unless the notice of hearing specifically states that they are to constitute a recommended decision. Thereafter, the participants in the proceeding could pursue the administrative and court remedies that are available as specified in proposed §§ 2.180 through 2.191.

PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE (SUBPART D)

Proposed Subpart D would govern all proceedings and activities of Food and Drug Administration advisory committees.

SCOPE OF SUBPART (§ 2.300)

Because of the requirements in this subpart for public notice and participation, all proceedings before a public advisory committee would constitute a public hearing on the matters involved. Any interested person would be entitled to present his views for the consideration of the advisory committee, and the committee proceedings would constitute part of the administrative record on the basis of which the agency would make its determination with respect to that matter.

The Commissioner could utilize a public advisory committee with respect to any matter on his own initiative, pursuant to specific provisions in other sections of agency regulations, or at the request of any interested person. Proposed § 2.300 (a) (2) lists five specific provisions in existing laws and regulations which provide for the use of a public hearing before a public advisory committee as part of the administrative process. Pursuant to § 2.117, a person who had a right to an opportunity for a formal evidentiary public hearing could waive that opportunity and in lieu thereof request a public hearing before a public advisory committee.

As defined in the Federal Advisory Committee Act and in proposed § 2.3(a) (14), an advisory committee means any group or subgroup thereof that is not composed wholly of full-time employees of the Federal government and is established or utilized by the Food and Drug Administration to obtain advice or recommendations. On the basis of guidelines established by the Office of Management and Budget and the Department of Justice, and other available materials, the Commissioner proposes in § 2.300(b) a set of general principles governing the determination whether a committee or group falls within the definition of an advisory committee. All Food and Drug Administration advisory committees are also listed in proposed § 2.340.

In general, an advisory committee would ordinarily have a fixed membership, a defined purpose of providing advice to the agency on a particular matter, regular or periodic meetings, and an organizational structure, and would serve as a source of independent advice rather than as a representative of or advocate for any particular interest. The Commissioner notes that the agency is charged with seeking out the views of all segments of the public on enforcement of the laws he administers. Thus, the fact that the agency meets with and requests the comments of a group on pending regulatory matters, or that a group regularly meets with the agency, does not necessarily mean that it is an advisory committee which is utilized by the agency. The provisions relating to advisory committees would not be applicable, for example, to routine meetings, discussions, and other dealings, including exchanges of views, between the agency and any committee representing or advocating the particular interests of consumers, industry, professional organizations, or others. If this were not true, the Food and Drug Administration would be precluded from meeting with any group of individuals interested in the activities of the agency. Thus, when a consumer organization or trade association meets with the agency to obtain a briefing on various matters, or to protest certain action or lack of action, it would not be an advisory committee for that purpose.

ESTABLISHMENT AND RENEWAL OF PUBLIC ADVISORY COMMITTEES (§ 2.301)

Before any advisory committee could be established by the Commissioner, it would first have to be approved by the Department and the Office of Management and Budget. Its establishment would then be published in the FEDERAL REGISTER, and the permanent list of standing advisory committees in proposed § 2.340 would be amended to include it.

TERMINATION OF PUBLIC ADVISORY COMMITTEES (§ 2.302)

All advisory committees except those established by statute would terminate every 2 years unless renewed for an additional period. The only two permanent statutory advisory committees established under the laws administered by the Commissioner are the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) and the Board of Tea Experts.

PURPOSE OF PUBLIC HEARING BEFORE PUBLIC ADVISORY COMMITTEE (§ 2.303)

The Commissioner could use a public advisory committee to hold a public hearing on any matter pending before the Food and Drug Administration. The function of the advisory committee would be to provide advice and recommendations to the Commissioner. The Commissioner is charged with sole statutory responsibility for making the ultimate determination with respect to action that would be taken and policy that would be expressed with respect to such matters.

PORTIONS OF PUBLIC ADVISORY COMMITTEE MEETINGS (§ 2.304)

An advisory committee meeting could have four separable portions as described below. Every advisory committee meeting would have to have at least the first portion (an open public hearing). Whether or not it also had the other three portions would depend upon the specific meeting involved.

1. *The open public hearing.* Every advisory committee meeting would have to include an open portion which would constitute a public hearing on the issues pending before the advisory committee. During this portion, any interested person could present data, information, or views, orally or in writing. Proposed § 2.312 specifies the manner in which the hearing would be conducted.

2. *The open committee discussion.* All discussion of any pending matter by an advisory committee would be in an open portion of its meeting, unless that portion had been closed in accordance with the provisions in proposed § 2.318. The Commissioner is of the opinion that, to the maximum extent feasible, an advisory committee should conduct its discussion of pending matters in the open portion. Ordinarily, there would be no public participation during this discussion by the advisory committee, but the chairman of the advisory committee could permit such further public participation when he concludes that it would be in the public interest and helpful to the advisory committee.

3. *The closed presentation of data.* On occasion, it may be important for an interested person to present to an advisory committee, for its consideration, data and information which are prohibited from public disclosure pursuant to the provisions relating to public information contained in Part 4 of the agency regulations. Such presentations would be made in a closed portion of a meeting. The Commissioner emphasizes, however, that this would be the exception rather than the rule, and would occur only when the information was clearly confidential.

4. *The closed committee deliberations.* Deliberations with respect to matters pending before an advisory committee could properly be made in a closed portion of its meeting, if the Commissioner made an appropriate determination pursuant to § 2.318. A court has specifically held that a Food and Drug Administration advisory committee may properly conduct its deliberations in private, and other courts have similarly recognized the need to protect the confidentiality of such internal discussions in order to promote free and frank consideration of issues among government employees and consultants. See Smart v. Food and Drug Administration (N.D. Cal. 1974); Washington Research Project, Inc. v. Department of Health, Education, and Welfare, 504 F.2d 238, 246–252 (D.C. Cir. 1974); Montrose Chemical Corp. v. Train, 491 F.2d 63, 66–71 (D.C. Cir. 1974); Grumman Aircraft Engineering Corp. v. Renegotiation Board, 482 F.2d 710, 718–720 (D.C. Cir. 1973); Wu v. National Endowment for Humanities, 460 F.2d 1030, 1032 (5th Cir. 1972); Soucie v. David, 448 F.2d 1067, 1078 n.44 (D.C. Cir. 1971).

NOTICE OF PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE (§ 2.305)

Before the first day of each month, and at least 15 days before any meeting, the Commissioner would have to issue a notice in the FEDERAL REGISTER containing information on all advisory committee meetings to be held during the coming month. Additional notices might also be published, at least 15 days in advance of the meeting, except that a shorter notice period could be authorized where an immediate meeting of an advisory committee was required, and no notice in the FEDERAL REGISTER would be required in emergency situations. Whenever shorter notice was given or no notice was published in the FEDERAL REGISTER, public notice would be given at the earliest time and in the most accessible form feasible.

The FEDERAL REGISTER notice would include all relevant information on the advisory committee meeting, including the agenda items and, if any portion of the

meeting is to be closed, the time of the open and closed portions. The name, address, and telephone number of the advisory committee executive secretary would also be included.

Where a public hearing before a public advisory committee is to be used in lieu of a formal evidentiary public hearing pursuant to proposed § 2.117, the initial notice of hearing would be published separately in the FEDERAL REGISTER containing all of the information described in § 2.117(e). The Commissioner could also publish such separate notices in the FEDERAL REGISTER whenever he concluded that it would be informative to do so, e.g., the notices relating to public hearings before advisory committees on intrauterine devices published in the FEDERAL REGISTER of July 15, 1974 (39 FR 25967), on reserpine published in the FEDERAL REGISTER of October 1, 1974 (39 FR 35404), and on medroxyprogesterone acetate injectable and other systemic steroidal contraceptives published in the FEDERAL REGISTER of March 21, 1975 (40 FR 12830).

In addition to the notice published in the FEDERAL REGISTER, the Food and Drug Administration would also distribute its list of advisory committee meetings to the press and would place them on its prospective public calendar.

CHAIRMAN OF A PUBLIC ADVISORY COMMITTEE (§ 2.306)

The advisory committee chairman would have full authority to conduct the meetings of the advisory committee. Each advisory committee would also have an executive secretary or other designated agency employee, and an alternate, appointed by the Commissioner, who would serve as staff to the advisory committee for the agency.

As required by the Federal Advisory Committee Act, a designated Federal employee would be assigned to each advisory committee, and would be authorized to adjourn any meeting whenever he determined adjournment to be in the public interest. No advisory committee meeting could be conducted without the presence and approval of the designated Federal employee.

MEETINGS OF A PUBLIC ADVISORY COMMITTEE (§ 2.307)

Proposed § 2.307 would require that there be an agenda for every advisory committee meeting. The Commissioner notes that, because the agenda would ordinarily have to be prepared at least 30 days in advance of a committee meeting to meet the requirement for publication in the FEDERAL REGISTER before the first day of each month and at least 15 days before the meeting, it is entirely possible that other agenda items might be added after its publication. The agency would take reasonable steps to anticipate agenda items, in order to minimize this problem. Where an agenda item was added to those published in the FEDERAL REGISTER, an attempt would be made to inform those persons known to be interested in the matter. Such changes would be announced at the beginning of the open portion of the meeting.

As a general rule, all advisory committee meetings would be held in Washington, DC, or Rockville, MD, where the Food and Drug Administration is located. A different location could be approved to obtain cost savings, or when it was at a more central location, or the majority of the advisory committee members would be there at no expense to the Food and Drug Administration for other reasons, or to facilitate increased participation on any matter, or to be near specific information or facilities relevant to the advisory committee's work, e.g., a laboratory working on a particular matter.

Discussion of advisory committee proceedings by members of the committee has often been a source of confusion. The proposed regulations would provide that such discussion is permissible, as soon as the meeting is completed and before official minutes or a report are available, within the specific rules set out in the regulations. In general, there could be no attribution of individual views or discussion relating to trade secrets or specific matters that were determined by the advisory committee or the agency to be confidential, but all other matters could be freely discussed.

CONSULTATION BY A PUBLIC ADVISORY COMMITTEE WITH OTHER PERSONS (§ 2.308)

An advisory committee could consult with any person who it concludes may have useful data, information, or views relating to any matter pending before it. Other interested persons could also recommend that the advisory committee consult with specific individuals, and the advisory committee could grant or deny such a request.

ADDITIONAL RULES FOR A PARTICULAR PUBLIC ADVISORY COMMITTEE (§ 2.309)

The Commissioner recognizes that, in addition to the rules established for all Food and Drug Administration advisory committees, any individual advisory committee might wish to adopt additional rules. Proposed § 2.309 would permit such additional rules with the concurrence of the agency, as long as they were not inconsistent with the new regulations or legal requirements.

COMPILATION OF MATERIALS FOR MEMBERS OF A PUBLIC ADVISORY COMMITTEE (§ 2.310)

The Food and Drug Administration has been criticized for failing to provide a comprehensive compilation of salient information and background material to all advisory committee members for their periodic review relating to their duties and responsibilities. Section 2.310 of the proposed regulations provides that such a compilation will be prepared and disseminated, and will contain all pertinent background information that may be helpful to the specific committee involved.

WRITTEN SUBMISSIONS TO A PUBLIC ADVISORY COMMITTEE (§ 2.311)

Proposed § 2.311 would permit any interested person to make written submissions to a public advisory committee before, during, or after any advisory committee meeting. Such submissions could be at the request of the advisory committee or on the initiative of any interested person. Ten copies of such submissions would be sent to the executive secretary of the advisory committee. No copies would have to be sent to the Hearing Clerk.

The Commissioner would provide to an advisory committee all data and information he concluded to be relevant to any matter pending before the advisory committee, but any member of the advisory committee would upon request also be provided whatever other material is available to the agency which related to the matter. In particular, any member of the advisory committee would be entitled to review raw data underlying any summary or report, if he wished to do so. Raw data could not routinely be provided to all committee members in all instances because of the massive amount of paperwork involved, but all advisory committee members who wished to review such data could do so.

CONDUCT OF A PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE (§ 2.312)

Under proposed § 2.312, no Food and Drug Administration advisory committee could meet without having an open portion for public participation which would be a public hearing on the matters being considered by the advisory committee. The hearing would be at least 1 hour long, unless the public participation did not last that long, and could last for whatever length of time the advisory committee chairman determined would facilitate the work of the committee.

In the past, agency notices of public advisory committee meetings have specified a 1-hour open portion, where the remainder of the meeting is closed, and have failed to point out that this is the minimum rather than the maximum time allocated for public participation. In many instances, the hearing has lasted far beyond the allotted hour, and has extended up to the entire day. Accordingly, notices of advisory committee meetings would make this clear. A particular advisory committee meeting which was scheduled for more than one day nonetheless would constitute a single meeting for purposes of scheduling the open and closed portions.

Proposed § 2.312 specifies the manner in which the public hearing before a public advisory committee would be conducted. Persons who wished to be assured of an opportunity to make an oral presentation would have to so inform the committee executive secretary prior to the meeting. The executive secretary would then allot to each such person reasonable time for his presentation.

At the hearing, each person could use his allotted time in any reasonable way. The person making the presentation could be accompanied by others, to assist him. Persons making presentations would be taken in order, and if anyone was not present for his allotted time an attempt would be made to hear him at the con-

clusion of the hearing, as well as others who did not request an opportunity to make an oral presentation.

The chairman and other members of the advisory committee would sit as a panel in conducting the hearing. They could question any person during or at the conclusion of his presentation, but no other person attending the hearing could conduct such questioning. The hearings would be informal in nature, without motions or objections or other similar legal procedures. In short, the hearing would be conducted very much like hearings conducted by legislative bodies, in the same manner as a public hearing before the Commissioner pursuant to Subpart E.

MINUTES AND REPORTS OF PUBLIC ADVISORY COMMITTEE MEETINGS (§ 2.313)

For every advisory committee proceeding, the executive secretary would have to prepare detailed minutes of the committee's activities. In the past, such minutes have at times been very detailed and at other times very general. The Commissioner has advised all executive secretaries that detailed minutes are required, and these regulations would so provide.

Under the proposed regulations, an advisory committee meeting is broken down into open and closed portions.

The open portion has two parts and includes both the open public hearing and the open advisory committee discussion. The open public hearing involves the presentation of views by interested members of the public, and any presentation of data and information by the Food and Drug Administration which are not confidential. The open portion may also include discussion by the advisory committee of all of the available data and information, to the extent that the presence of observers will not inhibit the discussion and thus interfere with the advisory committee or agency operations. The length of the open portion will vary from committee to committee, and from meeting to meeting, depending upon the agenda and other relevant factors. In general, it is the policy of the Commissioner to conduct as much of an advisory committee meeting in open session as is feasible.

The closed portion of an advisory committee meeting may include both the presentation of confidential information and closed advisory committee deliberations. Data and information that are prohibited from public disclosure pursuant to 21 U.S.C. 331(j) and 18 U.S.C. 1905, or by any provision in the public information regulations in 21 CFR Part 4, may properly be presented in such a closed portion. The person who owns such data and information may make such presentation, and may be accompanied by a reasonable number of persons to assist him. The use of this procedure will, however, be extremely rare. In accordance with 21 CFR Part 4 and the regulations referenced therein, a summary of safety and effectiveness data is itself not confidential. Accordingly, oral presentation of such data will be in open session unless it relates to matters that are truly confidential, e.g., an IND or NADA the existence of which has not previously been disclosed to the public.

The other part of a closed advisory committee meeting is the executive session, during which the advisory committee deliberations take place and the recommendations of the advisory committee are formulated. This portion is closed to permit free and open discussion of views, and formulation of the best advice possible for the consideration of the Commissioner. In addition, such closed session may involve discussion of trade secret material, information that may not be released on the ground that it would invade personal privacy, and confidential regulatory issues pending before the agency.

To facilitate release, advisory committee minutes would be kept separately for three portions of the meeting: The open portions, the closed portion for presentation of confidential information, and the closed executive session for advisory committee deliberations. The minutes of a closed executive session of a meeting would not refer to advisory committee members by name, to encourage free discussion of the issues involved.

TRANSCRIPTS OF PUBLIC ADVISORY COMMITTEE MEETINGS (§ 2.314)

Present law does not require that a transcript or other recording be made of either open or closed portions of an advisory committee meeting. The Commissioner has concluded that each advisory committee should decide whether some type of recording should be made and, if so, by what means, e.g., stenographer or tape. Any transcript or recording of any portion of an advisory committee meeting that is made by the agency, or otherwise furnished to the agency, would be retained by the agency and would not be discarded or erased.

The Commissioner emphasizes, however, that a transcript or recording of a closed portion of an advisory committee meeting would be retained as confidential by the agency and would not be considered by the agency or included in the record of the advisory committee proceeding, for the reasons set out in the preamble to the notices discussing this subject in the context of the OTC drug review, published in the FEDERAL REGISTER of June 4 and November 8, 1974 (39 FR 19878, 39556). The Commissioner would not refer to or otherwise consider any such transcript or recording in his review of the advisory committee recommendations and his decision on the matter involved.

ADMINISTRATIVE RECORD OF A PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE (§ 2.315)

Proposed § 2.315(a) specifies the administrative record of the advisory committee proceedings with respect to a specific matter. That record would be included as a part of the record of any administrative proceeding involving that matter.

EXAMINATION OF ADMINISTRATIVE RECORD AND OTHER ADVISORY COMMITTEE RECORDS (§ 2.316)

Proposed § 2.316(a) sets out, in detail, the specific time at which the various portions of the administrative record and other advisory committee records would be made available for public disclosure.

As a general rule, data and information contained in the administrative record which were provided to the advisory committee by the agency and are exempt from public disclosure pursuant to the public information regulations, or which were presented to the advisory committee by a person making a presentation and which are prohibited from public disclosure pursuant to such regulations, would not be available for public examination and copying. The sole exception to this general rule would be where a public hearing before a public advisory committee was being used in lieu of a formal evidentiary hearing pursuant to proposed § 2.117, in which case the limited disclosure of safety and effectiveness data pursuant to proposed § 2.5(j)(2) would be applicable.

The proposed regulations would require that the Public Records and Documents Center maintain a file for each advisory committee containing the principal records relating to that committee, i.e., the advisory committee charter, the list of members and their curricula vitae, the advisory committee minutes, and any formal advice or report of the advisory committee. These are the records for which public disclosure is most often sought.

PUBLIC INQUIRIES AND REQUESTS FOR PUBLIC ADVISORY COMMITTEE RECORDS (§ 2.317)

All requests for records would be in accordance with the recently promulgated public information regulations, and particularly § 4.40. General inquiries could be handled by the agency's Committee Management Officer or the executive secretary of a particular advisory committee.

DETERMINATION TO CLOSE PORTIONS OF PUBLIC ADVISORY COMMITTEE MEETINGS (§ 2.318)

Proposed § 2.318 sets out the circumstances under which the Commissioner could make a determination to close a portion of a public advisory committee meeting. As already noted, under no circumstances would all portions of a public advisory committee meeting be closed to the public.

The executive secretary of an advisory committee would prepare the initial request for a determination to close a portion of an advisory committee meeting, which would be forwarded to the agency Committee Management Officer and, from his office, to the office of the Chief Counsel and to the Commissioner. Based upon this request, the Commissioner could conclude to close a portion of the meeting, if the requirements of the regulations were satisfied, or could conclude that the portion should remain open.

The regulations set out various criteria for determining whether to close a portion of a meeting. Information prohibited from disclosure under 21 CFR Part 4 and the regulations referenced therein, e.g., trade secrets or material that would invade personal privacy, would be discussed only in closed session. Advisory committee deliberation on regulatory decisions with respect to specific ingredients or products or pending applications for IND or NDA products would ordinarily be conducted in closed session. On the other hand, discussion of policy issues, such as general testing protocols or labeling for a class of drugs, or other information that has already been disclosed to the public, would be conducted only in open session.

A closed session would be limited to the advisory committee members and employees and consultants of the Executive Branch of the Federal Government. If any other person attended such a portion, except to present confidential material, it would be opened to all interested persons. Of course, the Food and Drug Administration could properly limit attendance of consultants and employees at advisory committee meetings to those whose attendance was appropriate for the conduct of their work.

ADMINISTRATIVE REMEDIES (§ 2.319)

Proposed § 2.319 provides procedures under which any person could contest action taken by an agency employee or an advisory committee relating to any aspect of proposed Subpart D or the Federal Advisory Committee Act. If improper action had been taken, the Commissioner would take appropriate steps to remedy the error and to prevent its recurrence.

APPLICABILITY TO CONGRESS (§ 2.320)

Under the Federal Advisory Committee Act, Congress stands on the same legal footing as any other member of the public. Accordingly, the provisions of proposed Subpart D would apply to Congress in the same way that they would apply to any other member of the public, except that disclosure of advisory committee records to Congress would be governed by § 4.87 of the public information regulations.

COMMITTEES WORKING PURSUANT TO A CONTRACT WITH THE FOOD AND DRUG ADMINISTRATION (§ 2.321)

The Department of Justice has provided an opinion to the Food and Drug Administration that, when the agency contracts with another organization to obtain advice and recommendations on particular matters, and that organization in turn utilizes a committee to prepare such advice and recommendations, the provisions of the Federal Advisory Committee Act do not apply if the governing body of that organization undertakes substantial policy and factual review of the committee's work. In short, the applicability of Subpart D of the proposed regulations to such committee would depend upon whether the advice obtained is the advice of the organization or of a committee of the organization.

The Commissioner has concluded, as a matter of policy, that committees working pursuant to a contract with the Food and Drug Administration should be subject to certain minimum standards regardless whether the other provisions of Subpart D are applicable to that committee. The Commissioner believes that such minimum standards should be applicable to assure that a fair procedure will be followed by such committees even though they are not subject to the specific requirements of the Federal Advisory Committee Act and Subpart D of the proposed regulations.

Accordingly, proposed § 2.321(b) would require that any such committee give public notice of its meetings and agenda, and provide any interested person an opportunity to submit relevant data, information, and views orally and in writing. Such notice could be published in the FEDERAL REGISTER or disseminated by any other reasonable means, but would in any event be filed with the Hearing Clerk at least 15 days before the meeting involved. Minutes of all open sessions would be maintained, but minutes of closed sessions would not be required. Finally, the organization would be required to apply the same principles relating to conflicts of interest as the agency does in establishing its own public advisory committees, but the organization would in no way be obligated to consult with the Food and Drug Administration on such matters. Upon request, the agency would assist or provide guidance to any organization in meeting this requirement.

These minimum standards would apply only to a committee of an independent scientific or technical organization which was working pursuant to a contract initially executed with the Food and Drug Administration on or after July 1, 1975. Accordingly, such ongoing projects as the GRAS list review, being conducted by the Federation of American Societies of Experimental Biology, would not be affected. The Commissioner concludes that it would be unfair to impose such requirements retroactively upon such an organization which had entered into a project of this kind in good faith and had had no advance warning that such requirements might become applicable. In all future documents relating to contracts, such requirements will clearly be spelled out so that no misunderstanding can exist.

APPLICATION OF ANTICANCER CLAUSES (§ 2.322)

The Food and Drug Administration has previously determined issues relating to the potential application of the anticancer clauses in the act in a number of different ways. The Commissioner proposes that, in the future, such issues shall ordinarily be referred to the newly created Toxicology Advisory Committee, so that a consistent application of the law will be obtained.

QUALIFICATIONS FOR MEMBERS OF STANDING POLICY AND TECHNICAL ADVISORY COMMITTEES (§ 2.330).

Proposed § 2.330 sets out general qualifications for advisory committee members. The proposed regulations would recognize that representatives of particular interest groups, e.g., labor, industry, consumers, or agriculture, could properly be included on policy advisory committees, but not technical advisory committees, as voting members specifically to represent such interests, and the regulations would constitute a determination pursuant to 18 U.S.C. 208(b) that no disqualifying conflict of interest existed by reason of the fact of such representation. The representational role of these members is clearly understood, and the Commissioner concludes that their viewpoint is essential for the type of general and broad issues considered by a policy advisory committee.

Advisory committee members could be removed from membership by the Commissioner for good cause. Although it is not possible to specify the precise content of "good cause," excessive unjustified absenteeism from meetings, a demonstrated bias, or a failure to abide by the advisory committee rules and regulations, would be adequate justification for removal from the advisory committee.

NOMINATIONS OF VOTING MEMBERS OF STANDING ADVISORY COMMITTEES (§ 2.331)

Proposed § 2.331 provides a mechanism for any interested member of the public to nominate persons for consideration as voting members of standing advisory committees. The members of any advisory committee could be chosen from among the lists of nominees and from any other sources.

Voting members of standing technical advisory committees would serve as individuals, and not as representatives of any group or organization which might have nominated them or with which they might be affiliated.

NOMINATIONS AND SELECTION OF NONVOTING MEMBERS OF STANDING TECHNICAL ADVISORY COMMITTEES (§ 2.332)

Proposed § 2.332 provides a mechanism for nominating and selecting nonvoting members of standing technical advisory committees. In the past 3 years, the Commissioner has increasingly included such nonvoting members to represent consumer and industry interests on standing technical advisory committees. These members serve in a liaison function with those whom they represent.

Nonvoting consumer liaison members would be nominated and selected by consumer organizations and other interested consumers, and nonvoting industry liaison members would be selected by industry associations. Because they have no vote and their liaison role for particular interests is well understood, the regulations would constitute a determination pursuant to 18 U.S.C. 208(b) that any financial interest they may have in the particular class which they represent

does not constitute a disqualifying conflict of interest. Thus, an industry liaison representative would not be disqualified because he held stock in the regulated industry which he represents, but a consumer liaison representative would be disqualified if he were to hold stock in the regulated industry affected by the work of the technical advisory committee of which he was a member.

RIGHTS AND RESPONSIBILITIES OF NONVOTING MEMBERS OF ADVISORY COMMITTEES (§ 2.333)

Proposed § 2.333 sets out the rights and responsibilities of nonvoting consumer and industry liaison members of advisory committees. In general, it is their responsibility to represent the consumer and industry interests fairly in all deliberations, but they must also exercise restraint in performing these functions and not engage in unseemly advocacy or attempt to exert undue influence over the other members of the advisory committee.

The Commissioner notes that nonvoting consumer and industry liaison representatives have served on all of the OTC drug review advisory committees, the biologics review advisory committees, and the medical device classification panels, with enormous success. With rare exception, their conduct has been entirely dignified and proper, and they have made major contributions to the issues pending before those advisory committees.

AD HOC ADVISORY COMMITTEE MEMBERS (§ 2.334)

Proposed § 2.334 provides that, when the Commissioner, in his discretion, utilizes an ad hoc advisory committee to review and consider a specific matter, he may select the members pursuant to §§ 2.331 and 2.332 or in any other appropriate manner.

COMPENSATION OF PUBLIC ADVISORY COMMITTEE MEMBERS (§ 2.335)

Proposed § 2.335 provides for uniform compensation of all members of Food and Drug Administration public advisory committees, except for those who waive such compensation. The criteria under which an advisory committee member would be compensated for an agency-directed assignment when it was performed at a time other than at an advisory committee meeting are proposed in this regulation.

LIST OF STANDING ADVISORY COMMITTEES (§ 2.340)

Proposed § 2.340 sets out a list of all current Food and Drug Administration standing advisory committees, including the date established and the function of the advisory committee. This list will be amended to add and delete advisory committees as they are formed and terminated.

TECHNICAL ELECTRONIC PRODUCT RADIATION SAFETY STANDARDS COMMITTEE (TEPRSSC) (§§ 2.350–2.354)

Proposed §§ 2.350 through 2.354 would govern the establishment and procedures of TEPRSSC, one of the two permanent statutory advisory committees of the Food and Drug Administration. These provisions are to a large extent governed by provisions of the Radiation Control for Health and Safety Act of 1968, and have been in effect for this advisory committee for some time.

COLOR ADDITIVE ADVISORY COMMITTEES (§§ 2.360–2.364)

Proposed §§ 2.360 through 2.364 would govern the establishment and procedures of a color additive advisory committee pursuant to section 706(b)(5)(B) of the act, as added by the Color Additive Amendments of 1960. There is a legal right to such an advisory committee for the limited purpose of reviewing the application of the anticancer clause contained in section 706 of the act to a specific color additive, and the Commissioner could, in his discretion, also refer to any such advisory committee other issues relating to a color additive.

Section 706(b)(5)(D) of the act provides that a color additive advisory committee would be composed of experts selected by the National Academy of Sciences or, if the NAS was unable or refused to act, by the Secretary. The law is clear that the recommendations and advice should be provided by the advisory committee, not by the NAS. Accordingly, the provisions of the Federal Advisory Committee Act and Subpart D of Part 2 would be fully applicable, and § 2.321, relating to committees working pursuant to a contract with the Food and Drug Administration, would not be applicable.

The Commissioner notes that section 203 of the Color Additive Amendments of 1960, which contain transitional provisions relating to commercially established colors, provided for reference of matters to a color additive advisory committee and for an opportunity for a formal evidentiary public hearing on certain matters, for a period of 2½ years after enactment of that statute. Since that time period has now expired, those provisions are no longer applicable and thus there is no right either to a color additive advisory committee or to an opportunity for a hearing on such matters at this time.

Some of the provisions contained in these proposed sections are now contained in §§ 8.12 through 8.14 of the agency regulations. Those sections will therefore be revoked by this proposal.

STANDING TECHNICAL PUBLIC ADVISORY COMMITTEES FOR HUMAN PRESCRIPTION DRUGS (§§ 2.370–2.373)

Proposed §§ 2.370 through 2.373 would govern the use of standing technical public advisory committees to conduct public hearings on and to consider issues with respect to human prescription drugs, including antibiotic drugs and biologics. In the past few years, as the medical and scientific issues raised by the agency's review of human prescription drugs have increased in complexity, the Commissioner has increasingly relied upon the use of standing technical public advisory committees for advice and recommendations on such matters. Advisory committees of this nature have brought to the agency the experience and expertise of outstanding experts in the field. The Commissioner concludes that this use of advisory committees has important benefits for the public and the agency and should be subject to clear guidelines proposed in these new regulations.

Proposed § 2.371 would establish the criteria for those investigational and marketed drugs for which there is a high priority for review by the appropriate standing technical advisory committee. Such drugs include those which represent a significant therapeutic advance, new single chemical entities, and issues that have attracted wide public interest. An advisory committee could also request the Commissioner for an opportunity to hold a public hearing on and to review any particular drug which fell within the pharmacological class covered by the advisory committee. Advisory committee members could be invited to bureau meetings and discussions relating to particular issues.

In the past, advice and recommendations on pending issues relating to human prescription drugs have at times been provided by advisory committees orally. This practice has led to some uncertainty about the specific opinions rendered by the advisory committee. Accordingly, § 2.372 provides that advice and recommendations given by these advisory committees would ordinarily be in the form of a written report, which could consist of the approved minutes or a separate written document. The written report would respond to the specific issues posed to the advisory committee, and state the basis of the advice and recommendations given.

The Commissioner is aware that interested persons outside the agency might at times disagree with an important agency decision with respect to a particular drug. Section 2.373 would therefore permit such interested persons to request that the agency refer any such matter to an advisory committee. The Commissioner could, of course, grant or deny any such request.

PUBLIC HEARING BEFORE THE COMMISSIONER (SUBPART E)

Proposed Subpart E would establish procedures governing a legislative-type public hearing during which any person may state his views, together with supporting data and information, with respect to the matters involved.

The Commissioner has concluded that a hearing of this type, which is basically the same as a hearing held by legislative bodies, is very useful when the agency is considering new regulations or broad policy or requirements which affect many interested persons. See, e.g., the notices of hearings on prescription drugs indicated for cough and allergy published in the FEDERAL REGISTER of May 15, 1973 (38 FR 12769), and on the tentative final order for OTC antacid drugs published in the FEDERAL REGISTER of January 8, 1974 (39 FR 1359). Such hearings assure concerned members of the public that

the agency officials responsible for the matter will be directly presented with the issues involved, and provide agency officials with an opportunity to engage those concerned about the matter in a meaningful dialogue on those issues. See O'Keefe, A Fine New Twist—A brief Commentary on the Commissioner of Food and Drugs' First Oral Hearing, 29 Food Drug Cosmetic Law Journal 116 (March 1974).

SCOPE OF SUBPART (§ 2.400)

Proposed § 2.400 provides that a public hearing before the Commissioner pursuant to Subpart E could be held in the discretion of the Commissioner, or pursuant to specific provisions in other sections of agency regulations, or in lieu of a formal evidentiary public hearing pursuant to § 2.117. The only provision presently contained in Food and Drug Administration regulations which specifically provides for such a hearing is § 330.10(a)(8), which provides an opportunity for a public hearing before the Commissioner after the tentative final monograph is published for an over-the-counter (OTC) drug but before the final monograph is promulgated.

NOTICE OF A PUBLIC HEARING BEFORE THE COMMISSIONER (§ 2.401)

Proposed § 2.401 would require that public notice of a hearing before the Commissioner be published in the FEDERAL REGISTER. The hearing notice would state the purpose of the hearing and include or refer to any written document which was to be the subject matter of the hearing. If the hearing was in lieu of a formal evidentiary public hearing, the notice would comply with the requirements of § 2.117(e).

In some instances, such a hearing would be limited to review of an existing administrative record. For example, pursuant to § 330.10(a)(10) of the regulations governing the development of OTC drug monographs, the administrative record is closed when the advisory review committee issues its report and recommendations to the Commissioner. Thereafter, no additional data or information may be submitted or considered.

NOTICE OF APPEARANCE; SCHEDULE FOR HEARING (§ 2.402)

After the notice appeared in the FEDERAL REGISTER, any person interested in participating in the hearing would be required to inform the Hearing Clerk or, if only a short period of time was involved, a specifically named Food and Drug Administration employee, of that interest. A specific amount of time should be requested for each presentation. As promptly as possible after the time for making such requests expires, each person would be informed of the time of his presentation and the amount of time allocated for it.

CONDUCT OF A PUBLIC HEARING BEFORE THE COMMISSIONER (§ 2.403)

The Commissioner or his designee would preside at the hearing. Other agency employees could also accompany the presiding officer and could serve as a panel in conducting the hearing.

The hearing would be conducted in the same way that a legislative hearing is conducted. Those making presentations could be accompanied by anyone of their choosing and could present any relevant data, information, or views during their allotted time. The presiding officer and those who serve with him could ask such questions as they deem appropriate, but no other person could ask questions. Additional time could be allotted to any person, in the discretion of the presiding officer, but the time allotted for any person could not be reduced.

WRITTEN SUBMISSIONS PERTAINING TO A PUBLIC HEARING BEFORE THE COMMISSIONER (§ 2.404)

Following the hearing, the record would remain open for 15 days for the filing of additional written submissions unless the notice of hearing or the presiding officer specified otherwise.

ADMINISTRATIVE RECORD OF A PUBLIC HEARING BEFORE THE COMMISSIONER (§ 2.405)

Proposed § 2.405 specifies the administrative record of the hearing. Such record would be included as part of the record of any administrative proceeding involving the matter.

EXAMINATION OF ADMINISTRATIVE RECORD (§ 2.406)

The entire administrative record of a public hearing before the Commissioner would be available for public examination and copying, pursuant to the provisions of § 2.5(j)(1), except that where this form of hearing was being used as an alternative form of hearing in lieu of a formal evidentiary public hearing the limitations in § 2.5(j)(2) and (3) would be applicable.

REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION (SUBPART F)

Proposed Subpart F would govern all informal fact-finding hearings held by the Food and Drug Administration in determining whether any, or what type of, regulatory action should be taken with respect to a particular matter involving a specified person. This type of hearing would involve consideration of direct regulatory action in a specific fact situation limited to a particular firm, whether on an administrative basis or through the courts, and would not involve the type of policy issues usually considered in a public hearing before the Commissioner pursuant to Subpart E or other general matters such as the development of regulations. The requirements for a regulatory hearing, as proposed in this subpart, meet or exceed all the standards for procedural due process of law delineated in Golfberg v. Kelly, 397 U.S. 254 (1970).

SCOPE OF SUBPART (§ 2.500)

A regulatory hearing before the Commissioner would be appropriate in two quite different types of situations. In some instances, the Commissioner could be considering a particular matter and lack sufficient information to make a final determination as to whether any regulatory action is warranted and, if so, what type of action would be appropriate. In the past, the opportunity for informal presentation of views pursuant to section 305 of the act was frequently used for this purpose. The Food and Drug Administration concluded some time ago, however, that this was an improper use of section 305 of the act, and that section 305 should be limited to situations where criminal action is seriously being considered. Accordingly, wherever criminal action is not under serious consideration but additional information is needed for a regulatory determination, the Commissioner could use the regulatory hearing procedure proposed in this subpart as one method of gaining information to make a final determination on appropriate action. If the Commissioner concluded that the possibility of criminal action should be considered after a regulatory hearing was held, an opportunity for presentation of views would be given in accordance with section 305 of the act, but under no circumstances would a regulatory hearing be required prior to a section 305 citation.

In addition, under some provisions of current agency regulations, persons affected by adverse agency action have an opportunity for a hearing. Present provisions of law do not require that this be a "hearing on a record," and thus the provisions of Subpart B relating to a formal evidentiary public hearing would not be required to be applied. For the most part, present regulations simply provide an opportunity for a hearing, without specifying the form of the hearing or the procedure to be followed. Accordingly, the Commissioner proposes that a specific procedure should be incorporated in Subpart F for this purpose.

Proposed § 2.500(b) lists some 24 provisions of current agency regulations which provide a hearing, or which would be amended by these regulations to provide for a hearing, upon a determination by the Food and Drug Administration that is adverse to the interests of the persons involved. In each of these instances, the provisions of Subpart F would be applicable. The Commissioner invites all interested persons to identify, in comments on these proposed regulations, additional provisions of current regulations which should also be subject to an opportunity for a regulatory hearing.

The Commissioner emphasizes that the proposed regulations would provide a right to a regulatory hearing only with respect to those specific matters listed in § 2.500(b). In all other instances, an opportunity for a regulatory hearing would be solely within the discretion of the Commissioner.

INAPPLICABILITY AND LIMITED APPLICABILITY (§ 2.501)

Section 2.501(a) of the proposed regulations provides that the informal presentation of views before reporting a criminal violation pursuant to section 305 of the act and section 5 of the Federal Milk Import Act would not be governed by the provisions of Subpart F. The Com-

missioner intends in the near future to revise the regulations governing these presentations, in §§ 1.6 and 1210.31, to provide better guidance with respect to such matters. The Commissioner believes that these specific statutory proceedings are intended not to be adversarial in nature, but simply to provide an opportunity for discussion at an informal conference, for which the provisions of Subpart F would be inappropriate.

Similarly, proposed § 2.501(a) provides that the hearing held with respect to a refusal of admission of any product offered for import into the country would not be governed by proposed Subpart F. The courts have held that importation of any product subject to the act into the United States is entirely within the discretion of the Commissioner and is not subject to the requirements for an Adjudicatory hearing pursuant to the Administrative Procedure Act, 5 U.S.C. 554. See Sugarman v. Forbragd, 267 F. Supp. 817, 825–826 (N.D. Cal. 1967), aff'd, 405 F. 2d 1189 (9th Cir. 1968). The Commissioner concludes that, because of the large number of import detentions involved, the present procedure for informal conferences i more suited to this type of matter than a regulatory hearing under Subpart F.

The Commissioner recognizes that other specific procedural provisions in other sections of agency regulations, such as the new procedures governing emergency permit control under Subpart A of Part 90, should continue to govern those specific proceedings. Accordingly, where other specific procedural provisions exist, they would override the provisions of Subpart F except to the extent that the provisions in Subpart F supplemented but were not in conflict with them. Thus, § 2.501(b) provides that the additional procedural safeguards provided by the right to counsel, reconsideration and stay, and judicial review in Subpart F would be applicable in all instances, since no other Food and Drug Administration procedural regulations conflict with those provisions, except for the proceedings exempted in § 2.501(a).

PRESIDING OFFICER (§ 2.505)

Proposed § 2.505 provides that any Food and Drug Administration employee to whom the Commissioner delegated such authority, or any person designated by such employee, could serve as the presiding officer at a regulatory hearing. The presiding officer would be required to be, however, a neutral and unbiased official. Thus, he would not have participated in the investigation or action which was the subject of the hearing, or be directly subordinate to a person who had participated in such investigation. The Food and Drug Administration could substitute a different presiding officer for the one originally designated, without notice to the parties, since the person originally designated as the presiding officer could be unavailable when the hearing occurred.

RIGHT TO COUNSEL (§ 2.506)

Proposed § 2.506 would guarantee to every party to a hearing the fundamental due process right to be advised and accompanied by counsel.

REGULATORY HEARING ON THE INITIATIVE OF THE COMMISIONER (§ 2.510)

Proposed § 2.510 would govern the procedures to be followed at a regulatory hearing held on the initiative of the Commissioner. Such a hearing would be initiated by a notice of opportunity for hearing given by the Food and Drug Administration to the party or parties involved. Such notice would specify the facts and actions which are the subject of an opportunity for a hearing and require a response within a stated time period to a specified individual.

If no response was filed within the stated time period, the offer for a hearing would be deemed to have been refused, and no hearing would be held. If a hearing was requested, it would take place at a time and location agreed upon by the parties or, in the absence of such agreement, at a time and location designated by the presiding officer.

REGULATORY HEARING PURSUANT TO REGULATION (§ 2.511)

Proposed § 2.511 deals with regulatory hearings initiated at the request of a party, rather than on the initiative of the Commissioner. Pursuant to the various provisions of the agency regulations listed in § 2.500(b), any person who was adversely affected by the particular action specified therein would have a right to an opportunity for a regulatory hearing. The Food and Drug Administration would be required to furnish any such person a notice of opportunity for hearing, which would include the amount of time within which he could request a hearing. The failure to request a hearing would be deemed to constitute a waiver of any right to a hearing.

Before the hearing, the Food and Drug Administration would, upon request, give to the party requesting the hearing reasonable notice of the matters to be considered at the hearing, including a comprehensive statement of the basis for the decision or action taken or proposed by the Commissioner and a general summary of the information that would be presented by the agency at the hearing in support of such decision or action. The Commissioner believes that such notice would be necessary in order reasonably to inform the party of the matters involved. Because the time between the request for hearing and the hearing date could be short, however, such notice could be given either orally or in writing, in the discretion of the Commissioner.

The Commissioner could take such action pending a regulatory hearing under this section as he concludes to be necessary to protect the public health, except where expressly prohibited by statute or regulation. See Goldberg v. Kelly, 397 U.S. 254, 263 n. 10 (1970). If action was taken and not stayed pending the hearing, the hearing on the matter would be expedited. After the hearing is concluded, a written decision would be prepared stating the reasons for whatever administrative action was taken by the Commissioner, and the basis in the record.

HEARING PROCEDURE (§ 2.512)

Proposed § 2.512 specifies the procedure to be used in conducting any regulatory hearing pursuant to Subpart F. A regulatory hearing would be a private hearing unless the party who requested the hearing determines otherwise. The determination to make the hearing a public hearing could be made in either of two ways. First, the party requesting the hearing could simply request that it be conducted in public, in which case this would be done. Second, if the party requesting the hearing wished to be accompanied by any person other than an employee or consultant or other person subject to a commercial arrangement as defined in § 4.81(a), the hearing would have to be a public hearing and any interested person could attend.

At the hearing, employees of the agency would be required to give a full and complete statement of the action which was the subject of the hearing, together with the information and reasons supporting it, and could present any information relevant to the hearing. The Food and Drug Administration would have the burden of proof in any hearing conducted pursuant to the specific provisions listed in § 2.500(b). The party requesting the hearing would have the right to present any oral or written information relevant to the hearing. All parties could conduct reasonable cross-examination.

The Commissioner emphasizes that the regulatory hearing is intended to be informal in nature. The technical rules of evidence would not apply. Accordingly, objections on the basis of hearsay, leading questions, or similar legal technicalities, would not be heard. All information in any way reasonably related to the matter would be included in the record.

The presiding officer would prepare a written report of the hearing. This report could be reviewed and corrected by all parties to the hearing if time permitted, i.e., if immediate action was not necessary in the public interest as a result of information obtained during the hearing. If the hearing was transcribed, such transcription would be a part of the report of the hearing.

ADMINISTRATIVE RECORD OF A REGULATORY HEARING (§ 2.513)

Proposed § 2.513 specifies the record of the administrative proceeding. This record would be included as part of the record of any administrative proceeding involving the matter.

EXAMINATION OF ADMINISTRATIVE RECORD (§ 2.514)

The availability for public disclosure of the administrative record of a regulatory hearing would be governed by the provisions of the public information regulations. Thus, disclosure would depend upon the subject matter involved in the hearing. For example, trade secrets and information that would represent a clearly unwarranted invasion of personal

privacy would not be available for public disclosure, pursuant to §§ 4.61 and 4.63. If the hearing involved an IND plan, the provisions of §§ 312.5 and 314.14 would apply, and if the hearing involved the safety of a cosmetic ingredient any safety information voluntarily submitted to the agency at the hearing would be available for public disclosure pursuant to § 4.111 (data and information submitted voluntarily to the Food and Drug Administration). Investigatory records compiled for law enforcement purposes would be made available pursuant to the provisions of § 4.64, i.e., all information disclosed to the party would immediately be available for public disclosure, except where possible criminal prosecution was involved.

RECORD FOR ADMINISTRATIVE DECISION (§ 2.515)

For those matters where the Commissioner had offered an opportunity for a hearing in his discretion, pursuant to § 2.500(a), the Commissioner could consider all relevant data and information as well as the administrative record of the hearing in determining whether regulatory action should be undertaken and, if so, what form of action should be taken.

With respect to those regulatory hearings which would be provided pursuant to the specific provisions in the regulations cross-referenced in § 2.500(b), the administrative record of the hearing would constitute the exclusive record for decision by the Commissioner.

RECONSIDERATION AND STAY OF ACTION (§ 2.516)

Proposed § 2.516 provides that, following any final administrative action which was the subject of a hearing, any participant could petition for reconsideration or a stay of action pursuant to §§ 2.8 or 2.9. This would exclude, of course, any decision to institute civil or criminal action in the courts.

JUDICIAL REVIEW (§ 2.520)

The availability of judicial review with respect to any administrative action which was the subject of a hearing pursuant to Subpart F would be governed by § 2.11. The Commissioner has concluded that it would not be feasible to propose definitive rules with respect to the availability of judicial review of action taken as a result of a regulatory hearing, because of the different types of action that may be the subject of such a hearing. If a regulatory hearing resulted in a seizure or injunction action or section 305 citation and criminal prosecution in the Federal courts, the proper remedy for any aggrieved party would be to contest such action in the courts. Judicial review of the Commissioner's decision to take such action would not be permissible. Where the administrative action taken by the Commissioner was not final in nature, judicial review also would not be permitted. Where the Commissioner took final administrative action as a result of a regulatory hearing, however, judicial review of such final action would clearly be permitted in accordance with the provisions of § 2.11. Such review would, of course, be based solely upon the administrative record of the proceeding, and would not properly consider any data, information, or arguments not presented in the course of the regulatory hearing.

STANDARDS OF CONDUCT AND CONFLICTS OF INTEREST (SUBPART G)

Subpart G of the proposed regulations would include, or cross-reference, all regulations governing the standards of conduct and conflicts of interest with respect to present and former employees of the Food and Drug Administration, including special government employees and employees of the Food and Drug Division of the Office of General Counsel.

SCOPE OF SUBPART (§ 2.600)

Although Subpart G would be established to include all pertinent regulations with respect to these matters for all present and former agency employees, many of these regulations are still in the process of development. Accordingly, the provisions proposed in Subpart G at this time represent only brief and initial statements of very general policy. The Commissioner anticipates that substantial further regulations will be added to this subpart, particularly relating to former employees and all special government employees.

REFERENCE TO DEPARTMENT REGULATIONS (§ 2.610)

All Food and Drug Administration employees are fully subject to the regulations (45 CFR Part 73) governing standards of conduct for Department of Health, Education, and Welfare employees, except that agency special government employees are subject only to Subpart L of 45 CFR Part 73. In addition, only Food and Drug Administration employees are subject to the provisions of 45 CFR Part 73a, which supplement the Department regulations. The provisions of 45 CFR Part 73a do not apply to special government employees of the Food and Drug Administration.

CODE OF ETHICS FOR GOVERNMENT SERVICE (§ 2.611)

Proposed § 2.611 would make applicable to all Food and Drug Administration employees, including special government employees, the code of ethics for government service adopted by Congress in 1958. The Commissioner considers this code, embodying high ethical principles, applicable to all agency employees.

FOOD AND DRUG ADMINISTRATION CONFLICT OF INTEREST REVIEW BOARD (§ 2.612)

Under proposed § 2.612, the Commissioner would establish a permanent five-member Conflict of Interest Review Board which would review and make recommendations to the Commissioner with respect to all matters brought before it relating to conflicts of interest. The Associate Commissioner for Administration would be responsible for bringing issues to the Review Board. In addition, any individual inside or outside the agency who was the subject of an adverse determination of any kind by the Office of the Associate Commissioner for Administration would have the right to an appeal to the Review Board with respect to that matter.

The Review Board would be a permanent body whose purpose would be to establish guidelines and precedents, through written decisions, guidelines, and regulations, that would govern all conflict of interest issues within the agency. Whenever feasible, the policy adopted as a result of the work of the Review Board would be incorporated in regulations in Subpart G.

The Review Board would be sensitive to the privacy rights of individuals with respect to the information it received. In some instances, the only information that would be disseminated publicly would be written in a form that did not reveal the identity of the individual involved. In other instances, either pursuant to general regulations adopted by the agency or pursuant to a specific determination for a named individual, public disclosure of information related to an individual would be appropriate to provide public notice of the circumstances under which the individual was serving as a government employee or special government employee. For example, information could routinely be filed with the Public Records and Documents Center with respect to stockholdings of agency consultants which had been determined not to be substantial, to give public notice about such holdings.

DUTY TO REPORT VIOLATIONS (§ 2.613)

Proposed § 2.613 would provide that all agency employees who had factual information showing or who otherwise believed that any present or former Food and Drug Administration employee had violated or was violating any provision of the laws summarized in 45 CFR Part 73 should report such information directly to the agency's Policy Management Staff (HFA-20), which is responsible for handling all matters of this type. The Commissioner advises that, under existing statutory and case law, the failure to report a violation, by itself, is not sufficient to subject an individual who knows of such violation to potential criminal liability as an accessory or accomplice. Accordingly, § 2.613(a) would simply encourage reporting of violations, but no penalty would or could be imposed for failure to report under these circumstances. In considering reports submitted pursuant to this section, the Policy Management Staff would consult with the Conflict of Interest Review Board when close issues arose that required policy consideration.

The records received and generated pursuant to this section would be maintained by the agency in strictest confidence. Only those who were required to see such records in the performance of their duties would be given access to them.

The Commissioner has carefully considered the provisions proposed in this section, and has consulted with a cross-

section of employees throughout the agency on them. On the one hand, it is widely recognized that all citizens share a moral obligation to help enforce legal requirements. On the other hand, it is equally recognized that basic civil liberties must be respected, and that the rights of both the accuser and the accused must be fully protected. The Commissioner is of the opinion that the provisions in this section strike an adequate balance between these valid concerns. No one would be required to report violations, but all would be encouraged to do so. Only those reports which a person was willing to put in writing would be regarded as sufficiently serious to pursue. Those written records would be carefully safeguarded, so that there would be no concern about their improper release to persons who were not required to review them in the course of their duties.

PERMANENT DISQUALIFICATION OF FORMER EMPLOYEES (§ 2.620)

Proposed § 2.620 states the provisions of current law, 18 U.S.C. 207(a), with respect to permanent disqualification of former Food and Drug Administration employees on particular matters involving a specific party or parties in which the former employee participated personally and substantially. It is the intention of the Commissioner that this statutory language be supplemented in the future by interpretive regulations to give better guidance to former employees with respect to permissible and impermissible activity.

TEMPORARY DISQUALIFICATION OF FORMER EMPLOYEES (§ 2.621)

Proposed § 2.621 similarly summarizes the provisions of 18 U.S.C. 207(b) with respect to the 1-year disqualification of a former Food and Drug Administration employee on any matter which was under his official responsibility within 1 year preceding termination of such responsibility. Again, additional interpretive regulations will be issued to clarify this statutory disqualification.

CONFORMING CHANGES IN OTHER FOOD AND DRUG ADMINISTRATION REGULATIONS

The new procedures proposed in Part 2 of the regulations would require corresponding changes in numerous other existing agency regulations in Title 21 of the Code of Federal Regulations. The following is a brief summary of these changes. The Commissioner recognizes that other conforming changes might also be appropriate, and invites comment suggesting further amendments to the agency regulations.

EXEMPTION FROM REQUIRED LABEL STATEMENTS

Section 1.1a would be revised to provide that exemptions from required label statements shall be adopted pursuant to Part 2.

EXEMPTION FROM FOOD LABELING INFORMATION REQUIREMENTS

Section 1.8d(f) would be revised to state that a petition requesting an exemption from the food labeling information requirements in that section shall be submitted pursuant to Part 2.

DELEGATIONS OF AUTHORITY AND ORGANIZATION

Former Subparts H and M of Part 2 would be recodified as a new Part 5. References to the Assistant General Counsel for Food and Drugs, Office of General Counsel, Department of Health, Education, and Welfare would be revised to reflect that he now has the additional title of Chief Counsel for the Food and Drug Administration.

COLOR ADDITIVE ADVISORY COMMITTEES

Section 8.12 would be revised to cross-reference the new provisions relating to color additive advisory committees in §§ 2.360 through 2.364; prior provisions in §§ 8.12 through 8.14 would be revoked.

EXEMPTION FROM COLOR ADDITIVE CERTIFICATION

Section 8.18 would be revised to state that a petition for exemption from certification for a color additive shall be submitted pursuant to Part 2.

OBJECTIONS AND HEARINGS RELATING TO COLOR ADDITIVE REGULATIONS

The existing provisions in §§ 8.19 through 8.21 would be revoked, and a new § 8.19 would provide that objections and hearings relating to color additive regulations shall be governed by Part 2.

COLOR ADDITIVE CERTIFICATION REFUSAL

Section 8.27(b) would be amended to add a sentence stating that a person who wishes to contest a refusal to certify a batch of a color additive has an opportunity for a regulatory hearing pursuant to Subpart F. No opportunity for a hearing now exists.

CERTIFICATION SERVICE REFUSAL

Section 8.28(b) would be revised to provide that a person who wishes to contest refusal of certification service has an opportunity for a regulatory hearing pursuant to Subpart F of Part 2. The current provisions, which would be revoked, provide for a formal evidentiary public hearing. The Commissioner is of the opinion that the statute does not require an opportunity for a formal evidentiary public hearing, and that a regulatory hearing is more appropriate for this type of proceeding..

INVESTIGATIONAL USE OF COLOR ADDITIVES

Section 8.33(a) would be amended to add a new sentence providing an opportunity for a regulatory hearing pursuant to Subpart F upon a refusal to permit the use of food derived from animals on which investigational color additives are used. No opportunity for a hearing now exists.

FOOD STANDARDS

Section 10.2 would be revised to state that the procedure for establishing a food standard shall be governed by Part 2. The provisions now contained in this section would be superseded by the more detailed provisions of Part 2.

FOOD STANDARD TEMPORARY PERMITS

A new paragraph (l) would be added to § 10.5 to provide that a person who wishes to contest denial, modification, or revocation of a temporary permit to vary from a standard of identity has an opportunity for a regulatory hearing pursuant to Subpart F of Part 2. No opportunity for a hearing exists.

STANDARDS OF QUALITY

Section 11.1(e) would be revised to state that standards of quality for foods for which there are no standards of identity may be established pursuant to Part 2 and to delete the reference to a former provision in Part 2 that would be revoked by the proposed regulations.

SPECIAL DIETARY FOODS

Section 80.1(b)(4) would be revised to delete the reference to a former provision in Part 2 that would be revoked by the proposed regulations.

EMERGENCY PERMIT CONTROL

Section 90.2(a) would be revised to refer to the provisions in Part 2 and to delete the reference to a former provision in Part 2 that would be revoked by the proposed regulation.

NUTRITIONAL QUALITY GUIDELINES FOR FOODS

Section 100.2 would be revised to refer to the provisions in Part 2 and to delete the reference to a former provision in Part 2 that would be revoked by the proposed regulations.

COMMON OR USUAL NAMES FOR NONSTANDARDIZED FOODS

Section 102.2(a) and (b) would be revised to refer to the provisions in Part 2 and to delete the reference to a former provision in Part 2 that would be revoked by the proposed regulations.

FOOD ADDITIVES

Sections 121.40(c)(1), 121.41(b)(1), and 121.4000(c) would be revised to refer generally to the new procedures contained in Part 2 rather than to procedures now used.

Section 121.55 would be revised to state that objections and hearings relating to food additive regulations shall be governed by Part 2. All of the previous procedural provisions relating to food additives in Part 121 would be revoked.

Section 121.74 would be revised to state that the procedure for amending and repealing food additive regulations would be governed by Part 2.

APPROVAL OF PRESCRIPTION DRUG ADVERTISEMENTS

Section 202.1(j)(5) would be added to state that a regulatory hearing pursuant to Subpart F of Part 2 is available with respect to any determination that prior approval is required for advertisements concerning a particular prescription drug, or that a particular advertisement is not approvable. No opportunity for a hearing now exists.

PRESCRIPTION EXEMPTION PROCEDURE FOR NEW DRUGS

Section 310.200(b) would be revised to replace the procedure now set out in that provision with a reference to Part 2.

PHASE IV CLINICAL STUDIES

Section 310.303(b) would be revised to state that a proposal to require additional or continued studies for a new drug shall be pursuant to Part 2.

INVESTIGATIONAL NEW DRUGS

Section 312.1 (c) (1) and (4) and (d) would be revised to state that any person who wishes to contest any issue arising out of disqualification of an investigator and his work, and termination of an IND, has an opportunity for a regulatory hearing pursuant to Subpart F of Part 2. This would replace the current procedure which is similar in nature but not specified in detail.

These provisions would also be revised to state that an IND plan may be terminated immediately upon a finding of a danger to health, rather than requiring an imminent hazard to health, in order to conform them to proposed § 2.511(e). Section 505(i) of the act does not require the Commissioner to find an imminent hazard to health before an IND plan may be terminated.

LABORATORY RESEARCH ON INVESTIGATIONAL NEW DRUGS

Section 312.9(c)(2) would be revised to state that any person who wishes to contest termination of an investigational exemption for use of a new drug in laboratory research animals or in vitro tests has an opportunity for a regulatory hearing pursuant to proposed Subpart F of Part 2. Now, a conference is permitted but there is no opportunity for a hearing.

HEARINGS INVOLVING NEW DRUGS

Section 314.200 would be revised to delete material that is duplicative of requirements contained in proposed Subpart B of Part 2.

Section 314.201 would be added to state that hearings relating to new drugs shall be governed by Part 2. All of the prior procedural provisions relating to new drug hearings would be revoked.

Section 314.235 would be revised to conform it to the provisions of proposed Subpart B by deleting duplicative material.

IN VITRO DIAGNOSTIC PRODUCTS FOR HUMAN USE

Section 328.30(a) would be revised to refer to Part 2 and to delete the reference to a provision in Part 2 which would be revoked by the proposed regulations.

OTC DRUG REVIEW

Section 330.10(a)(12) would be revised to state that a petition to amend or repeal any OTC drug monograph shall be submitted pursuant to Part 2.

INSULIN

Section 429.50 would be revised to state that, upon suspension of insulin certification service, a person shall have an opportunity for a regulatory hearing pursuant to Subpart F of Part 2. Now, a formal evidentiary public hearing is provided. The Commissioner is of the opinion that a formal evidentiary public hearing is not required by statute and that a regulatory hearing pursuant to Subpart F is more appropriate for this type of proceeding.

ANTIBIOTIC REGULATIONS

Section 430.20(a) would be revised to state that the procedures for the issuance, amendment, or repeal of antibiotic regulations shall be governed by proposed Part 2. The remaining procedural provisions relating to antibiotic hearings would be revoked.

Section 430.20(d), relating to requests for hearings with respect to the failure to issue an antibiotic regulation, or amendment or repeal of such a regulation, would be revised to make the same modifications that have been proposed in § 314.200 for new drugs, to conform it to the provisions in Subpart B.

CERTIFICATION OF ANTIBIOTIC DRUGS

Section 431.52 would be revised to state that, upon suspension of certification service, a person shall have an opportunity for a regulatory hearing pursuant to Subpart F of Part 2. Now, suspension of certification service is subject to a formal evidentiary public hearing. The Commissioner is of the opinion that the statute does not require a formal evidentiary public hearing under these circumstances and that Subpart F provides a more appropriate procedure for this type of proceeding.

EXEMPTIONS FROM ANTIBIOTIC CERTIFICATION AND LABELING REQUIREMENTS

A number of specific sections in Part 433, relating to exemptions from antibiotic certification and labeling requirements, would be revised to provide that a person who wishes to contest adverse action by the Food and Drug Administration shall be subject to an opportunity for a regulatory hearing pursuant to Subpart F of Part 2. Now, these provisions state only that such action is subject to a hearing, without specifying the type of hearing, or do not specify that any hearing is permitted.

The current provisions state that such exemptions can in some instances be revoked only after notice and opportunity for hearing. The proposed cross-reference to the provisions governing a regulatory hearing under Subpart F of Part 2 would mean that the Commissioner could make any such revocation effective immediately if he found that this was necessary to protect the public health, pursuant to § 2.511(e).

NEW ANIMAL DRUGS

A number of specific provisions in Parts 511 and 514 relating to investigational and marketed new animal drugs would be revised in the same way as their counterpart provisions relating to investigational and marketed new drugs, to refer to the new procedural provisions in Part 2. The prior procedural provisions relating to hearings would be revoked.

LICENSING OF BIOLOGICALS

The procedural provisions in Part 601 relating to licensing of biologicals, revocation and suspension of a license, and hearings on such matters would be substantially revised, consolidated, and simplified. Hearings on denial, revocation, or suspension of a biologics license would be governed by Part 2. The procedural requirements for new drugs in § 314.200 would be incorporated by reference. Previous procedural provisions relating to biologics would be revoked.

COSMETIC LABELING

Section 701.3 (b) and (e) would be revised to refer to the provisions in Part 2 and to delete the reference to a provision in Part 2 that would be revoked by the proposed regulations.

NOTIFICATION OF DEFECTS IN ELECTRONIC PRODUCTS

Section 1003.11(a) would be amended and § 1003.31(d) would be added to include a provision stating that a person who wishes to contest a determination that a product fails to comply or has a defect, and a denial of an exemption from the notification provisions, has an opportunity for a regulatory hearing pursuant to Subpart F of Part 2. Now, no opportunity for a hearing exists.

REPURCHASE, REPAIRS, OR REPLACEMENT OF ELECTRONIC PRODUCTS

Section 1004.6 would be amended to add a new provision stating that, upon denial of a plan with respect to repurchase, repair, or replacement of an electronic product, a person shall have an opportunity for a regulatory hearing pursuant to Subpart F of Part 2. Now, no opportunity for a hearing exists.

HEARINGS UNDER THE FEDERAL IMPORT MILK ACT

Section 1210.30 would be revised to state that a person who wishes to contest denial, suspension, or revocation of a permit has an opportunity for a regulatory hearing pursuant to Subpart F of Part 2. All of the prior procedural provisions would be revoked.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act, (Sec. 201 et seq., 52 Stat. 1040; 21 U.S.C. 321 et seq.), the Public Health Service Act (sec. 1 et seq., 58 Stat. 682, as amended; 42 U.S.C. 201 et seq.), the Comprehensive Drug Abuse Prevention and Control Act of 1970 (sec. 4, 84 Stat. 1241; 42 U.S.C. 257a), the Controlled Substances Act (sec. 301 et seq., 84 Stat. 1253; 21 U.S.C. 821 et seq.), the Federal Meat Inspection Act (sec. 409(b), 81 Stat. 600; 21 U.S.C. 679(b)), the Poultry Products Inspection Act (sec. 24(b), 82 Stat. 807; 21 U.S.C. 467f(b)), the Egg Products Inspection Act (sec. 2 et seq., 84 Stat. 1620; 21 U.S.C. 1031 et seq.), the Federal Import Milk Act (44 Stat. 1101; 21 U.S.C. 141 et seq.), the Tea Importation Act (21 U.S.C. 41 et seq.), the Federal Caustic Poison Act (44 Stat. 1406; 15

U.S.C. 401–411 notes), the Fair Packaging and Labeling Act (80 Stat. 1296; 15 U.S.C. 1451 et seq.), and all other statutory authority delegated to him (21 CFR 2.120), the Commissioner proposes to amend Chapter I of Title 21 of the Code of Federal Regulations as follows:

PART 1—REGULATIONS FOR THE ENFORCEMENT OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND THE FAIR PACKAGING AND LABELING ACT

1. By revising § 1.1a to read as follows:

§ 1.1a Foods, drugs, devices, and cosmetics; labeling; procedure for requesting variations and exemptions from required label statements.

Section 403(e) of the act (in this Part 1, the term "act" means the Federal Food, Drug, and Cosmetic Act) provides for the establishment by regulation of reasonable variations and exemptions for small packages from the required declaration of net quantity of contents. Section 403(i) of the act provides for the establishment by regulation of exemptions from the required declaration of ingredients where such declaration is impracticable, or results in deception or unfair competition. Section 502(b) of the act provides for the establishment by regulation of reasonable variations and exemptions for small packages from the required declaration of net quantity of contents. Section 602(b) of the act provides for the establishment by regulation of reasonable variations and exemptions for small packages from the required declaration of net quantity of contents. Section 5(b) of the Fair Packaging and Labeling Act provides for the establishment by regulation of exemptions from certain required declarations of net quantity of contents, identity of commodity, identity and location of manufacturer, packer, or distributor, and from declaration of net quantity of servings represented, based on a finding that full compliance with such required declarations is impracticable or not necessary for the adequate protection of consumers, and a further finding that the nature, form, or quantity of the packaged consumer commodity or other good and sufficient reasons justify such exemptions. The Commissioner, on his own initiative or on petition of an interested person, may propose a variation or exemption based upon any of the foregoing statutory provisions, including proposed findings if section 5(b) of the Fair Packaging and Labeling Act applies, pursuant to Part 2 of this chapter.

2. By revising § 1.8d(f) to read as follows:

§ 1.8d Food labeling; information panel.

* * * * *

(f) If the label of any package of food is too small to accommodate all of the information required by §§ 1.8a, 1.8c, 1.10, 1.13, 1.17, and 1.18, and Parts 80 and 125 of this chapter, the Commissioner may establish by regulation an acceptable alternative method of disseminating such information to the public, e.g., a type size smaller than one-sixteenth inch in height, or labeling attached to or inserted in the package or available at the point of purchase. A petition requesting such a regulation, as an amendment to this paragraph shall be submitted pursuant to Part 2 of this chapter.

3. By revising Part 2 to read as follows:

PART 2—ADMINISTRATIVE PRACTICES AND PROCEDURES

Subpart A—General

Subpart B—Formal Evidentiary Public Hearings

Subpart C—Public Hearing Before a Public Board of Inquiry

Subpart D—Public Hearing Before a Public Advisory Committee

AUTHORITY: Sec. 201 et seq., Pub. L. 717, 52 Stat. 1040 as amended (21 U.S.C. 321 et seq.); sec. 1 et seq., Pub. L. 410, 58 Stat. 682 as amended (42 U.S.C. 201 et seq.); sec. 4, Pub. L. 91-513, 84 Stat. 1241 (42 U.S.C. 257a); sec. 301 et seq., Pub. L. 91-513, 84 Stat. 1253 (21 U.S.C. 821 et seq.); sec. 409(b), Pub. L. 242, 81 Stat. 600 (21 U.S.C. 679); sec. 24(b), Pub. L. 85-172, 82 Stat. 807 (21 U.S.C. 467f (b)); sec. 2 et seq., Pub. L. 91-597, 84 Stat. 1620 (21 U.S.C. 1031 et seq.); sec. 1 et seq., Pub. L. 625, 44 Stat. 1101-1103 as amended (21 U.S.C. 141 et seq.); sec. 1 et seq., Chapter 358, 29 Stat. 604-607 as amended (21 U.S.C. 41 et seq.); Pub. L. 783, 44 Stat. 1406 as amended by 74 Stat. 381 (15 U.S.C. 401-411 notes); sec. 2 et seq., Pub. L. 89-755, 80 Stat. 1296 (15 U.S.C. 1451 et seq.).

Subpart A—General

§ 2.1 Scope.

(a) Part 2 governs practices and procedures applicable to all petitions, hearings, and other administrative proceedings and activities conducted by the Food and Drug Administration pursuant to the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and other laws with respect to which authority has been delegated to the Commissioner of Food and Drugs pursuant to § 5.1 of this chapter, except to the extent that specific provisions in other sections of this chapter state different requirements with respect to a particular matter.

(b) Where a specific provision in another section of this chapter states a different requirement with respect to a particular matter (e.g., the use of a form different from the one specified in § 2.7 (b)), the sections in this Part shall apply to the extent that they do not conflict with such other provisions (e.g., the requirements for inclusion of all data and information and for translations of foreign language in § 2.5(b) shall apply regardless of which form is used).

§ 2.3 Definitions.

(a) As used in this Part, the following terms shall have the meanings specified:

(1) "Act" means the Federal Food, Drug, and Cosmetic Act unless otherwise indicated.

(2) "Department" means the United States Department of Health, Education, and Welfare.

(3) "Secretary" means the Secretary of Health, Education, and Welfare.

(4) "Commissioner" means the Commissioner of Food and Drugs, Food and Drug Administration, United States Department of Health, Education, and Welfare, or his designee.

(5) "Agency" means the Food and Drug Administration.

(6) "Person" includes an individual, partnership, corporation, association, or other legal entity.

(7) "Presiding officer" means the Commissioner or his designee or an Administrative Law Judge appointed as provided in 5 U.S.C. 3105.

(8) "Hearing Clerk" means the Hearing Clerk of the Food and Drug Administration, United States Department of Health, Education, and Welfare, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852.

(9) "Proceeding" and "administrative proceeding" mean any undertaking to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action.

(10) "Party" means the bureau of the Food and Drug Administration responsible for the matter involved and every person who either has exercised a right to request or has been granted the right by the Commissioner to have a formal evidentiary public hearing pursuant to Subpart B of this Part or a regulatory hearing before the Commissioner pursuant to Subpart F of this Part, or who has waived any such right in order to obtain the establishment of a Public Board of Inquiry pursuant to Subpart C of this Part, and as a result of whose action a formal evidentiary hearing or a regulatory hearing before the Commissioner has been granted or a Public Board of Inquiry has been established.

(11) "Participant" means any person participating in any proceeding, including each party and any other interested person.

(12) "Interested person" or "any person who will be adversely affected" means any person who submits a petition or comment or objection or otherwise requests an opportunity to participate in any informal or formal administrative proceeding or court action.

(13) "Public Board of Inquiry" or "Board" means an administrative law tribunal constituted pursuant to the provisions of Subpart C of this Part.

(14) "Public advisory committee" or "advisory committee" means any committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup thereof, that is not composed wholly of full-time officers or employees of the Federal government and is established or utilized by the Food and Drug Administration to obtain advice or recommendations.

(15) "Formal evidentiary public hearing" means any hearing conducted pursuant to the provisions of Subpart B of this Part.

(16) "Public hearing before a Public Board of Inquiry" means any hearing conducted by a Board pursuant to the provisions of Subpart C of this Part.

(17) "Public hearing before a public advisory committee" means any hearing conducted by an advisory committee pursuant to the provisions of Subpart D of this Part.

(18) "Public hearing before the Commissioner" means any hearing conducted by the Commissioner or his designee pursuant to the provisions of Subpart E of this Part.

(19) "Regulatory hearing before the Food and Drug Administration" means any hearing conducted by an authorized employee of the Food and Drug Administration pursuant to the provisions of Subpart F of this Part.

(20) "The laws administered by the Commissioner" means all the statutory provisions with respect to which authority has been delegated to the Commissioner pursuant to § 5.1 of this chapter.

(21) "Petition" means any petition, application, or other document requesting the Commissioner to establish, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action, under the laws administered by him.

(22) "Regulation" means any agency rule of general or particular applicability and future effect implementing or applying any law administered by the Commissioner or relating to administrative practices and procedures. Pursuant to § 2.20(a), all agency regulations shall be promulgated in the FEDERAL REGISTER and codified in the Code of Federal Regulations.

(23) "Order" means any final agency disposition, other than the issuance of a regulation, in a proceeding concerning any matter and includes action on any new drug application, new animal drug application, or biological license.

(24) "Meeting" means any oral discussion, whether by telephone or in person.

(25) "Office of the Commissioner" includes the offices of the associate and assistant commissioners and excludes the bureaus, the office of the Executive Director for Regional Operations, and all regional and district offices.

(26) "Administrative action" includes every form and kind of act, including the refusal or failure to act, involved in the implementations of the laws administered by the Commissioner, except that it does not include the referral of apparent violations to United States attorneys for the institution of civil and criminal proceedings and acts preparatory or incidental thereto.

(27) "Administrative file" or "administrative record" means the file maintained by the Food and Drug Administration, either by the Hearing Clerk or by any other agency employee, in which all documents comprising the official record of any administrative proceeding are retained.

(28) "Food and Drug Administration employee" or "Food and Drug Administration representative" shall be deemed to include members of the Food and Drug Division of the office of the General Counsel of the Department of Health, Education, and Welfare.

(b) Any term which is defined in section 201 of the Federal Food, Drug, and Cosmetic Act or Part 1 of this chapter shall have that definition.

(c) Words in the singular form shall be deemed to include the plural, words in the masculine form shall be deemed to include the feminine form, and vice versa, as the case may require.

(d) Whenever any reference is made in this Part to any person in the Food and Drug Administration, e.g., the director of a bureau, such reference shall also be deemed to include all persons to whom that person has delegated the specific function involved.

§ 2.4 Summaries of administrative practices and procedures.

The Commissioner shall prepare for public distribution summaries of Food and Drug Administration administrative practices and procedures in terms that are readily understood in order to encourage and facilitate participation in all agency activities.

§ 2.5 Submission of documents to Hearing Clerk; computation of time; availability for public disclosure.

(a) All submissions to the Hearing Clerk of petitions, comments, objections, notices, compilations of data and information, and any other documents pursuant to this Part or other sections in this chapter shall be filed in quintuplicate, except as otherwise specifically provided in any relevant FEDERAL REGISTER notice or in other sections of this chapter. The Hearing Clerk shall be the agency custodian of such documents.

(b) All such submissions shall be signed by the person making the submission, or by an attorney or other authorized representative on his behalf. If a submission is signed by an attorney or other authorized representative on behalf of another person, the submission shall be accompanied by a signed statement of authorization or other documentation verifying his authority to sign the submission as such person's representative, unless such authorization has previously been submitted as part of the administrative file in the same proceeding. Submissions by trade associations shall also be subject to the requirements of § 2.23(b).

(c) All data and information referred to or in any way relied upon in any such submissions shall be included in full and may not be incorporated by reference, unless previously submitted as part of the administrative file in the same proceeding.

(1) A copy of any article or other reference or source cited shall be included.

(2) If any part of the material submitted is in a foreign language, it shall be accompanied by an English translation verified under oath to be complete and accurate, together with the name, address, and a brief statement of the qualifications of the person making the translation. Translations of literature or other material in a foreign language shall be accompanied by copies of the original publication.

(3) Where relevant data or information are contained in a document also containing irrelevant matter, the irrelevant matter shall be deleted and only the relevant data or information shall be submitted.

(4) Pursuant to § 4.63 (a) and (b) of this chapter, the names and other information which would identify patients or research subjects shall be deleted from any record before it is submitted to the Hearing Clerk in order to preclude a clearly unwarranted invasion of personal privacy.

(5) Defamatory, scurrilous, or intemperate matter shall be deleted from any record before it is submitted to the Hearing Clerk.

(6) The failure to comply with the requirements of this paragraph or any other requirement in this Part shall result in rejection of the submission for filing or, if it is filed, in exclusion from consideration of any portion of the submission which fails to comply. If a submission fails to meet any requirement of this section and such deficiency becomes know to the Hearing Clerk, the Hearing Clerk shall return the submission with a copy of the applicable regulations indicating those provisions not complied with in the submission. A deficient submission may be corrected or supplemented and subsequently filed.

(d) The filing of a submission shall mean only that the Hearing Clerk has not determined that it fails to meet the technical requirements for filing established in this section and in any other applicable sections in this chapter, e.g., § 2.7 relating to a citizen petition. The filing of a petition shall not mean or imply that it in fact meets all applicable requirements or that it contains reasonable grounds for the action requested or that the action requested is in accordance with law.

(e) All submissions to the Hearing Clerk shall be considered as submitted on the date on which they are postmarked or, if delivered in person during regular business hours, on the date on which they are so delivered, unless a provision in this Part or an applicable FEDERAL REGISTER notice specifically states that such documents must be received by a specified date, e.g., § 2.8(g) relating to a petition for reconsideration, in which case they shall be considered submitted on the date actually received.

(f) All such submissions shall be mailed or delivered in person to the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852, except that a submission which is required to be received by the Hearing Clerk by a specified date may be delivered in person to the Food and Drug Administration building in downtown Washington, Rm. 6819, 200 C St., SW., Washington, DC 20201 and shall be considered as received by the Hearing Clerk on the date on which it is logged in at Rm. 6819.

(g) The Food and Drug Administration ordinarily will not acknowledge or give receipt for such documents, except:

(1) Documents delivered in person or submitted by certified or registered mail with a return receipt requested.

(2) Petitions for which acknowledgement of receipt of filing is provided by regulations in this chapter or by customary practice, e.g., § 2.7(c) relating to a citizen petition.

(h) Saturdays, Sundays, and Federal legal holidays shall be included in computing the time allowed for the submission of any document, except that when such time expires on a Saturday, Sunday, or Federal legal holiday, such period shall be extended to include the next following business day.

(i) All submissions to the Hearing Clerk constitute a representation that, to the best of the knowledge, information, and belief of the person making the submission, all statements made in the submission are true and accurate. All such submissions are subject to the False Reports to the Government Act, 18 U.S.C. 1001, under which a willfully false statement is a criminal offense.

(j) The availability for public examination and copying of submissions to the Hearing Clerk shall be governed by the following rules:

(1) Except to the extent provided in paragraphs (j)(2) and (3) of this section, the following submissions, including all supporting material, shall be on public display and shall be available for public examination during regular business hours on Monday through Friday. Requests for copies of such submissions shall be filed and handled pursuant to the provisions of Subpart C of Part 4 of this chapter.

(i) Petitions.

(ii) Comments on petitions, on documents published in the FEDERAL REGISTER, and on similar public documents.

(iii) Objections and requests for hearings filed pursuant to Subpart B of this Part.

(iv) Material submitted at a formal evidentiary public hearing pursuant to Subpart B of this Part, a public hearing before a Public Board of Inquiry pursuant to Subpart C of this Part, a public hearing before the Commissioner pursuant to Subpart E of this Part, or an alternative form of hearing before a public advisory committee pursuant to § 2.117(a)(2).

(v) Material placed on public display pursuant to regulations in this chapter, e.g., agency guidelines filed pursuant to § 2.20(b).

(2)(i) Material submitted with objections and requests for hearings filed pursuant to Subpart B of this Part, or at a formal evidentiary public hearing pursuant to Subpart B, a public hearing before a Public Board of Inquiry pursuant to Subpart C of this Part, or an alternative form of public hearing before a public advisory committee or a public hearing before the Commissioner pursuant to § 2.117(a) (2) or (3), of the following types shall be on public display and shall be available for public examination during regular business hours on Monday through Friday, but shall not be available for copying or any other form of verbatim recording or transcription unless it is otherwise available for public disclosure pursuant to the provisions of Part 4 of this chapter and the regulations referenced therein:

(*a*) Safety and effectiveness data and information, which include all studies and tests of an ingredient or product on animals and humans and all studies and tests on the ingredient or product for identity, stability, purity, potency, bioavailability, performance, and usefulness.

(*b*) A protocol for a test or study.

(ii) Material submitted pursuant to the provisions of this paragraph (j)(2) shall be segregated from all other submitted material and clearly so marked. Any person who does not agree that such a submission is properly subject to the provisions of this paragraph (j)(2) may request a ruling thereon from the Assistant Commissioner for Public Affairs whose decision on the matter shall be final, subject to judicial review pursuant to § 4.46 of this chapter.

(iii) Material submitted pursuant to the provisions of this paragraph (j)(2) shall be retained on public display and available for public examination only for such period of time as is appropriate to permit public participation in a public hearing and any related judicial review, and shall thereafter be subject to the provisions of paragraph (j)(3) of this section.

(iv) In accordance with the policy stated in § 4.86 of this chapter, the limited availability of material pursuant to this paragraph (j)(2) shall be deemed not to constitute prior disclosure to the public as defined in § 4.81 of this chapter and no such data and information shall, if copied or otherwise recorded or transcribed in violation of the provisions of this paragraph (j)(2), be submitted to or received or considered by the Food and Drug Administration by any other person in support of a petition or other request.

(3)(i) Material prohibited from public disclosure pursuant to § 4.63 of this chapter (clearly unwarranted invasion of personal privacy) as interpreted and applied in Part 4 of this chapter and the regulations referenced therein, and material submitted with objections and requests for hearings filled pursuant to Subpart B of this Part, or at a formal evidentiary public hearing pursuant to Subpart B of this Part, a public hearing before a Public Board of Inquiry pursuant to Subpart C of this Part, or an alternative form of public hearing before a public advisory committee or a public hearing before the Commissioner pursuant to § 2.117(a) (2) or (3), of the following types shall not be on public display, shall not be available for public examination, and shall not be available for copying or any other form of verbatim transcription unless they are otherwise available for public disclosure pursuant to the provisions of Part 4 of this chapter and the regulations referenced therein:

(*a*) Manufacturing methods of processes, including quality control procedures.

(*b*) Production, sales, distribution, and similar data and information, except any compilation of such data and information aggregated and prepared in a way that does not reveal confidential data and information.

(*c*) Quantitative or semiquantitative formulas.

(*d*) Data and information on design or construction of products.

(ii) Material submitted pursuant to the provisions of this paragraph (j)(3) shall be segregated from all other submitted material and clearly so marked. Any person who does not agree that such a submission is properly subject to the provisions of this paragraph (j)(3) may request a ruling thereon from the Assistant Commissioner for Public Affairs whose decision on the matter shall be final, subject to judicial review pursuant to § 4.46 of this chapter.

§ 2.6 Initiation of administrative proceedings.

An administrative proceeding under the laws administered by the Commissioner may be initiated in any of the following three ways:

(a) Any interested person may petition the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action, under the laws administered by him. Any such petition shall be either (1) in the form specified in other applicable sections in this chapter, e.g., the form for a food additive petition in § 121.51 of this chapter or for a new drug application in § 314.1 of this chapter or for a new animal drug application in § 514.1 of this chapter, or (2) in the form for a citizen petition in § 2.7.

(b) The Commissioner may on his own initiative institute a proceeding to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action, under the laws administered by him. The Food and Drug Administration has primary jurisdiction to make the initial determination on issues within its statutory mandate, and will request a court to dismiss, or to hold in abeyance its determination of or refer to the agency for administrative determination, any such issue which has not previously been determined by the agency or which, if it has previously been so determined, the agency concludes should be reconsidered and subject to a new administrative determination. The Commissioner may, in his discretion, utilize any of the procedures established in this Part in reviewing and making a determination on any matter on his own initiative.

(c) The Commissioner shall institute a proceeding to determine whether he should issue, amend, or revoke a regulation or order, or take or refrain from taking any other form of administrative action under the laws administered by him, whenever any court holds in abeyance or refers any such matter to him for an administrative determination and he concludes that such an admin-

istrative determination is feasible in light of agency priorities and resources.

§ 2.7 Citizen petition.

(a) The provisions of this section shall apply to any petition submitted by any person, except to the extent that specific provisions in other sections of this chapter state different requirements with respect to a particular matter.

(b) Any petition (including any attachments) shall be submitted in accordance with § 2.5 and in the following form:

(Date)

Hearing Clerk, Food and Drug Administration, Department of Health, Education, and Welfare, Rm. 4-65, 5600 Fishers Lane, Rockville MD 20852.

CITIZEN PETITION

The undersigned submits this petition pursuant to ---------- (relevant statutory sections, if known) of the ---------- (Federal Food, Drug, and Cosmetic Act and/or the Public Health Service Act and/or any other statutory provision with respect to which authority has been delegated to the Commissioner of Food and Drugs pursuant to 21 CFR 5.1) to request the Commissioner of Food and Drugs to ---------- (issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action).

A. *Action Requested.*

((1) If the petition requests the Commissioner to issue, amend, or revoke a regulation, the exact wording of the existing regulation (if any) and the proposed regulation or amendment requested.)

((2) If the petition requests the Commissioner to issue, amend, or revoke an order, a copy or the exact wording of and citation to the existing order (if any) and the exact wording requested for the proposed order.)

((3) If the petition requests the Commissioner to take or refrain from taking any other form of administrative action, the specific action or relief requested.)

B. *Statement of Grounds.*

(A full statement of the factual and legal grounds upon which the petitioner relies. Such grounds shall include all relevant data, information, and views on which the petitioner relies, as well as representative data and information known to the petitioner which are unfavorable to the petitioner's position, and shall be submitted in a well-organized format.)

C. *Environmental Impact.*

(An environmental impact analysis report in the form specified in 21 CFR 6.1(g), except for the types of actions specified in 21 CFR 6.1(e).)

The undersigned certifies, that, to the best of his knowledge and belief this petition includes all data, information, and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Very truly yours,

(Signature)

(Name of petitioner)

(Mailing address)

(Telephone number)

(c) Any petition which appears to meet the requirements of paragraph (b) of this section and § 2.5 shall be filed by the Hearing Clerk, stamped with the date of filing, and assigned a docket number. The docket number shall be used to identify the administrative file established by the Hearing Clerk for all submissions relating to the petition, as provided in this Part. All subsequent submissions relating to the matter shall refer to such docket number and shall be filed in such administrative file. Identical, similar, or related petitions may be filed together and given the same docket number. The Hearing Clerk shall promptly notify the petitioner in writing of the filing and docket number of a petition.

(d) Any interested person may submit written comments to the Hearing Clerk on any filed petition, which shall become part of the administrative file. Such comments shall specify the docket number of the petition and may support or oppose the petition in whole or in part. Any request for alternative or different administrative action shall be in the form of a separate petition.

(e) The Commissioner shall review and rule upon every petition filed pursuant to paragraph (c) of this section as promptly as is feasible, taking into consideration (1) the agency resources available to handle the category of subject matter involved, (2) the priority assigned to the petition in relation both to the category of subject matter involved and the overall work of the agency, and (3) time requirements established by statute. The Commissioner may grant or deny such a petition, in whole or in part, and may grant such other relief or take such other action as he may determine to be warranted by the petition. The petitioner shall be notified in writing of the Commissioner's decision on a petition. Such decision shall be placed in the public docket file in the office of the Hearing Clerk and may also be in the form of a notice published in the FEDERAL REGISTER.

(f) If a petition filed pursuant to paragraph (c) of this section requests the Commissioner to issue, amend, or revoke a regulation, the provisions of § 2.10 or § 2.12 shall also apply.

(g) A petitioner may supplement, amend, or withdraw his petition upon written request without agency approval prior to the time the Commissioner rules on the petition unless the petition has been referred for a hearing under Subparts B, C, D, or E of this Part. In all other instances, a petition may be supplemented, amended, or withdrawn only with approval of the Commissioner.

(h) In reviewing any matter which is the subject of a petition filed pursuant to paragraph (c) of this section, the Commissioner may, in his discretion, utilize any of the following procedures.

(1) Conferences, meetings, discussions, and correspondence pursuant to § 2.15.

(2) A formal evidentiary public hearing pursuant to Subpart B of this Part.

(3) A public hearing before a Public Board of Inquiry pursuant to Subpart C of this Part.

(4) A public hearing before a public advisory committee pursuant to Subpart D of this Part.

(5) A public hearing before the Commissioner pursuant to Subpart E of this Part.

(6) A regulatory hearing before the Food and Drug Administration pursuant to Subpart F of this Part.

(7) A notice published in the FEDERAL REGISTER requesting data, information, and views.

(8) A proposal to issue, amend, or revoke a regulation, in accordance with the provisions of § 2.10 or § 2.110.

(9) Any other specific public procedure established by the provisions in other sections of this chapter and explicitly made applicable to the matter by those provisions.

(i) The record of the administrative proceeding shall consist of the following:

(1) The petition, including all data and information on which it relies, filed by the Hearing Clerk.

(2) All comments received on the petition, including all data or information submitted as a part of such comments.

(3) If the petition resulted in a proposal to issue, amend, or revoke a regulation, all of the documents specified in § 2.10(g).

(4) The record, consisting of any transcripts, minutes of meetings, reports, FEDERAL REGISTER notices, and other documents, resulting from any of the optional procedures specified in paragraph (g) of this section, except that it shall not include the transcript of any closed portion of any public advisory committee meeting.

(5) The Commissioner's decision on the petition, including all data and information identified or filed by the Commissioner with the Hearing Clerk as part of the record supporting the decision.

(6) All documents filed with the Hearing Clerk pursuant to § 2.15(f).

(7) If any petition for reconsideration or for a stay of action is filed pursuant to paragraph (j) of this section, the administrative record specified in § 2.8(k) or § 2.9(h) respectively.

(j) The administrative record specified in paragraph (i) of this section shall constitute the exclusive record for the Commissioner's decision. The record of the administrative proceeding shall be closed as of the date of the Commissioner's decision unless some other date for the closing of the record is specified by the Commissioner. Thereafter any interested person may submit a petition for reconsideration pursuant to § 2.8 and a petition for stay of action pursuant to § 2.9. Any person who wishes to rely upon data, information, or views not included in the administrative record shall submit it to the Commissioner with a new petition to modify the decision pursuant to this section.

(k) The provisions of this section shall not apply to requests, suggestions, and

recommendations made informally in routine correspondence received by the Food and Drug Administration. Such correspondence does not constitute a petition within the meaning of this section unless it purports to meet the requirements of this section. Action with respect to such routine correspondence does not constitute final administrative action which is subject to judicial review pursuant to § 2.11.

(l) The Hearing Clerk shall maintain a chronological list of all petitions filed pursuant to this section and § 2.19, but excluding petitions submitted elsewhere in the agency pursuant to § 2.6(a)(1), showing:

(1) The docket number.

(2) The date the petition was filed by the Hearing Clerk.

(3) The name of the petitioner.

(4) The subject matter involved.

§ 2.8 Administrative reconsideration of action.

(a) The Commissioner may at any time conclude to reconsider any matter, on his own initiative or on the petition of any interested person.

(b) Any interested person may request reconsideration of any part or all of a decision of the Commissioner on any petition submitted pursuant to § 2.6(a). Any such request shall be submitted in accordance with § 2.5 and in the following form no later than 30 days after the date of the decision involved.

_____
(Date)

Hearing Clerk, Food and Drug Administration, Department of Health, Education, and Welfare, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852

PETITION FOR RECONSIDERATION

Docket No. _____

The undersigned submits this petition for reconsideration of the decision of the Commissioner of Food and Drugs in Docket No. _____

A. *Decision Involved.*

(A concise statement of the decision of the Commissioner which the petitioner wishes to have reconsidered.)

B. *Action Requested.*

(The decision which the petitioner requests the Commissioner to make upon reconsideration of the matter.)

C. *Statement of Grounds.*

(A full statement of the factual and legal grounds upon which the petitioner relies. Such grounds shall demonstrate that relevant data, information, and views contained in the administrative record were not previously or not adequately considered by the Commissioner. No new data, information, or views may be included in a petition for reconsideration.)

Very truly yours,

_____
(Signature)

_____
(Name of petitioner)

_____
(Mailing address)

_____
(Telephone number)

(c) A petition for reconsideration relating to a petition submitted pursuant to § 2.6(a)(2) shall be subject to the requirements of § 2.7 (c) and (d), except that it shall be filed in the same docket file as the petition to which it relates.

(d) The Commissioner shall promptly review a petition for reconsideration. The Commissioner may grant such a petition in any proceeding when he determines that it is in the public interest and in the interest of justice. The Commissioner shall grant a petition for reconsideration in any proceeding if he determines that all of the following apply: (1) the petition demonstrates that relevant data, information, or views contained in the administrative record were not previously or not adequately considered by the Commissioner, (2) the petitioner's position is not frivolous and is being pursued in good faith, (3) the Petitioner has demonstrated sound public policy grounds supporting reconsideration, and (4) reconsideration is not outweighed by public health considerations or other public interests.

(e) A petition for reconsideration shall be based only on data, information, and views contained in the administrative record on which the Commissioner made his decision. Any interested person who wishes to rely upon data, information, or views not included in such administrative record shall submit it to the Commissioner with a new petition to modify the decision pursuant to § 2.6(a).

(f) The Commissioner's decision on a petition for reconsideration shall be in writing and shall be placed on public display as part of the administrative file on the matter in the office of the Hearing Clerk. A determination to grant reconsideration shall be published in the FEDERAL REGISTER if the Commissioner's original decision was published in the FEDERAL REGISTER. Any other determination to grant or to deny reconsideration may also be published in the FEDERAL REGISTER.

(g) The Commissioner will consider a petition for reconsideration only if it is submitted within 30 days of the date of the decision involved and before such petitioner brings legal action in the courts to review such action, except that such a petition shall also be considered if the Commissioner has denied a petition for stay of action and such petitioner has petitioned for judicial review of the Commissioner's action and requested the reviewing court to grant a stay pending consideration of such review. A petition for reconsideration submitted later than 30 days after the date of the decision involved shall be denied as untimely. A petition for reconsideration shall be considered as submitted on the day it is received by the Hearing Clerk.

(h) The Commissioner may on his own initiative decide to reconsidered all or part of any matter at any time after it has been decided or action has been taken. If review of such matter is pending in the courts, the Commissioner may request that the court refer the matter back to the agency or hold its review in abeyance pending administrative reconsideration. The administrative record of the proceeding shall include all additional documents relating to such reconsideration.

(i) After determining to reconsider a matter, whether on the petition of an interested person or on his own initiative, the Commissioner shall review and rule on the merits of the matter pursuant to § 2.7(e). The Commissioner may reaffirm, modify, or overrule his prior decision, in whole or in part, and may grant such other relief or take such other action as he may determine to be warranted.

(j) The Commissioner's reconsideration of any matter relating to a petition submitted pursuant to § 2.6(a)(2) shall be subject to the provisions of § 2.7(f) through (h), (j), and (k).

(k) The record of the administrative proceeding shall consist of the following.

(1) The record of the original petition specified in § 2.7(i).

(2) The petition for reconsideration, including all data and information on which it relies, filed by the Hearing Clerk.

(3) All comments received on such petition, including all data or information submitted as a part of such comments.

(4) The Commissioner's decision on such petition pursuant to paragraph (f) of this section, including all data and information identified or filed by the Commissioner with the Hearing Clerk as part of the record supporting the decision.

(5) Any FEDERAL REGISTER notices or other documents resulting from such petition.

(6) All documents filed with the Hearing Clerk pursuant to § 2.15(f).

(7) If the Commissioner reconsiders the matter, the administrative record relating to such reconsideration specified in § 2.7(i).

§ 2.9 Administrative stay of action.

(a) The Commissioner may stay (including extend) the effective date of any relevant action pending or following his decision on any matter, on his own initiative or on the petition of any interested person.

(b) Any interested person may request the Commissioner to stay the effective date of any administrative action. Such a stay may be requested for a specific time period or for an indefinite time period. Any such request shall be submitted in accordance with § 2:5 and in the following form no later than 30 days after the date of the decision involved.

_____
(Date)

Hearing Clerk, Food and Drug Administration, Department of Health, Education, and Welfare, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852

PETITION FOR STAY OF ACTION

The undersigned submits this petition requesting that the Commissioner of Food and Drugs stay the effective date of his action with respect to the following matter.

A. *Decision Involved.*

(The specific administrative action being taken by the Commissioner for which a stay is requested, including the docket number or other citation to the action involved.)

B. *Action Requested.*
(The length of time for which the stay is requested, which may be for a specific or indefinite time period.)
C. *Statement of Grounds.*
(A full statement of the factual and legal grounds upon which the petitioner relies for the stay.)
Very truly yours,

(Signature)

(Name of petitioner)

(Mailing address)

(Telephone number)

(c) A petition for stay of action relating to a petition submitted pursuant to § 2.6(a)(2) shall be subject to the requirements of paragraphs (c) and (d) of § 2.7, except that it shall be filed in the same docket file as the petition to which it relates.

(d) Neither the filing of a petition for a stay of action pursuant to this section nor action taken by an interested person in accordance with any other administrative procedure in this part or in any other section of this chapter, e.g., the filing of a citizen petition pursuant to § 2.7 or a petition for reconsideration pursuant to § 2.8 or a request for an advisory opinion pursuant to § 2.18, shall operate to stay or otherwise delay any administrative action by the Commissioner, including enforcement action of any kind, unless one of the following applies:

(1) The Commissioner, in his discretion, determines that a stay or delay is in the public interest and stays the action.

(2) A statutory provision requires that the matter be stayed.

(3) A court orders that the matter be stayed.

(e) The Commissioner shall promptly review a petition for stay of action. The Commissioner may grant or deny such a petition, in whole or in part, and may grant such other relief or take such other action as he may determine to be warranted by the petition. The Commissioner may grant a stay in any proceeding if he determines that it is in the public interest and in the interest of justice. The Commissioner shall grant a stay in any proceeding if he determines that all of the following apply: (1) The petitioner will otherwise suffer irreparable injury, (2) the petitioner's case is not frivolous and is being pursued in good faith, (3) the petitioner has demonstrated sound public policy grounds supporting the stay, and (4) the delay resulting from the stay is not outweighed by public health considerations or other public interests.

(f) The Commssioner's decision on a petition for stay of action shall be in writing and shall be placed on public display as part of the file on the matter in the office of the Hearing Clerk. A determination to grant a stay shall be published in the FEDERAL REGISTER if the Commissioner's original decision was published in the FEDERAL REGISTER. Any other determination to grant or to deny a stay may also be published in the FEDERAL REGISTER.

(g) A petition for a stay of action submitted later than 30 days after the date of the decision involved shall be denied as untimely. A petition for a stay of action shall be considered as submitted on the day it is received by the Hearing Clerk.

(h) The record of the administrative proceeding shall consist of the following:

(1) The record of the proceeding to which the petition for stay of action is directed.

(2) The petition for stay of action, including all data and informtaion on which it relies, filed by the Hearing Clerk.

(3) All comments received on such petition, including all data or information submitted as a part of such comments.

(4) The Commissioner's decision on such petition pursuant to paragraph (e) of this section, including all data and information identified or filed by the Commissioner with the Hearing Clerk as part of the record supporting the decision.

(5) Any FEDERAL REGISTER notices or other documents resulting from such petition.

(6) All documents filed with the Hearing Clerk pursuant to § 2.15(f).

§ 2.10 Promulgation of regulations for the efficient enforcement of the law.

(a) The Commissioner may propose and promulgate regulations for the efficient enforcement of the laws administered by him whenever he concludes that it is necessary or appropriate to do so. The issuance, amendment, or revocation of any such regulation may be initiated in any of the ways specified in § 2.6.

(1) This section shall apply to any regulation (i) not subject to § 2.12 and Subpart B of this Part or (ii) if it is subject to § 2.12 and Subpart B of this Part, to the extent that those provisions make this section applicable.

(2) A regulation proposed by an interested person in a petition submitted pursuant to § 2.6(a) shall be published by the Commissioner in the FEDERAL REGISTER as a proposal if he determines that:

(i) The petition contains facts demonstrating reasonable grounds for the proposal.

(ii) The petition contains a substantial showing that the proposal is in the public interest and will promote the objectives of the act and the agency.

(iii) The requested proposal is lawful.

(3) The Commissioner may publish two or more alternative proposed regulations on the same subject in order to obtain comment on the different alternatives.

(4) The Commissioner may publish a regulation proposed by an interested person in a petition submitted pursuant to § 2.6(a) together with the Commissioner's preliminary views on the proposal and any alternative proposal.

(b) Except as provided in paragraphs (d) and (e) of this section, any such regulation shall be the subject of a notice of proposed rule making published in the FEDERAL REGISTER.

(1) Such notice shall contain (i) a general statement in the first or second paragraph describing the substance of the document in easily understandable terms, (ii) a preamble which summarizes the proposal and the facts and policy underlying it, (iii) references to all data and information on which the Commissioner relies for the proposal (copies or a full list of which shall be a part of the administrative file on the matter in the office of the Hearing Clerk), (iv) the authority under which the regulation is proposed, (v) either the terms or substance of the proposed regulation or a description of the subjects and issues involved, (vi) a proposed effective date, (vii) a reference to the existence or lack of need for an environmental impact statement pursuant to § 6.3(a)(3) (ii) or (iii) of this chapter, (viii) the time, place, and method for interested persons to submit written comments on the proposal, and a statement that comments shall be submitted in accordance with the requirements of this Part and (ix) the docket number of the matter, which shall be used to identify the administrative file established by the Hearing Clerk for all submissions relating to the matter, as provided in this Part.

(2) Such proposal shall ordinarily provide 60 days for comment, although the Commissioner may reduce or extend this time period for good cause. In no event shall the time for comment be less than ten days.

(3) After publication of the notice of proposed rule making, any interested person may request the Commissioner to extend the comment period for an additional specified period of time by submitting a written request to the Hearing Clerk stating the grounds therefor. Such requests shall be pursuant to § 2.9, except that the heading shall be "REQUEST FOR EXTENSION OF COMMENT PERIOD."

(i) Any such request shall demonstrate why comments could not reasonably be submitted within the time permitted, or that important new information will shortly be available, or that sound public policy otherwise supports an extension of the time for comment. The Commissioner may grant or deny such request or may grant an extension for a time period different than that requested. Extensions of time to comment will not ordinarily be granted. An extension of time to comment may be limited to specific persons who have made and justified such a request, but shall ordinarily apply to all interested persons.

(ii) Any extension of time to comment of 30 days or longer shall be the subject of a notice published in the FEDERAL REGISTER and shall be applicable to all interested persons. Any extension of time to comment of less than 30 days shall be the subject either of a letter or memorandum filed with the Hearing Clerk or of a notice published in the FEDERAL REGISTER.

(4) All comments shall be submitted in quintuplicate to the Hearing Clerk, except that individuals may submit single copies of comments. Comments will be stamped with the date of receipt and will be numbered chronologically.

(5) Persons submitting comments critical of a proposed regulation are encouraged to include alternative wording that they believe would be preferable.

(c) After the time for comment on a proposed regulation has expired, the Commissioner shall review the entire administrative record on the matter, including all comments, and shall terminate the proceeding, issue a new proposal, or promulgate a final regulation, by notice published in the FEDERAL REGISTER.

(1) The quality and persuasiveness of the comments shall determine the Commissioner's decision with respect to such comments. The number or length of comments shall not be a significant factor in such decision.

(2) The decision of the Commissioner with respect to the matter shall be based solely upon the administrative record.

(3) The preamble to a final regulation published in the FEDERAL REGISTER shall contain in the first and second paragraphs reference to prior notices relating to the same matter and a general statement describing the substance of the document in easily understandable terms, and shall summarize each type of comment submitted on the proposal and the Commissioner's conclusions with respect to each such type of comment. The preamble shall contain a thorough and comprehensible articulation of the reasons for the Commissioner's decision on each issue.

(4) The notice promulgating a final regulation published in the FEDERAL REGISTER shall specify the effective date. Such effective date shall be not less than 30 days after the date of publication in the FEDERAL REGISTER, except for:

(i) A regulation which grants an exemption or relieves a restriction.

(ii) Any other regulation where the Commissioner finds, and states in the notice, good cause for an earlier effective date.

(d) The provisions for notice and comment in paragraphs (b) and (c) of this section shall apply to interpretive rules and to rules of agency practice and procedure except as provided in paragraph (e) of this section. The provisions of paragraphs (b) and (c) of this section shall not apply to general statements of policy in the form of informational notices published in the FEDERAL REGISTER or to matters involving agency organization.

(e) The requirements of notice and public procedure in paragraph (b) of this section shall not apply in any of the following situations:

(1) When the Commissioner determines for good cause that they are impracticable, unnecessary, or contrary to the public interest. In such cases, the notice promulgating the regulation shall state the reasons for such determination, and shall provide an opportunity for the submission of comments to determine whether the regulation should subsequently be modified or revoked.

(2) To food additive and color additive petitions, which are subject to the provisions of § 2.110(b)(2).

(3) To new animal drug regulations, which shall be promulgated by notice pursuant to section 512(i) of the act.

(f) In addition to the notice and public procedure required pursuant to paragraph (b) of this section, the Commissioner may, in his discretion, also subject any proposed or final regulation, before or after publication in the FEDERAL REGISTER, to any of the following additional procedures, where they are reasonably applicable to the matter involved:

(1) Conferences, meetings, discussions, and correspondence pursuant to § 2.15.

(2) A formal evidentiary public hearing pursuant to Subpart B of this Part.

(3) A public hearing before a Public Board of Inquiry pursuant to Subpart C of this Part.

(4) A public hearing before a public advisory committee pursuant to Subpart D of this Part.

(5) A public hearing before the Commissioner pursuant to Subpart E of this Part.

(6) A notice published in the FEDERAL REGISTER requesting data, information, and views before the Commissioner determines whether to propose a regulation.

(7) A draft of a proposed regulation placed on public display in the office of the Hearing Clerk. If this procedure is used, the Commissioner shall publish an appropriate notice in the FEDERAL REGISTER stating that the document is available and specifying the time within which comments may be submitted orally or in writing on the draft of the proposed regulation.

(8) A revised proposal published in the FEDERAL REGISTER, which shall be subject to all the provisions in this section relating to proposed regulations.

(9) A tentative final regulation or tentative revised final regulation placed on public display at the office of the Hearing Clerk. If this procedure is used, the Commissioner shall publish an appropriate notice in the FEDERAL REGISTER stating that the document is available and specifying the time within which comments may be submitted orally or in writing on the tentative final regulation and shall mail a copy of the tentative final regulation and the FEDERAL REGISTER notice to each person who submitted comments on the proposed regulation.

(10) A final regulation published in the FEDERAL REGISTER which provides an opportunity for the submission of further comments to determine whether the regulation should subsequently be modified or revoked.

(11) Any other specific public procedure established by the provisions in other sections of this chapter and explicitly made applicable to the matter by the terms of those provisions.

(g) The record of the administrative proceeding shall consist of all of the following:

(1) If the regulation was initiated by a petition, the administrative record specified in § 2.7(i).

(2) If any petition for reconsideration or for a stay of action is filed, the administrative record specified in § 2.8(k) and § 2.9(h) respectively.

(3) The notice of proposed rule making published in the FEDERAL REGISTER, including all data and information identified or filed by the Commissioner with the Hearing Clerk as part of the administrative record supporting the proposal.

(4) All comments received on the proposal, including all data or information submitted as a part of such comments.

(5) The notice promulgating the final regulation, including all data and information identified or filed by the Commissioner with the Hearing Clerk as part of the administrative record supporting the final regulation.

(6) The transcripts, minutes of meetings, reports, FEDERAL REGISTER notices, and other documents resulting from any of the optional procedures specified in paragraph (f) of this section, except that it shall not include any transcript of any closed portion of any public advisory committee meeting.

(7) All documents submitted to the Hearing Clerk pursuant to § 2.15(f).

(h) The record of the administrative proceeding shall be closed as of the date the Commissioner's decision is published in the FEDERAL REGISTER or otherwise made available for public disclosure unless some other date for the closing of the record is specified by the Commissioner. Thereafter any interested person may submit a petition for reconsideration pursuant to § 2.8 and a petition for stay of action pursuant to § 2.9. Any person who wishes to rely upon data, information, or views not included in the administrative record shall submit it to the Commissioner with a new petition to modify the final regulation.

(i) The Hearing Clerk shall maintain a chronological list of all regulations proposed and promulgated pursuant to this section and § 2.12, but excluding regulations resulting from petitions filed and assigned a docket number pursuant to § 2.7, showing:

(1) The docket number, which in the case of a petition submitted directly to a bureau shall be the number or other designation assigned by the bureau, e.g., the number assigned to a food additive petition.

(2) The name of the petitioner, if any.

(3) The subject matter involved.

§ 2.11 Court review of final administrative action; exhaustion of administrative remedies.

(a) The provisions of this section shall apply to court review of any final administrative action taken by the Commissioner, including action taken pursuant to §§ 2.6 through 2.10 and § 2.500(b), except action subject to the provisions of § 2.12 and Subpart B of this Part.

(b) Any request that the Commissioner take or refrain from taking any form of administrative action shall first be the subject of a final administrative

decision based upon a petition submitted to the Commissioner pursuant to § 2.6(a) or, where applicable, a hearing pursuant to § 2.500(b) of this Part before any legal action is filed in a court complaining of the Commissioner's action or failure to act. If any court action is filed complaining of the Commissioner's action or failure to act prior to the submission of and decision on a petition pursuant to § 2.6(a) or, where applicable, a hearing pursuant to § 2.500(b) of this Part, the Commissioner will request dismissal of such court action or referral to the agency for an initial administrative determination on the grounds of a failure to exhaust the administrative remedies provided in this Part, the lack of final agency action as required by 5 U.S.C. 701 et seq., and the lack of an actual controversy as required by 28 U.S.C. 2201.

(c) Any request that any form of administrative action be stayed shall first be the subject of an administrative decision based upon a petition for stay of action submitted to the Commissioner pursuant to § 2.9 before any request is made that a court stay such action. If any court action is filed requesting a stay of any administrative action taken by the Commissioner prior to the Commissioner's decision on a petition submitted in a timely manner pursuant to § 2.9, the Commissioner will request dismissal of such court action or referral to the agency for an initial administrative determination on the grounds of a failure to exhaust the administrative remedies provided in this subpart, the lack of final agency action as required by 5 U.S.C. 701 et seq., and the lack of an actual controversy as required by 28 U.S.C. 2201. If any court action is filed requesting a stay of any administrative action taken by the Commissioner after a petition for a stay of action is denied because it was submitted after expiration of the 30-day time period specified in § 2.9, or after the time for submitting such a petition has expired, the Commissioner will request dismissal of such court action on the ground of a failure to exhaust the administrative remedies set out in this subpart.

(d) The Commissioner's final decision on a petition submitted pursuant to § 2.6(a), on a petition for reconsideration submitted pursuant to § 2.8, on a petition for stay of action submitted pursuant to § 2.9, or on any matter involving administrative action which is the subject of an opportunity for a hearing pursuant to § 2.500(b), each constitutes final agency action reviewable in the courts pursuant to 5 U.S.C. 701 et seq. and, where appropriate, 28 U.S.C. 2201.

(1) It is the position of the Food and Drug Administration except as otherwise provided in subparagraph (2) of this paragraph, that:

(i) Any such final agency action exhausts all administrative remedies and is ripe for preenforcement judicial review as of the date of such final decision, unless applicable law explicitly requires that the petitioner take further action before judicial review is available.

(ii) Any interested person is affected by, and thus has standing to obtain judicial review of, such final agency action.

(iii) It is not appropriate to move to dismiss a suit for preenforcement judicial review of such final agency action on the ground that indispensable parties are not joined or that it is an unconsented suit against the United States if such defect could be cured by amending the complaint.

(2) The Commissioner will object to judicial review of any matter if:

(i) The matter is committed by law to the discretion of the Commissioner, e.g., a decision to recommend or not to recommend civil or criminal enforcement action under sections 302, 303, and 304 of the act.

(ii) Review is not sought in a proper court.

(e) Any interested person may request judicial review of any final decision of the Commissioner in the courts without first petitioning the Commissioner for reconsideration or for a stay of action, except that in accordance with paragraph (c) of this section such person shall request a stay by the Commissioner pursuant to § 2.9 before he may request a stay by the court.

(f) The Commissioner will take the position in any action for judicial review under 5 U.S.C. 701 et seq., whether or not it includes a request for a declaratory judgment under 28 U.S.C. 2201, or in any other case in which the validity of administrative action is properly challenged, that the validity of the action shall be determined solely on the basis of the administrative record specified in §§ 2.7(i), 2.8(k), 2.9(h), 2.10(g), and 2.513(a), or the administrative record applicable with respect to any decision or action under the regulations referenced in § 2.500(b), and that additional data, information, or views may not be considered. Any interested person who wishes to rely upon data, information, or views not included in the administrative record shall submit it to the Commissioner with a new petition to modify the action pursuant to § 2.6(a).

(g) The Commissioner requests that all petitions for judicial review of a particular matter be filed in a single United States district court. If such petitions are filed in more than one jurisdiction, the Commissioner shall take appropriate action to prevent a multiplicity of suits in various jurisdictions, such as:

(1) A request for transfer of one or more suits to consolidate separate actions, pursuant to 28 U.S.C. 1404(a) or 28 U.S.C. 2112(a).

(2) A request that actions in all but one jurisdiction be stayed pending the conclusion of one proceeding.

(3) A request that all but one action be dismissed pending the conclusion of one proceeding, with the suggestion that the other plaintiffs intervene in that one suit.

(4) A request that one of the suits be maintained as a class action in behalf of all affected persons.

(h) Upon judicial review of administrative action pursuant to this section:

(1) If a court determines that the administrative record is inadequate to support the action, the Commissioner shall determine whether he wishes to proceed with such action.

(i) If the Commissioner concludes that such action should be pursued, he shall either request that the court remand the matter to the agency to reopen the administrative proceeding and record, or on his own initiative reopen the administrative proceeding and record upon receipt of the court determination. Any such reopened administrative proceeding shall be conducted pursuant to the provisions of this part and in accordance with any directions of the court.

(ii) If the Commissioner concludes that the public interest requires that the action remain in effect pending further administrative proceedings, he shall request that the court not stay the matter in the interim and shall expedite the further administrative proceedings.

(2) If a court determines that the administrative record is adequate, but the rationale for the action requires further elucidation:

(i) The Commissioner shall request either that such further explanation be provided in writing directly to the court without further administrative proceedings, or that the administrative proceeding be reopened pursuant to paragraph (h)(1)(i) of this section.

(ii) If he concludes that the public interest requires that the action remain in effect pending further court or administrative proceedings, he shall request that the court not stay the matter in the interim and shall expedite such further proceedings.

§ 2.12 Promulgation of regulations and orders after an opportunity for a formal evidentiary public hearing.

(a) The Commissioner shall promulgate regulations and orders after an opportunity for a formal evidentiary public hearing, in accordance with the procedures established in Subpart B of this Part, whenever all of the following apply:

(1) The subject matter of the regulation or order involved is subject by statute to an opportunity for a formal evidentiary public hearing.

(2) The person requesting such a hearing has a right to an opportunity for a hearing and submits adequate justification for such a hearing as required by §§ 2.110 through 2.115 and other applicable provisions in this chapter, e.g., §§ 314.200, 430.20(b), 514.200, and 601.7(a).

(b) The Commissioner may order a formal evidentiary public hearing on any matter whenever he determines, in his discretion, that it would be in the public interest to do so.

(c) The statutory provisions which permit a person who would be adversely affected by administrative action an opportunity for a formal evidentiary public hearing are as follows:

(1) Section 401 of the act relating to definitions and standards for food.

(2) Section 403(j) of the act relating to regulations for labeling of foods for special dietary uses.

(3) Section 404(a) of the act relating to regulations providing for emergency permit control.

(4) Section 406 of the act relating to tolerances for poisonous substances in food.

(5) Section 409 (c), (d), and (h) of the act relating to food additive regulations.

(6) Section 501(b) of the act relating to tests or methods of assay for drugs described in official compendia.

(7) Section 502(d) of the act relating to regulations designating habit-forming drugs.

(8) Section 502(h) of the act relating to regulations designating requirements for drugs liable to deterioration.

(9) Section 502(n) of the act relating to prescription drug advertising regulations.

(10) Section 506(c) of the act relating to insulin regulations.

(11) Section 507(f) of the act relating to regulations for antibiotic drug certification.

(12) Section 512(n)(5) of the act relating to regulations for animal antibiotic drugs and certification requirements.

(13) Section 706 (b) and (c) of the act relating to regulations for color additives listing and certification.

(14) Section 4(a) of the Fair Packaging and Labeling Act relating to food, drug, device, and cosmetic labeling.

(15) Section 5(c) of the Fair Packaging and Labeling Act relating to additional economic regulations for food, drugs, devices, and cosmetics.

(16) Section 505 (d) and (e) of the act relating to new drug applications.

(17) Section 512 (d), (e), (m)(3), and (m)(4) of the act relating to new animal drug applications.

(18) Section 351(a) of the Public Health Service Act relating to plant and product licenses for a biologic.

§ 2.13 Separation of functions; ex parte communications.

(a) The provisions of this section shall apply with respect to any matter which is subject by statute to an opportunity for a formal evidentiary public hearing, as listed in § 2.12(c), and any matter subject to a public hearing before a Public Board of Inquiry pursuant to Subpart C of this Part.

(b) In the case of any matter listed in § 2.12(c) (1) through (10) and (12) through (15):

(1) Any interested person may meet or correspond with any representative of the Food and Drug Administration with respect to any such matter prior to publication in the FEDERAL REGISTER of a notice announcing a formal evidentiary public hearing or a public hearing before a Public Board of Inquiry on the matter. The provisions of § 2.15 shall apply to such meetings and correspondence.

(2) Upon publication in the FEDERAL REGISTER of a notice announcing a formal evidentiary public hearing or a public hearing before a Public Board of Inquiry, the following separation of functions shall apply:

(i) The bureau responsible for the matter involved in the hearing shall, as a party to the hearing, be responsible for all investigative functions and for presentation of the position of the bureau at the hearing and in any pleading or oral argument before the Commissioner. Representatives of the bureau shall not participate or advise in any decision except as witness or counsel in public proceedings. There shall be no other communication between representatives of the bureau and representatives of the office of the Commissioner with respect to the matter involved in the hearing prior to the decision of the Commissioner. All members of the Food and Drug Administration other than representatives of the involved bureau shall be available to advise and participate with the office of the Commissioner in its functions relating to the hearing and the final decision.

(ii) The Chief Counsel for the Food and Drug Administration shall designate those members of his office who shall advise and participate with the bureau in its functions in the hearing. The members of the office of General Counsel so designated shall not participate or advise in any decision except as counsel in public procedings. Such designation shall be in the form of a memorandum filed with the Hearing Clerk and made a part of the administrative record in the proceeding. There shall be no other communication between those members of the office of General Counsel so designated and any other persons in the office of General Counsel or in the Food and Drug Administration except the members of the involved bureau with respect to the matter involved in the hearing, prior to the decision of the Commissioner. All members of the office of General Counsel other than those so designated shall be available to advise and participate with the office of the Commissioner in its functions relating to the hearing and the final decision. The Chief Counsel shall always advise and participate with the office of the Commissioner in its functions relating to the hearing and the final decision.

(iii) The office of the Commissioner shall be responsible for the agency review of and final decision on the matter, with the advice and participation of anyone in the Food and Drug Administration other than representatives of the involved bureau and those members of the office of General Counsel who have been designated to assist in the bureau's functions relating to the hearing.

(c) In the case of any matter listed in § 2.12(c) (11) and (16) through (18), the specific provisions relating to separation of functions set forth in §§ 314.200 (f), 430.20(b)(9), 514.200, and 601.7(a) of this chapter shall be applicable prior to publication in the FEDERAL REGISTER of a notice announcing a formal evidentiary public hearing or a public hearing before a Public Board of Inquiry. Upon publication of any such notice the rules in paragraph (b)(2) of this section shall apply.

(d) Between the date that separation of functions applies pursuant to paragraph (b) or (c) of this section and the date of the Commissioner's decision on the matter, communication with respect to the matter involved in the hearing shall be restricted as follows:

(1) No person shall have any ex parte communication, orally or in writing, with the presiding officer or any person representing the office of the Commissioner with respect to the matter involved in the hearing. All such communications shall be public communications, as witness or counsel, in accordance with the applicable provisions of this Part.

(2) Any participant in the hearing may submit a written communication to the office of the Commissioner with respect to a proposal for settlement. Such written communications shall be in the form of pleadings and shall be served on all other participants and filed with the Hearing Clerk in the same manner as any other pleading.

(3) Any written communication contrary to this section shall immediately be filed with the Hearing Clerk, and any oral communication contrary to this section shall immediately be recorded in a written memorandum and filed with the Hearing Clerk, as a part of the administrative record of the proceeding. Any person, including any representative of any participant in the hearing, who is involved in any such oral communication shall be made available for cross-examination during the hearing with respect to the substance of that conversation. Rebuttal testimony pertinent to any such written or oral communication shall be permitted. Any cross-examination and rebuttal testimony shall be transcribed and filed in the administrative record of the proceeding.

§ 2.14 Referral by court.

(a) The provisions of this section shall apply whenever any Federal, State, or local court holds in abeyance, or refers to the Commissioner, any matter for an initial administrative determination pursuant to § 2.6(c) or § 2.11(b).

(b) The Commissioner shall promptly agree or decline to accept such referral. Whenever feasible in light of agency priorities and resources, the Commissioner shall egree to accept any such referral and shall institute a proceeding to determine the matter so referred.

(c) In reviewing such a matter, the Commissioner may, in his discretion, utilize any of the following procedures:

(1) Conferences, meetings, discussions, and correspondence pursuant to § 2.15.

(2) A formal evidentiary public hearing pursuant to Subpart B of this Part.

(3) A hearing before a Public Board of Inquiry pursuant to Subpart C of this Part.

(4) A public hearing before a public advisory committee pursuant to Subpart D of this Part.

(5) A public hearing before the Commissioner pursuant to Subpart E of this Part.

(6) A regulatory hearing before the Food and Drug Administration pursuant to Subpart F of this Part.

(7) A notice published in the FEDERAL REGISTER requesting data, information, and views before the Commissioner makes his decision on it.

(8) Any other specific public procedure established by the provisions in other sections of this chapter and explicitly made applicable to the matter by those provisions.

(d) If the Commissioner's review of the matter results in the proposal of a regulation, the provisions of § 2.10 or § 2.12 shall also apply.

§ 2.15 Meetings and correspondence.

(a) In addition to the public hearings and proceedings established by the provisions of this Part and in other sections of this chapter, meetings may be held and correspondence may be exchanged between representatives of the Food and Drug Administration and any interested person outside the Food and Drug Administration with respect to any matter within the jurisdiction of the laws administered by the Commissioner. Action with respect to such meetings and correspondence does not constitute final administrative action which is subject to judicial review pursuant to § 2.11.

(b) The Commissioner may conclude, in his discretion, that it would be in the public interest to hold an open public meeting to discuss a matter (or class of matters) pending before the Food and Drug Administration, at which any interested person may participate.

(1) The Commissioner shall give public notice through the public calendar described in § 2.22(a) of the time and place of the meeting and of the matters to be discussed, and may also publish such notice in the FEDERAL REGISTER.

(2) The meeting shall be conducted informally, i.e., any interested person may attend and participate fully in the discussion without giving prior notice to the agency or requesting time to make a presentation.

(3) No transcript or recording of any such meeting shall be required. A written memorandum summarizing the substance of the meeting shall be prepared by a representative of the Food and Drug Administration.

(c) Any meeting with any person outside the Department, including any person in the Executive or Legislative Branch of the Federal Government, relating to a pending court case, administrative hearing, or other regulatory action or decision, which involves more than a brief description of the matter shall be summarized in a written memorandum which shall be filed in the administrative file on the matter.

(d) Every person outside the Federal Government has a right to request and obtain a private meeting with a representative of the Food and Drug Administration in agency offices to discuss any matter in which he is interested.

(1) The person requesting such a meeting may be accompanied by a reasonable number of employees, consultants, or other persons with whom he has a commercial arrangement within the meaning of § 4.81(a) of this chapter. Neither the Food and Drug Administration nor any other person may require the attendance of any person who is not an employee of the Executive Branch of the Federal Government without the agreement of the person requesting the meeting. Any person may attend by mutual consent of the person requesting the meeting and the Food and Drug Administration.

(2) The Food and Drug Administration shall determine which representatives of the Food and Drug Administration shall attend the meeting. The person requesting the meeting may request but not require or preclude the attendance of any specific Food and Drug Administration employee.

(3) Whenever appropriate (e.g., the meeting involved a matter covered by paragraph (c) of this section or any other important matter, a decision on an issue, or statements or advice or conclusions to which future reference may be required as part of an administrative record), a written memorandum summarizing the substance of the meeting shall be prepared by a representative of the Food and Drug Administration.

(4) Any person who wishes to attend a specific private meeting, but who is not permitted to attend because the person requesting the meeting or the Food and Drug Administration does not grant permission for such attendance, or because it is conducted by telephone, may request and obtain a separate meeting with the Food and Drug Administration to discuss the same matter or any additional matter.

(e) Food and Drug Administration employees have a responsibility to meet with all segments of the public in order to promote the objectives of the act and the agency. In pursuing this responsibility the following general policy shall apply where agency employees are invited by persons outside the Federal Government to attend or participate in meetings outside agency offices as representatives of the agency.

(1) A person outside the Executive Branch of the Federal Government may invite an agency representative to attend or participate in a meeting outside agency offices. The agency representative is not obligated to attend or participate in any such meeting, but may do so where he concludes that it is in the public interest and will promote the objectives of the act and the agency.

(2) An agency representative may request that any such meeting be an open meeting when he concludes that this would be in the public interest. The agency representative may agree to decline to participate in any such meeting which is held as a private meeting, depending upon which action he concludes will best serve the public interest.

(3) An agency representative shall not knowingly participate in any meeting which is closed on the basis of sex, race, or religion.

(4) Any such meeting, whether open or closed, shall be subject to the requirements of paragraph (d)(3) of this section with respect to memoranda summarizing the substance of the meeting.

(f) Representatives of the Food and Drug Administration may initiate a meeting or correspondence with any person outside the Federal Government with respect to any matter relating to the laws administered by the Commissioner.

(1) Any meeting initiated by the Food and Drug Administration which involves a small number of interested persons, e.g., a meeting with a petitioner or with two manufacturers of a particular product which requires additional testing or with a trade association employee to discuss an industry labeling problem, may be a private meeting. Any meeting initiated by the Food and Drug Administration which involves a large number of interested persons, e.g., 10 manufacturers of an ingredient to discuss appropriate testing or labeling, shall be held as an open conference or meeting pursuant to paragraph (b) of this section.

(2) Whenever appropriate (e.g., the meeting involved a matter covered by paragraph (c) of this section or any other important matter, a decision on an issue, or statements or advice or conclusions to which future reference may be required as part of the administrative record), a written memorandum summarizing the substance of any meeting shall be prepared by a representative of the Food and Drug Administration.

(g) Any person who participates in any meeting described in paragraphs (b) through (f) of this section may prepare and submit to the Food and Drug Administration for inclusion in the administrative file a written memorandum summarizing the substance of the meeting.

(h) All memoranda of such meetings prepared by a representative of the Food and Drug Administration or by any other person and all correspondence which relate to any matter pending before the agency shall promptly be filed in the relevant administrative file and made a part of the administrative record of the proceeding.

(i) Any meeting with a representative of Congress relating to a pending or potential investigation, inquiry, or hearing by a congressional committee or a member of Congress shall be summarized in a written memorandum which shall be forwarded to the Food and Drug Administration, Office of Legislative Services. This provision shall not restrict the right of any agency employee to participate in any such meeting.

(j) Any meeting of an advisory committee shall be subject to the requirements of Subpart D of this Part.

(k) Pursuant to 42 U.S.C. 2631(a)(8), a log or summary shall be made of all meetings held between representatives of the Food and Drug Administration and representatives of industry and other interested parties with respect to implementation of the Radiation Control for Health and Safety Act of 1968.

§ 2.16 Documentation of significant decisions in administrative file.

(a) The provisions of this section shall apply to every significant Food and Drug

Administration decision on any matter under the laws administered by the Commissioner, whether it is raised formally, e.g., by a petition, or informally, e.g., by correspondence.

(b) The Food and Drug Administration employees responsible for handling any matter shall be responsible for assuring the completeness of the administrative file relating to it. Such file:

(1) Shall contain appropriate documentation of the basis for the decision, including relevant evaluations, reviews, memoranda, letters, opinion of consultants, minutes of meetings, and all other written documents pertinent to the matter.

(2) Shall contain the recommendations and decisions of individual employees, including supervisory personnel, responsible for handling the matter.

(i) Such recommendations and decisions shall reveal any significant controversies or differences of opinion and their resolution.

(ii) Any agency employee working on a matter shall have the opportunity to record his views on that matter in a written memorandum, which shall be included in the file.

(c) All written documents placed in such an administrative file:

(1) Shall relate to the factual, scientific, legal, or related issues under consideration.

(2) Shall be dated and signed by the author.

(3) Shall be directed to the file, to appropriate supervisory personnel, and to other appropriate employees, and shall show all persons to whom copies were sent.

(4) Shall avoid defamatory language, intemperate remarks, undocumented charges, or irrelevant matters (e.g., personnel complaints).

(5) Shall, if it records the views, analyses, recommendations, or decisions of any agency employee in addition to the author, be given to such other employees.

(6) Shall, once completed (i.e., typed in final form, dated, and signed), not be altered, added to, or removed. Subsequent additions to, or revisions of, any such document shall be accomplished by the preparation of a new document.

(d) Memoranda or other documents prepared by agency employees not contained in the administrative file shall have no status or effect.

(e) All Food and Drug Administration employees working on a matter shall have access to the administrative file on that matter, as appropriate for the conduct of their work. Reasonable restrictions may be placed upon such access to assure the proper cataloging and storage of documents, the availability of the file to others, and the completeness of the file for review.

§ 2.17 Internal agency review of decisions.

(a) Any decision of a Food and Drug Administration employee other than the Commissioner on any matter, e.g., an informal opinion on the need for further animal toxicology tests to support a food additive regulation or new drug application, is subject to review by the employee's supervisor under any of the following circumstances:

(1) At the request of the employee,

(2) On the initiative of the supervisor.

(3) At the request of any interested person outside the agency.

(4) As required by duly promulgated delegations of authority.

(b) Such review shall be accomplished by consultation between the employee and the supervisor or by review of the administrative file on the matter, or both. Such review shall ordinarily follow the established agency channels of supervision or review for that matter.

(c) Any interested person outside the agency may request internal agency review of any such decision through the established agency channels of supervision or review for that matter. Personal review of such matters by bureau directors or the office of the Commissioner shall take place for any of the following purposes:

(1) To resolve an issue which cannot be resolved at lower levels within the agency:

(i) Between two parts of a bureau or other component of the agency, or

(ii) Between two bureaus or other components of the agency, or

(iii) Between the agency and an interested person outside the agency.

(2) To review policy matters requiring the attention of bureau or agency management.

(3) In unusual situations requiring an immediate review in the public interest.

(4) As required by duly promulgated delegations of authority.

(d) Internal agency review of any such decision shall be based upon the data and information available in the administrative file. In the event that any interested person presents new data or information not contained in such file, the matter shall be retured to the appropriate lower level within the agency for a reevaluation based upon such new information.

§ 2.18 Dissemination of draft Federal Register notices and regulations.

(a) Any representative of the Food and Drug Administration may discuss orally or in writing with any interested person ideas and recommendations for FEDERAL REGISTER notices or regulations. The Food and Drug Administration welcomes assistance in developing ideas for, and in gathering the data and information to support, notices and regulations.

(b) Once it is determined that a proposed notice or regulation will be prepared, the general concepts may be discussed by a representative of the Food and Drug Administration with any interested person. Details of a draft of a proposed notice or regulation may be discussed with any person outside the Executive Branch of the Federal Government only with the specific permission of the Commissioner. A draft of a proposed notice or regulation or its preamble, or any portion thereof, may be furnished to an interested person outside the Executive Branch of the Federal Government only if it is made available to all interested persons by a notice published in the FEDERAL REGISTER.

(c) After publication of a proposed regulation in the FEDERAL REGISTER, and before preparation of a draft of the final regulation, a representative of the Food and Drug Administration may discuss the proposal with any interested person to understand and resolve questions raised and concerns expressed about the proposal.

(d) Details of a draft of a final notice or regulation may be discussed with any interested person outside the Executive Branch of the Federal Government only with the specific permission of the Commissioner. A draft of a final notice or regulation or its preamble, or any portion thereof, may be furnished to an interested person outside the Executive Branch of the Federal Government only if it is made available to all interested persons by a notice published in the FEDERAL REGISTER, except as otherwise provided in paragraphs (g) and (j) of this section.

(1) The final notice or regulation and its preamble shall be prepared solely on the basis of the administrative record.

(2) If any additional technical information from a person outside the Executive Branch of the Federal government is necessary to draft the final notice or regulation or its preamble, it shall be requested by the Food and Drug Administration in general terms and furnished directly to the Hearing Clerk to be included as part of the administrative record.

(3) If direct discussion by the Food and Drug Administration of a draft of a final notice or regulation or its preamble is required with a person outside the Executive Branch of the Federal Government, appropriate protective procedures will be undertaken to make certain that a full and impartial administrative record is established. Such procedures may include:

(i) The scheduling of an open public meeting conducted pursuant to § 2.15(b) at which any interested person may participate in review of and comment on the draft document.

(ii) The preparation of a tentative final regulation or tentative revised final regulation pursuant to § 2.10(f)(9), on which all interested persons will be given an additional period of time for oral and written comment.

(e) After a final regulation is published in the FEDERAL REGISTER, a representative of the Food and Drug Administration may discuss any aspect of it with any interested person.

(f) In addition to the requirements of this section, the provisions of § 2.13 shall apply to the promulgation of any regulation subject to the provisions of § 2.12 and Subpart B of this Part.

(g) A draft of a final food additive, color additive, or new animal drug regulation or a proposed or final antibiotic regulation may be furnished to the petitioner for comment on the technical accuracy of such regulation. Every meeting with a petitioner relating to such a draft shall be recorded in a written

memorandum, and all such memoranda and correspondence shall be filed with the Hearing Clerk as part of the administrative record of the regulation, pursuant to the provisions of § 2.15.

(h) Pursuant to 42 U.S.C. 263f, the Commissioner is required to consult with interested persons in the development of, and with the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) before prescribing, any performance standard for an electronic product. Accordingly, the Commissioner shall publish in the FEDERAL REGISTER an announcement when a proposed or final performance standard, including any amendment thereof, is being considered for an electronic product, and thereafter any draft of any such document shall be furnished to any interested person upon request and may be discussed in detail with any interested person at any time.

(i) The provisions of § 2.15 shall apply to meetings and correspondence relating to draft FEDERAL REGISTER notices and regulations.

(j) The provisions of this section restricting discussion and disclosure of draft FEDERAL REGISTER notices and regulations shall not apply to those situations covered by §§ 4.83 through 4.89 of this chapter.

§ 2.19 Advisory opinions.

(a) Any person may request an advisory opinion from the Commissioner with respect to any matter of general applicability in which he is interested.

(1) Such request shall be granted whenever feasible.

(2) Such request may be denied if any of the following apply:

(i) The request contains incomplete information on which to base an informed advisory opinion.

(ii) The Commissioner concludes that an advisory opinion cannot reasonably be given on the matter involved.

(iii) The matter is adequately covered by a prior advisory opinion or a regulation.

(iv) The request covers a particular product or ingredient or label and does not raise a policy issue of broad applicability.

(v) The Commissioner otherwise concludes, in his discretion, that an advisory opinion would not be in the public interest.

(b) A request for an advisory opinion shall be submitted in accordance with § 2.5, shall be subject to the provisions of § 2.7(c) through (l), and shall be in the following form:

(Date)

Hearing Clerk, Food and Drug Administration, Department of Health, Education, and Welfare, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852

REQUEST FOR ADVISORY OPINION

The undersigned submits this request for an advisory opinion of the Commissioner of Food and Drugs with respect to ---------- (the general nature of the matter involved).

A. *Issues Involved.*

(A concise statement of the issues and questions on which an opinion is requested.)

B. *Statement of Facts and Law.*

(A full statement of all facts and legal points relevant to the request.)

The undersigned certifies that, to the best of his knowledge and belief, this request includes all data, information, and views relevant to the matter, whether favorable or unfavorable to the position of the undersigned, which is the subject of the request.

Very truly yours,

(Signature)

(Person making request)

(Mailing address)

(Telephone number)

(c) The Commissioner may, in his discretion, handle any oral or written request to the agency as a request for an advisory opinion, in which case the request shall be filed with the Hearing Clerk and shall be subject to the provisions of this section.

(d) Any statement of policy or interpretation made in any of the following documents shall constitute an advisory opinion:

(1) Any portion of a FEDERAL REGISTER notice other than a proposed or final regulation, e.g., a notice to manufacturers or a preamble to a proposed or final regulation.

(2) Trade Correspondence (TC) Nos. 1-431 and 1A-8A issued by the Food and Drug Administration between 1938 and 1946.

(3) Compliance Policy Guides issued by the Food and Drug Administration beginning in 1968 and codified in the Compliance Policy Guides manual.

(4) Other documents specifically identified as advisory opinions, e.g., advisory opinions on the performance standard for diagnostic x-ray systems, issued prior to July 1, 1975, and filed in a permanent public file for such prior advisory opinions maintained in the Public Records and Documents Center.

(5) Guidelines issued by the Food and Drug Administration pursuant to § 2.20 (b).

(e) An advisory opinion represents the formal position of the Food and Drug Administration on the matter involved, and except as provided in paragraph (f) of this section obligates the agency to follow it until it is amended or revoked. The Commissioner shall not recommend legal action against any person or product with respect to any action taken in conformity with an advisory opinion which has not been amended or revoked.

(f) In unusual situations involving an immediate and significant danger to health, the Commissioner may take appropriate civil enforcement action contrary to an advisory opinion issued pursuant to this section prior to amending or revoking such advisory opinion as provided in paragraph (g) of this section. Such action shall be taken only with the approval of the Commissioner, which may not be delegated. Appropriate amendment or revocation of the advisory opinion involved shall be expedited.

(g) An advisory opinion may be amended or revoked at any time after it has been issued. Notice of such amendment or revocation shall be given in the same manner in which notice was originally given of the advisory opinion or in the FEDERAL REGISTER, and in any event shall be placed on public display as part of the file on the matter in the office of the Hearing Clerk.

(h) Action undertaken or completed in conformity with an advisory opinion issued pursuant to this paragraph which has subsequently been amended or revoked shall remain acceptable to the Food and Drug Administration unless the Commissioner determines that substantial public interest considerations preclude such continued acceptance. Whenever possible, an amended or revoked advisory opinion shall state when it has been determined that action previously undertaken or completed in conformity with a prior advisory opinion does not remain acceptable, and any transition period that may be applicable.

(i) Any interested person may submit written comments on an advisory opinion or modified advisory opinion. Three copies of any comments shall be sent to the Hearing Clerk for inclusion in the public file on the advisory opinion. Such comments shall be considered in determining whether further modification of an advisory opinion is warranted.

(j) An advisory opinion may be used in administrative or court proceedings to illustrate acceptable and unacceptable procedures or standards, but not as a legal requirement.

(k) A statement made or advice provided by an employee of the Food and Drug Administration shall constitute an advisory opinion only if it is issued in writing pursuant to this section. A statement or advice given by a Food and Drug Administration employee orally, or given in writing but not pursuant to this section or § 2.20, is an informal communication that represents the best information and opinion available to that employee at that time but does not constitute an advisory opinion, does not necessarily represent the formal position of the Food and Drug Administration, and thus does not bind or otherwise obligate or commit the agency to the views expressed.

§ 2.20 Food and Drug Administration regulations, guidelines, recommendations, and agreements.

(a) *Regulations.* All Food and Drug Administration regulations having general applicability and legal effect shall be promulgated in the FEDERAL REGISTER pursuant to § 2.10 or § 2.12 and codified in the Code of Federal Regulations. Regulations may contain provisions which will be enforced as legal requirements, or which are intended only as guidelines and recommendations, or both. The dissemination of draft notices and regulations shall be subject to the provisions of § 2.17.

(b) *Guidelines.* All Food and Drug Administration guidelines having general applicability shall be included in the

public file of guidelines established by the Hearing Clerk, pursuant to this paragraph, unless they have been published in the FEDERAL REGISTER as regulations pursuant to paragraph (a) of this section.

(1) Guidelines establish principles or practices of general applicability and do not include decisions or advice limited to particular situations. Guidelines relate to such matters as performance characteristics, preclinical and clinical test procedures, manufacturing practices, product standards, scientific protocols, compliance criteria, ingredient specifications, labeling, or other technical or policy criteria. Guidelines state procedures or standards of general applicability which are not legal requirements but which are acceptable to the Food and Drug Administration for a subject matter which falls within the laws administered by the Commissioner, e.g., a protocol for a particular type of animal toxicity test or human clinical trial.

(i) A person may rely upon a guideline with assurance that it is acceptable to the Food and Drug Administration, or may follow different procedures or standards. Where a person chooses to use different procedures or standards, he may, but is in no instance required to, discuss the matter in advance with the Food and Drug Administration to prevent the expenditure of money and effort on activity that may later be determined to be unacceptable.

(ii) Use of testing guidelines established by the Food and Drug Administration assures acceptance of a test as scientifically valid, if properly conducted, but does not assure approval of any ingredient or product so tested. The results of any such test or other available information may require disapproval or that additional testing be undertaken.

(2) A guideline represents the formal position of the Food and Drug Administration on the matter involved, and except as provided in paragraph (b)(3) of this section obligates the agency to follow it until it is amended or revoked. The Commissioner shall not recommend legal action against any person or product with respect to any action taken in conformity with a guideline issued pursuant to this section that has not been amended or revoked.

(3) In unusual situations involving an immediate and significant danger to health, the Commissioner may take appropriate civil enforcement action contrary to a guideline issued pursuant to paragraph (b) of this section prior to amending or revoking such guideline as provided in paragraph (b)(5) of this section. Such action shall be taken only with the approval of the Commissioner, which may not be delegated. Appropriate amendment or revocation of the guideline involved shall be expedited.

(4) A guideline shall be included in the public file upon approval of the guideline by the relevant bureau director and publication by the Commissioner in the FEDERAL REGISTER of a notice of its availability. The notice shall state (i) the title of the guideline, (ii) the subject matter it covers, and (iii) the office or individual responsible for maintaining the guideline.

(5) A guideline may be amended or revoked upon approval of the amended guideline or revocation of the guideline by the relevant bureau director and publication by the Commissioner in the FEDERAL REGISTER of a notice of such amendment or revocation. The notice shall state (i) the title of the guideline, (ii) the subject matter it covers, and (iii) the office or individual responsible for maintaining the guideline. All original guidelines and subsequent amendments shall be retained in the public file on a permanent basis so that a complete record of the development of each guideline remains available.

(6) Action undertaken or completed in conformity with a guideline issued pursuant to paragraph (b) of this section which has subsequently been amended or revoked shall remain acceptable to the Food and Drug Administration unless the Commissioner determines that substantial public interest considerations preclude such continued acceptance. Such determination may be made at the time of or subsequent to amendment or revocation of the guideline. Whenever possible, the notice of an amended or revoked guideline published pursuant to paragraph (b)(3) of this section shall state when it has been determined that action previously undertaken or completed in conformity with a prior guideline does not remain acceptable, and any transition period that may be applicable.

(7) The notice of a guideline or amended or revoked guideline published pursuant to paragraph (b) (2) or (3) of this section shall state that any interested person may submit written comments on the guideline or amended guideline. Two copies of any comments shall be sent to the Public Records and Documents Center for inclusion in the public file on the guideline and two copies shall be sent to the office or individual designated in the notice as responsible for maintaining the guideline. Such comments shall be considered in determining whether further amendments to or reinstitution of a guideline are warranted.

(8) A guideline may be used in administrative or court proceedings to illustrate acceptable and unacceptable procedures or standards, but not as establishing a legal requirement.

(9) A statement relating to acceptable procedures or standards given by a Food and Drug Administration employee orally, or in writing but not pursuant to § 2.19 or this section, is an informal communication that represents the best information and opinion available to that employee at that time but does not constitute a guideline, does not necessarily represent the formal position of the Food and Drug Administration, and thus does not bind or otherwise obligate the agency to the views expressed.

(10) Because of the large number of analytical methods involved in Food and Drug Administration activities, their length and complexity, and the volume and frequency of amendment, the provisions of this paragraph shall not apply to such material except to the extent that the Commissioner concludes, in his discretion, that particular analytical methods should be included in the public file for a particular purpose. Food and Drug Administration analytical methods are available for public disclosure pursuant to the provisions of Part 4 of this chapter.

(11) The dissemination of draft guidelines shall be subject to the same provisions as the dissemination of draft notices and regulations pursuant to § 2.18.

(c) *Recommendations.* In addition to the guidelines subject to paragraph (b) of this section, the Food and Drug Administration often formulates and disseminates recommendations about matters which are authorized by, but do not involve direct regulatory action under, the laws administered by the Commissioner, e.g., model state and local ordinances, or personnel practices for reducing radiation exposure, issued pursuant to 42 U.S.C. 243 and 263d(b). Such recommendations may, in the discretion of the Commissioner, be handled pursuant to the procedures established in paragraph (b) of this section, except that such recommendations shall be included in a separate public file of recommendations established by the Public Records and Documents Center and shall be separated from the guidelines in the notice of availability published in the FEDERAL REGISTER, or be published in the FEDERAL REGISTER as regulations pursuant to paragraph (a) of this section.

(d) *Agreements.* All formal agreements, memoranda of understanding, or other similar written documents executed by the Food and Drug Administration and another person shall be included in the public file on agreements established by the Public Records and Documents Center pursuant to § 4.108 of this chapter. Any such document not included in the public file shall be deemed to be rescinded and shall have no force or effect whatever.

§ 2.21 Participation in outside standard-setting activities.

(a) *General.* This section applies to participation by Food and Drug Administration employees in any standard-setting activities outside the Food and Drug Administration. Standard-setting activities include such matters as the development of performance characteristics, testing methodology, manufacturing practices, product standards, scientific protocols, compliance criteria, ingredient specifications, labeling, or other technical or policy criteria. The Food and Drug Administration encourages employee participation in outside standard-setting activities that are in the public interest.

(b) *Standard-setting activities by other Federal government agencies.* (1) Any Food and Drug Administration employee may participate in such activities after the approval by the appropriate bureau director or the Commissioner of Form PHS-3763 "Request for approval of appointment as liaison representative."

(2) The Form PHS–3763 and all pertinent background information describing such activities shall be included in the public file on standard-setting activities established in the Public Records and Documents Center.

(3) If any members of the public are invited by the Food and Drug Administration to present views to, or to accompany, the Food and Drug Administration employee at any meeting, such invitations shall be extended to a representative sampling of the public, including consumer groups, industry associations, professional societies, and academic institutions.

(4) A Food and Drug Administration employee appointed as the liaison representative to such an activity shall refer all requests for information about or participation in the activity involved to the group or organization responsible for such activity.

(c) *Standard-setting activities by State and local government agencies and by United Nations organizations and other international organizations and foreign governments pursuant to treaty.* (1) Any Food and Drug Administration employee may participate in such activities after the approval by the appropriate bureau director or the Commissioner of Form PHS–3763.

(2) The Form PHS–3763 and all pertinent background information describing such activities shall be included in the public file on standard-setting activities established in the Public Records and Documents Center.

(3) The availability for public disclosure of records relating to such activities shall be governed by the regulations in Part 4 of this chapter.

(4) If any members of the public are invited by the Food and Drug Administration to present views to, or to accompany, the Food and Drug Administration employee at any meeting, such invitations shall be extended to a representative sampling of the public, including consumer groups, industry association, professional societies, and academic institutions.

(5) A Food and Drug Administration employee appointed as the liaison representative to such an activity shall refer all requests for information about or participation in the activity involved to the group or organization responsible for such activity.

(d) *Standard-setting activities by private groups and organizations.* (1) Any Food and Drug Administration employee may engage in such activities after the approval by the appropriate bureau director or the Commissioner of Form PHS–3763. A request for such official participation shall be made by the group or organization in writing, shall describe the scope of the activity involved, and shall demonstrate that the minimum standards set out in paragraph (d)(5) of this section are met by the activity involved. Except as provided in paragraph (d)(7) of this section, any such request that is granted shall be the subject of a letter from the Commissioner or the bureau director to the organization stating:

(i) Whether participation by the individual will be as a voting or nonvoting liaison representative.

(ii) That participation by the individual shall not conote Food and Drug Administration agreement with, or endorsement of, any decisions reached.

(iii) That participation by the individual disqualifies him from serving as the deciding official on the standard involved if it should later come before the Food and Drug Administration. The "deciding official" is the person who signs a document ruling upon such standard.

(2) The letter requesting official Food and Drug Administration participation, the Form PHS–3763, and the Commissioner's or bureau director's letter, together with all pertinent background information describing the activities involved, shall be included in the public file on standard-setting activities established in the Public Records and Documents Center.

(3) The availability for public disclosure of records relating to such activities shall be governed by the regulations in Part 4 of this chapter.

(4) A Food and Drug Administration employee appointed as the liaison representative to such an activity shall refer all requests for information about or participation in the activity involved to the group or organization responsible for such activity.

(5) The following minimum standards shall apply to all outside private standard-setting activities in which Food and Drug Administration employees participate.

(i) The activities shall be based upon consideration of sound scientific and technological information, shall permit revision on the basis of new information, and shall be designed to protect the public against unsafe, ineffective, or deceptive products or practices.

(ii) The activities and resulting standards shall not be designed for the economic benefit of any company, group, or organization, shall not be used as devices for such antitrust violations as fixing prices or hindering competition, and shall not involve establishment of certification or specific approval of individual products or services.

(iii) The group or organization responsible for the standard-setting activities shall have a procedure through which any interested person shall have an opportunity to provide information and views on the activities and standards involved, without the payment of fees, and such information and views shall be considered. The manner in which this is accomplished, including whether such presentation shall be in person or in writing, shall be decided by the group or organization responsible for the activities.

(6) Membership of a Food and Drug Administration employee in an organization that also conducts standard-setting activities does not invoke the provisions of this paragraph unless the employee participates in such standard-setting activities. Participation in any standard-setting activity shall be subject to the provisions of this paragraph.

(7) The Commissioner may determine in writing that, because direct involvement by the Food and Drug Administration in a particular standard-setting activity is in the public interest and will promote the objectives of the act and the agency, such participation shall be exempt from the requirements set forth in paragraph (d)(1)(ii) and/or (iii) of this section. Any such determination shall be included in the public file on standard-setting activities established by the Public Records and Documents Center and in any relevant administrative file. Such activities may include the establishment and validation of analytical methods for regulatory use, drafting uniform laws and regulations, and the development of recommendations concerning public health and preventive medicine practices by national and international organizations.

(8) Because of the close daily cooperation between the Food and Drug Administration and the associations of State and local government officials listed below, and the large number of agency employees who are members of or work with these associations, such participation in the activities of these associations shall be exempt from the provisions of paragraphs (d)(1) through (d)(7) of this section, except that a list of all committees and other groups of these associations shall be included in the public file on standard-setting activities established in the Public Records and Documents Center:

(i) Association of Food and Drug Officials.

(ii) International Association of Milk, Food and Environmental Sanitarians, Inc.

(iii) Conference of Radiation Control Program Directors.

(iv) Association of American Feed Control Officials, Inc.

(v) National Environmental Health Association.

(vi) National Conference on Weights and Measures.

(vii) American Public Health Association.

(viii) Conference of State Sanitary Engineers.

(ix) National Conference on Interstate Milk Shipments.

(x) National Shellfish Sanitation Program.

(xi) Interstate Seafood Seminar.

(xii) Association of Official Analytical Chemists.

§ 2.22 Public calendars.

(a) *Prospective public calendar of public proceedings.* (1) A public calendar shall be prepared and made publicly available each week showing, to the extent feasible, for the following 4 weeks all public meetings, public conferences, public hearings, public advisory committee meetings, public seminars, and other public proceedings of the Food and Drug Administration, and other significant public events involving the Food and Drug Administration, e.g., congressional

hearings and trial or argument of court cases.

(2) A copy of this public calendar shall be placed on public display in the following places:

(i) Office of the Hearing Clerk.

(ii) Office of the Assistant Commissioner for Public Affairs.

(iii) A central place in each bureau.

(iv) A central place in each field office.

(v) A central place at the National Center for Toxicological Research.

(b) *Retrospective public calendar of meetings.* (1) A public calendar shall be prepared and made publicly available each week showing for the previous week all meetings with persons outside the Federal government and other significant events involving the representatives of the Food and Drug Administration designated under paragraph (b)(3) of this section, except that telephone conversations shall be included on an optional basis and meetings with the working press and with on-site contractors shall not be included.

(2) Such calendar shall include all meetings, conferences, seminars, social events sponsored by the regulated industry, and speeches. The calendar shall specify the date, the person involved, and the subject matter involved. Where more than one Food and Drug Administration representative is in attendance, only the presiding or head representative shall report the meeting on the public calendar. If a large number of persons are involved, the name of each need not be specified. Meetings the existence of which would prejudice law enforcement activities (e.g., a meeting with an informant) or invade privacy (e.g., a meeting with a candidate for possible employment in the Food and Drug Administration) shall not be reported.

(3) The following Food and Drug Administration representatives and their deputies shall be subject to the requirements of paragraphs (b) (1) and (2) of this section:

(i) Commissioner of Food and Drugs.

(ii) Deputy Commissioner.

(iii) Associate Commissioners.

(iv) Assistant Commissioners.

(v) Executive Director for Regional Operations.

(vi) Director, Office of Legislative Services.

(vii) Director, National Center for Toxicological Research.

(viii) Bureau Directors.

(ix) Chief Counsel for the Food and Drug Administration.

(4) A copy of this public calendar shall be placed on public display in the following places:

(i) Office of the Hearing Clerk.

(ii) Office of the Assistant Commissioner for Public Affairs.

(iii) A central place in each bureau.

(iv) A central place in each field office.

(v) A central place at the National Center for Toxicological Research.

§ 2.23 Representation by an organization.

(a) An organization may represent its members by filing petitions, comments, and objections, and otherwise participating in any administrative proceeding subject to this Part.

(b) Any such petitions, comments, objections, or other representation by a trade association shall be on behalf of its members and shall constitute a representation on behalf of each member of the trade association, except those specifically excluded by name in any such submission.

(1) Every petition, comment, objection, or other representation by a trade association in an administrative proceeding shall have attached thereto a current list of all of the members of such trade association, or shall refer to such a list that is placed on permanent file with the Hearing Clerk and is kept current by the trade association.

(2) The filing by a trade association of an objection or request for hearing pursuant to §§ 2.110 through 2.112 shall not provide to any member any legal right with respect to such objection or request for hearing that the member may exercise in its own name. All subsequent action by the trade association with respect to such objection or request for hearing shall bind each member except to the extent that any member independently files its own objection or request for hearing.

(c) In any court proceeding in which an organization participates, the Commissioner will take appropriate legal measures to have the case brought or considered as a class action or otherwise as binding upon all members of the organization except those specifically excluded by name for the reason that the organization does not represent their views. Regardless whether the case is brought or considered as a class action or as otherwise binding upon all members of the organization except those specifically excluded by name, the Commissioner will take the position in any subsequent suit involving the same issues and any member of the organization that such issues are precluded from further litigation by such member pursuant to the doctrines of collateral estoppel or res judicata.

§ 2.24 Settlement proposals.

At any time in the course of any proceeding subject to this Part, any person may propose settlement of any of the issues involved. All participants in any proceeding shall have an opportunity to consider any proposed settlement. Unaccepted proposals of settlement and related matters, e.g., proposed stipulations not agreed to, shall not be admissible in evidence in any administrative proceeding of the Food and Drug Administration. The Food and Drug Administration will oppose the admission in evidence of any such information in any court proceeding or in any other administrative proceeding.

§ 2.25 Waiver, suspension, or modification of procedural requirements.

The Commissioner or the presiding officer, with respect to matters pending before him, may on his own initiative or at the request of any participant waive, suspend, or modify any provision in Subparts B through F of this Part applicable to the conduct of a public hearing by announcement at the hearing or by notice in advance of the hearing, if he determines that no participant will be prejudiced, the ends of justice will thereby be served, and such action is in accordance with law.

Subpart B—Formal Evidentiary Public Hearings

§ 2.100 Scope of subpart.

Subpart B governs the procedures applicable whenever any of the following applies:

(a) A person has a right to an opportunity for a hearing under the provisions of the laws administered by the Commissioner specified in § 2.12(c).

(b) The Commissioner concludes, in his discretion, that it would be in the public interest to hold a formal evidentiary public hearing on any matter, or class of matters, of importance pending before the Food and Drug Administration.

Initiation of Proceedings

§ 2.110 Initiation of a formal evidentiary public hearing involving the issuance, amendment, or revocation of a regulation.

(a) An administrative proceeding in which there is an opportunity for a formal evidentiary public hearing pursuant to sections 409(f), 502(n), 507(f), 512(n)(5), 701(e), or 706(d) of the act or sections 4 or 5 of the Fair Packaging and Labeling Act involving the issuance, amendment, or revocation of a regulation shall be initiated:

(1) By the Commissioner on his own initiative, e.g., as provided in § 121.72 for food additives, or

(2) By a petition from an interested person:

(i) In the form specified in other applicable sections in this chapter, e.g., the form for a color additive petition in § 8.4 of this chapter or the form for an antibiotic petition in § 431.50 of this chapter, or

(ii) If no form is specified in other applicable sections of this chapter, in the form specified in § 2.7.

(b) Upon receiving a petition submitted pursuant to paragraph (a)(2) of this section, the Commissioner shall:

(1) If it involves any matter subject to section 701(e) of the act or sections 4 or 5 of the Fair Packaging and Labeling Act, and meets the requirements for filing, follow the provisions of § 2.10 (b) through (f).

(2) If it relates to a color additive or food additive, and the petition meets the requirements for filing in §§ 8.4, 8.5, and 121.51 through 121.53 of this chapter, publish a notice of filing of the petition in the Federal Register within 30 days after the petition is filed in lieu of a notice of proposed rule making.

(c) The Commissioner may issue, amend, or revoke an antibiotic regulation without the requirements of notice and public procedure in § 2.10(b) or delayed effective date in § 2.10(c)(4) on his own initiative or as a result of a petition containing the required evidence of

safety and effectiveness when the regulation is technical in nature, interested persons have been consulted, and there are no significant points of controversy, or when the regulation imposes safety requirements which the Commissioner concludes are important for the public health.

(d) The notice published in the FEDERAL REGISTER promulgating the regulation shall state the time, place, and method for adversely affected persons to submit objections and requests for hearing, and that objections and requests for hearing shall be submitted in accordance with the requirements of this Part.

(e) On or before the 30th day after the date of the publication in the FEDERAL REGISTER of a final regulation, or of a notice withdrawing a proposal initiated by a petition pursuant to § 2.6(a), subject to this section, any person who would be adversely affected if such regulation were placed in effect may submit written objections thereto to the Commissioner and may make a written request for a formal evidentiary public hearing on the stated objections. This 30-day period shall not be extended by the Commissioner. In the case of any petition or proposal to issue, amend, or repeal a color additive regulation after publication of the final regulation, if referral of such petition or proposal is made to an advisory committee in accordance with section 706(b)(5)(C) of the act, written objections and requests for a hearing may be submitted on or before the 30th day after the date on which the Commissioner publishes his order confirming or modifying his previous order.

§ 2.111 Initiation of a formal evidentiary public hearing involving the issuance, amendment, or revocation of an order.

(a) An administrative proceeding in which there is an opportunity for a formal evidentiary public hearing pursuant to sections 505 (d) or (e), 512 (d), (e), (m)(3), or (m)(4) of the act, or section 351(a) of the Public Health Service Act, involving the issuance, amendment, or revocation of an order shall be initiated:

(1) By the Commissioner on his own initiative, or

(2) By a petition submitted in the form specified in other applicable sections in this chapter, e.g., § 314.1(c) for new drug applications, § 514.1 for new animal drug applications, § 514.2 for applications for animal feeds, or § 601.3 for licenses for biologic products, or

(3) By a petition from an interested person in the form specified in § 2.7.

(b) A notice of opportunity for hearing on any proposal to deny or revoke approval of an order or any part thereof shall be published in the FEDERAL REGISTER together with an explanation of the grounds for the proposed action. The notice of opportunity for hearing shall state the time, place, and method for adversely affected persons to submit requests for hearing, and that requests for hearing shall be submitted in accordance with the requirements of this Part. The applicant for or holder of the approval or license that is the subject of the order in question and all other persons subject to the notice shall have 30 days after issuance of the notice within which to request a hearing on the proposed action pursuant to the provisions of §§ 314.200, 514.200, and 601.7(a) of this chapter. This 30-day period shall not be extended by the Commissioner.

(c) In considering the issuance, amendment, or revocation of an order, the Commissioner may use any applicable optional procedure specified in § 2.7(g).

§ 2.112 Filing objections and requests for a hearing on a regulation or order.

(a) Objections to agency action and requests for a hearing submitted pursuant to § 2.110(d) shall be submitted to the Hearing Clerk and shall be accepted for filing if they comply with all of the following conditions:

(1) Objections and requests for a hearing shall be submitted on or before the day specified in § 2.110(d).

(2) Each objection to a specific provision of the Commissioner's regulation or proposed order shall be separately numbered.

(3) Each numbered objection shall specify with particularity the provision of the regulation or proposed order to which objection is made.

(4) Each numbered objection on which a hearing is requested shall specifically so state. The failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection.

(5) Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. The failure to include such description and analysis for any particular objection shall constitute a waiver of the right to a hearing on that objection, but such description and analysis shall be used only for the purpose of determining whether a hearing has been justified pursuant to § 2.113 and shall not limit the evidence that may be presented if a hearing is granted.

(i) A copy of any report, article, survey, or other written document relied upon shall be submitted.

(ii) A summary of the nondocumentary testimony to be presented by any witnesses relied upon shall be submitted.

(b) Requests for hearing submitted pursuant to § 2.111(b) shall be submitted to the Hearing Clerk and shall be accepted for filing if they comply with all of the following conditions:

(1) Requests for hearing shall be submitted on or before the 30th day after the date of publication of the notice of opportunity for hearing in the FEDERAL REGISTER.

(2) Requests for hearing shall comply with the requirements specified in §§ 314.200, 514.200, and 601.7(a) of this chapter.

(c) Any objection or request for a public hearing which meets the requirements of this section shall be filed by the Hearing Clerk in the relevant docket file. If an objection or request for a public hearing fails to meet the requirements of this section and the deficiency becomes known to the Hearing Clerk, the Hearing Clerk shall return it with a copy of the applicable regulations, indicating those provisions not complied with. A deficient objection or request for a hearing may be supplemented and subsequently filed if submitted within the 30-day time period specified in § 2.110(d) or § 2.111(b).

(d) If an objection to a regulation issued pursuant to a petition submitted pursuant to § 2.110(a)(2) is submitted by a person other than the petitioner and is filed by the Hearing Clerk, the petitioner may submit a written reply thereto to the Hearing Clerk.

§ 2.113 Ruling on objections and requests for hearing.

(a) As promptly as is feasible the Commissioner shall review all objections and requests for hearing filed pursuant to § 2.112 and shall determine:

(1) Whether any of the objections or requests for hearing filed justify modification or revocation of the regulation or order involved pursuant to § 2.114.

(2) If a formal evidentiary public hearing has been requested, whether it has been justified as required by this section.

(3) If a public hearing has been requested before a Public Board of Inquiry pursuant to Subpart C of this Part, or before a public advisory committee pursuant to Subpart D of this Part, or before the Commissioner pursuant to Subpart E of this Part, whether it has been justified.

(b) A request for a formal evidentiary public hearing shall be granted on a matter involving the issuance, amendment, or revocation of a regulation or order if, based upon the data, information, and views contained in his objection and request for hearing, a person has shown that all of the following are true:

(1) There is a genuine and substantial issue of fact for resolution at a hearing. A hearing will not be granted on issues of policy or law.

(2) The factual issue is capable of being resolved by available and specifically identified reliable evidence. A hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions.

(3) The data and information identified in the objection and request for hearing, if established at a hearing, would be adequate to justify resolution of the factual issue in the way sought by the person. A hearing will be denied if the Commissioner concludes that, even assuming the truth and accuracy of all of the data and information submitted in support of the objection and request for hearing, they are insufficient to justify the factual determination urged.

(4) Resolution of the factual issue in the way sought by the person is adequate to justify the action requested. A hearing

will not be granted on factual issues that are not determinative or controlling with respect to the action requested, e.g., when the Commissioner concludes that his action would be the same even if the factual issue were resolved in the way sought, or in the case of a request that a final regulation include a provision not reasonably encompassed within the proposal. A hearing will be granted upon proper objection and request for hearing when a food standard or other regulation is shown to have the effect of excluding or otherwise affecting a product or ingredient, but not when such standard or regulation does not have such an effect.

(5) The action requested is not on its face inconsistent with or in violation of any provision in the act or any regulation in this chapter particularizing statutory standards. The proper procedure in such circumstances is for the person requesting the hearing to petition for an amendment or waiver of the regulation involved, e.g., a hearing will be denied with respect to withdrawal of approval of a new drug application which is not in compliance with an applicable OTC drug monograph promulgated pursuant to the procedures established in Part 330 of this chapter or which is not supported by evidence of effectiveness meeting the requirements of §§ 314.111(a)(5) and 330.10(a)(4)(ii) of this chapter on the ground that the procedure is to petition for an amendment to the monograph pursuant to § 330.10(a)(11) of this chapter or to obtain approval of a deviation pursuant to § 330.11 of this chapter, or to request a waiver of the requirements for proof of effectiveness as provided in §§ 314.111(a)(5) and 330.10(a)(4)(ii) of this chapter.

(6) All of the conditions and requirements specified in other applicable provisions of this chapter, e.g., §§ 2.5, 2.111, 2.112, 314.200, 430.20(b), 514.200, and 601.7(a), and in the notice promulgating the final regulation or the notice of opportunity for hearing are fully met.

(c) In making his determination pursuant to paragraph (a) of this section, the Commissioner may use any of the optional procedures specified in § 2.7(g) and in other applicable provisions of this chapter, e.g., §§ 314.200, 430.20(b), 514.200, and 601.7(a).

(d) Where a person files an objection and request for hearing pursuant to §§ 2.110 through 2.112 relating to a regulation or order, it is uncertain whether a hearing has been justified pursuant to the principles established in paragraph (b) of this section, and the Commissioner concludes that summary decision against the person requesting a hearing should be considered, he may serve upon such person by registered mail a proposed order denying a hearing. Such person shall have 30 days after receipt of such proposed order to demonstrate that the submission justifies a hearing.

§ 2.114 Modification or revocation of regulation or order.

If the Commissioner determines upon review of an objection or request for hearing filed pursuant to §§ 2.110 through 2.112 that the regulation or order involved in the proceeding should properly be modified or revoked, he shall promptly issue a notice of such modification or revocation in the FEDERAL REGISTER. Further objections or requests for hearing may be submitted to such modification or revocation, but not to any other provisions in the regulation or order, pursuant to §§ 2.110 through 2.112.

§ 2.115 Denial of formal evidentiary public hearing in whole or in part.

If the Commissioner determines upon review of the objections or requests for hearing filed pursuant to §§ 2.110 through 2.114 that a formal evidentiary public hearing is not justified, in whole or in part, he shall publish a notice of such determination in the FEDERAL REGISTER.

(a) The notice shall state whether the hearing is denied in whole or in part. If the hearing is denied in part, the notice shall be combined with the notice of hearing required by § 2.118, and shall specify the objections and requests for hearing which have been granted and denied.

(1) Any determination denying a hearing in whole or in part shall specify in detail the reasons therefor. If such determination rests upon an analysis of the data and information submitted to justify a hearing, the inadequacy of such data and information submitted shall be explained.

(2) The notice shall confirm or modify or stay the effective date of the regulation or order involved.

(b) The record of the administrative proceeding relating to denial of a public hearing in whole or in part on any objection and request for hearing shall consist of all of the following:

(1) If the proceeding involves the issuance, amendment, or revocation of a regulation:

(i) All of the documents specified in § 2.10(g).

(ii) All objections and requests for hearing filed by the Hearing Clerk with respect to such regulation pursuant to §§ 2.110 and 2.112.

(iii) If it involves a color additive regulation which was referred to an advisory committee in accordance with section 706(b)(5)(C) of the act, the complete administrative record of the advisory committee proceedings and its report on the matter.

(iv) The notice denying a formal evidentiary public hearing published in the FEDERAL REGISTER.

(2) If the proceeding involves the issuance, amendment, or revocation of an order:

(i) The notice of opportunity for hearing.

(ii) All requests for hearing filed by the Hearing Clerk with respect to such order pursuant to §§ 2.111 and 2.112 of this chapter.

(iii) The record, consisting of the transcripts, minutes of meetings, reports, FEDERAL REGISTER notices, and other documents, resulting from any of the optional procedures specified in § 2.113(c), except that it shall not include the transcript of any closed portion of any public advisory committee meeting.

(iv) The notice denying a formal evidentiary public hearing published in the FEDERAL REGISTER.

(c) The administrative record specified in paragraph (b) of this section shall constitute the exclusive record for the Commissioner's decision on denial of a formal evidentiary public hearing in whole or in part. The record of the administrative proceeding shall be closed as of the date of the Commissioner's decision unless some other date for the closing of the record is specified by the Commissioner. Thereafter any person who requested and was denied a hearing may submit a petition for reconsideration pursuant to § 2.8 and a petition for stay of action pursuant to § 2.9. Any person who wishes to rely upon data, information, or views not included in the administrative record shall submit it to the Commissioner with a new petition to modify the final regulation or order pursuant to § 2.6(a).

(d) Any determination denying a request for a formal evidentiary public hearing in whole or in part by any person who has an opportunity for such a hearing under the provisions of the laws administered by the Commissioner specified in § 2.12(c) constitutes final agency action reviewable in the courts, pursuant to the specific statutory provisions governing the matter involved, as of the date of publication in the FEDERAL REGISTER of the denial of the public hearing in whole or in part.

(1) Before requesting an order from a court for relief pending review, any person seeking judicial review shall first submit a petition for a stay of action pursuant to § 2.9.

(2) The Food and Drug Administration will request consolidation in a single court of all petitions for judicial review related to a particular matter pursuant to 28 U.S.C. 2112(a).

(3) The time for filing a petition for judicial review of a determination by the Commissioner denying a public hearing on a particular objection or issue shall begin as of the date of publication in the FEDERAL REGISTER of the Commissioner's determination. The failure to file such a petition within the period established in the specific statutory provisions governing the matter involved shall constitute a waiver of the right to judicial review of that objection or issue at any later time, regardless whether a hearing has been granted on other objections and issues.

§ 2.116 Judicial review after waiver of hearing on a regulation.

(a) Any person who has a right to submit objections and a request for hearing pursuant to § 2.110(d) may instead submit objections and waive the right to request a hearing. Such waiver may consist either of an explicit statement waiving such right, or of a failure to request a hearing as provided in § 2.112(a)(4).

(b) Where any person submits an objection and waives the right to request a hearing, the Commissioner shall rule

upon such objection pursuant to §§ 2.113 through 2.115. The Commissioner may, in his discretion, order a hearing on the matter pursuant to any of the provisions of this Part regardless whether a hearing is requested.

(c) If, after the notice published by the Commissioner in the FEDERAL REGISTER ruling upon any such objection, no hearing is granted with respect to the matters covered by such objection, and the Commissioner rules adversely on such objection, the person may petition for judicial review of the Commissioner's ruling on such objection in a United States Court of Appeals pursuant to the applicable provisions in the act.

(1) The record for judicial review shall be the record designated in § 2.115 (b)(1).

(2) The time for filing such a petition for judicial review shall begin as of the date of publication in the FEDERAL REGISTER of the Commissioner's ruling on such objection.

§ 2.117 Request for alternative form of public hearing.

(a) A person who has a right to an opportunity for a hearing under this Subpart B may waive that opportunity and in lieu thereof request one of the following alternative forms of public hearing:

(1) A public hearing before a Public Board of Inquiry pursuant to Subpart C of this Part.

(2) A public hearing before a public advisory committee pursuant to Subpart D of this Part.

(3) A public hearing before the Commissioner pursuant to Subpart E of this Part.

(b) Any such request:

(1) May be on his own initiative or at the suggestion of the Commissioner.

(2) Shall be submitted in writing to the Hearing Clerk pursuant to § 2.7.

(3) Shall be submitted at any time prior to publication of a notice of hearing pursuant to § 2.118 or a denial of hearing pursuant to § 2.115.

(4) Shall be:

(i) In lieu of a request for a hearing under this Subpart B, or

(ii) If submitted after or with a request for a hearing under this Subpart B, in the form of a waiver of the right to an opportunity for such a hearing conditioned upon an alternative form of public hearing. Upon acceptance by the Commissioner, such a waiver becomes binding and can thereafter be withdrawn only by waiving any right to any form of a hearing unless the Commissioner for good cause determines otherwise.

(c) Where more than one person has requested and justified a hearing under this Subpart B, an alternative form of hearing will be used only if all such persons concur and waive their right to an opportunity for a hearing under this Subpart B.

(d) The Commissioner will determine whether an alternative form of public hearing should be used, and if so which alternative will be acceptable to him, after considering the requests submitted and the appropriateness of the alternative forms of public hearing for the issues raised in the objections. Upon acceptance by the Commissioner, such acceptance becomes binding upon him unless the Commissioner for good cause determines otherwise.

(e) The Commissioner shall publish in the FEDERAL REGISTER a notice of hearing announcing an alternative form of public hearing pursuant to this section, setting forth the following information:

(1) A statement of the provisions of the regulation or order which is the subject of the public hearing.

(2) A statement specifying any part of the regulation or order which has been stayed.

(i) Any part of a regulation or order which is subject to an opportunity for a hearing under this Subpart B pursuant to statutory provisions under which the filing of proper objections and a request for hearing automatically stays the regulation or order, and for which a public hearing has been granted, shall be stayed.

(ii) The Commissioner may, in his discretion, stay in whole or in part any regulation or order which is not required by statute to be stayed.

(3) The time, date, and place of the hearing, or a statement that such information shall be contained in a subsequent notice published in the FEDERAL REGISTER.

(4) The names of the parties to the public hearing.

(5) A statement of the issues to be considered at the public hearing. The statement of the issues determines the scope of the public hearing.

(6) If the public hearing will be conducted by a Public Board of Inquiry:

(i) The time within which the parties may submit nominees for the Board pursuant to § 2.203(b).

(ii) The time within which appearances shall be filed by any person who wishes to participate in the proceeding. An appearance shall be filed in the form and pursuant to the requirements specified in § 2.131.

(iii) The time within which participants shall submit written data and information pursuant to § 2.205. The notice shall list the contents of the portions of the administrative record of the proceeding as of that time relevant to the issues to be considered at the public hearing before the Board, and shall state that such portions have been placed on public display in the office of the Hearing Clerk and that additional copies of any material already submitted pursuant to § 2.205 need not be included with any later submissions by participants in the proceeding.

(7) If the public hearing will be conducted by a Public Board of Inquiry or a public advisory committee, a statement whether the findings and conclusions resulting from such public hearing shall have the legal status and be handled as a recommended decision or as an initial decision pursuant to § 2.180. If the notice of hearing is silent on this matter, the findings and conclusions shall be an initial decision.

(f) The findings and conclusions resulting from a public hearing before a Public Board of Inquiry or a public advisory committee pursuant to this section shall have the same legal status and be handled as a recommended decision or an initial decision of a presiding officer issued pursuant to § 2.180, as determined by the notice of hearing published pursuant to paragraph (e) of this section. The findings and conclusions resulting from a public hearing before the Commissioner pursuant to this section shall have the same legal status and be handled as a tentative order issued pursuant to § 2.181. Thereafter, the participants in the proceeding may pursue the administrative and court remedies that are available as specified in §§ 2.180 through 2.191.

(g) If a public hearing before a public advisory committee pursuant to Subpart D of this Part or a public hearing before the Commissioner pursuant to Subpart E of this Part is used as an alternative form of hearing pursuant to this section, all submissions relating to the hearing which constitute the administrative record of the hearing shall be made to the Hearing Clerk and the provisions of § 2.5(j) shall govern the availability of such submissions for public examination and copying.

§ 2.118 Notice of hearing; stay of action.

(a) If the Commissioner determines upon review of the objections and requests for hearing filed pursuant to §§ 2.110 through 2.114 that a formal evidentiary public hearing has been justified on any issue, he shall publish a notice of such determination in the FEDERAL REGISTER, setting forth the following information:

(1) A statement of the provisions of the regulation or order which is the subject of the formal evidentiary public hearing.

(2) A statement specifying any part of the regulation or order that has been stayed.

(i) Any part of a regulation or order which is subject to an opportunity for a hearing under this Subpart B pursuant to statutory provisions under which the filing of proper objections and a request for hearing automatically stays the regulation or order, and for which a hearing has been requested and justified, shall be stayed.

(ii) The Commissioner may, in his discretion, stay in whole or in part any regulation or order which is not required by statute to be stayed.

(3) The names of the parties to the formal evidentiary public hearing.

(4) A statement of the issues of fact raised by the objections and request for hearing as to which a hearing has been justified.

(5) A statement of any objections or requests for hearing as to which a hearing has not been justified, which shall be subject to the provisions of § 2.115.

(6) The designation of the presiding officer to conduct the hearing or a statement that the presiding officer will be designated in a subsequent notice.

(7) The time within which notices of appearance shall be filed pursuant to § 2.131.

(8) The date, time, and place when the prehearing conference will commence or a statement that such date, time, and place will be announced in a subsequent notice. The prehearing conference shall not commence until after the time for disclosure of data and information specified in § 2.153 has expired.

(9) The time within which participants shall submit written data, information, and views pursuant to § 2.153. The notice shall list the contents of the portions of the administrative record of the proceeding as of that time relevant to the issues to be considered at the public hearing and shall state that such portions have been placed on public display in the office of the Hearing Clerk and that additional copies of any material already submitted pursuant to § 2.153 need not be included with any later submissions by participants in the proceeding.

(10) Whether the presiding officer will prepare a recommended decision or an initial decision pursuant to §§ 2.180 through 2.184.

(b) The statement of the issues of fact raised by the objections or request for hearing as to which a hearing has been justified determines the scope of the formal evidentiary public hearing and the matters as to which the development of evidence will be permitted. The statement of the issues of fact may be revised by order of the presiding officer, except that it shall not be revised to include any issue as to which the Commissioner has not granted a hearing.

(c) A formal evidentiary public hearing shall be deemed to commence as of the date of publication of the notice of hearing in the FEDERAL REGISTER.

§ 2.119 Effective date of a regulation.

(a) If no objections are filed and no hearing is requested on a regulation pursuant to § 2.110(e), the regulation shall be effective on the date specified in the notice promulgating it.

(b) The Commissioner shall publish a notice in the FEDERAL REGISTER stating that fact. Such notice may extend the time for compliance with the regulation.

§ 2.120 Effective date of an order.

(a) If a person who is subject to a notice of opportunity for hearing published in the FEDERAL REGISTER pursuant to § 2.111(b) does not request a hearing, the Commissioner:

(1) Shall issue a final order published in the FEDERAL REGISTER withdrawing approval of an NDA, NADA, or biologics license, in whole or in part, and establishing the effective date of such final order.

(2) If the final order involves an NADA, shall forthwith revoke, in whole or in part, the applicable regulation pursuant to section 512(i) of the act.

(b) If a person who is subject to a notice of opportunity for hearing published in the FEDERAL REGISTER pursuant to § 2.111(b) requests a hearing and others do not, the Commissioner may issue a final order covering all such drug products at once or may issue more than one final order covering different drug products at different times.

APPEARANCE AND PRACTICE

§ 2.130 Appearance.

(a) Any interested person may appear in person or by or with counsel or other duly qualified representative in any formal evidentiary public hearing and, subject to § 2.155, may be heard with respect to all matters relevant to the issues under consideration.

(b) Any person appearing in a representative capacity in any such hearing shall submit a signed statement of authorization or other documentation verifying his authority to do so.

§ 2.131 Written notice of appearance.

(a) Any interested person desiring to appear at any formal evidentiary public hearing shall, within 30 days after publication of the notice of hearing in the FEDERAL REGISTER pursuant to § 2.117, file with the Hearing Clerk in accordance with § 2.5 a written notice of appearance in the form specified in paragraph (b) of this section. The notice shall state with particularity the person's interest in the proceeding and shall set forth the issues on which the person desires to be heard.

(b) The form of the written notice of appearance shall be as follows:

(Date)

Hearing Clerk, Food and Drug Administration, Department of Health, Education, and Welfare, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852

NOTICE OF APPEARANCE

Docket No. ------

Pursuant to the provisions of 21 CFR Part 2, Subpart B, governing the procedure in this matter, please enter the appearance of:

(Name)

(Street address)

(City and State)

(Telephone number)

on behalf of:

(Name)

(Street address)

(City and State)

(Telephone number)

The following statements are made as part of this notice of appearance.

A. *Specific Interest.* (A statement of the specific interest of the person in the proceeding, including the specific issues of fact concerning which the person desires to be heard.)

B. *Commitment to Participate.* (A statement that the person will present documentary evidence or testimony at the hearing and will comply with the requirements of 21 CFR 2.153, or, in the case of a hearing before a Public Board of Inquiry, with the requirements of 21 CFR 2.205.)

C. *Statement of Representation.* (If the person is appearing in a representative capacity, a statement that he is authorized to do so. A signed statement of authorization or other documentation verifying his authority shall be attached.)

(Signed)

(c) All notices, pleadings, documents, and other submissions to be served upon a person in the course of the hearing pursuant to § 2.151 shall be mailed to the address shown in the notice of appearance or delivered in person to the person specified in the notice of appearance.

(d) A written notice of appearance may be amended by filing a new written notice of appearance and serving it upon all participants in the hearing.

(e) No person may participate in any aspect or at any stage of a formal evidentiary public hearing if he has not filed a written notice of appearance or if his notice of appearance has been stricken pursuant to paragraph (g) of this section.

(f) The presiding officer may, upon motion, permit a person to file a written notice of appearance in the hearing after the 30-day time period for filing such notices has expired, but only upon a showing of good cause as to why such a notice was not filed within such time period.

(g) The presiding officer may strike the appearance of any person, after giving him an opportunity to show cause why his appearance should not be stricken, for nonparticipation in the hearing, for failure to comply with any requirement of this subpart, e.g., disclosure of information as required by § 2.153 or the prehearing order issued pursuant to § 2.158, or for violation of the rules of conduct established in § 2.156. Any person whose appearance has been stricken may petition the Commissioner for interlocutory review of such action.

PRESIDING OFFICER

§ 2.140 Presiding officer.

A presiding officer shall preside over every formal evidentiary public hearing held pursuant to this subpart. The presiding officer shall be the Commissioner, a member of the office of the Commissioner to whom the Commissioner has delegated the responsibility for the matter involved, or an Administrative Law Judge qualified under 5 U.S.C. 3105 and designated by the Commissioner to conduct the hearing in the notice of hearing or in a later notice published pursuant to § 2.118(a)(6) of this chapter.

§ 2.141 Commencement of functions.

The functions of the presiding officer shall commence upon his designation and terminate upon the forwarding of the recommended decision or the filing of the initial decision pursuant to § 2.180.

§ 2.142 Authority of presiding officer.

The presiding officer shall have the authority and duty to conduct a fair and expeditious hearing and to maintain order. He shall have all powers necessary

to these ends, including, but not limited to, the power to:

(a) Arrange and issue notice of the date, time, and place of oral hearings and conferences and, upon proper notice, to change the date, time, and place of oral hearings and conferences previously set.

(b) Establish the methods and procedures to be used in the development of evidentiary facts, including the procedures specified in § 2.158(b) and to rule upon the need for oral testimony and cross-examination pursuant to § 2.154 (b).

(c) Prepare, after considering the views of the participants, written statements of areas of factual disagreement among the participants.

(d) Hold conferences to settle, simplify, or determine the issues in a hearing or to consider other matters that may facilitate the expeditious disposition of the hearing.

(e) Administer oaths and affirmations.

(f) Regulate the course of the hearing and govern the conduct of participants therein.

(g) Examine witnesses and inform witnesses that they must fully respond to all questions or have all of their testimony stricken.

(h) Rule on, admit, exclude, or limit evidence.

(i) Establish the time for filing motions, petitions, briefs, findings, or other submissions.

(j) Rule on motions and other procedural matters pending before him.

(k) Rule on motions for summary decision in accordance with § 2.159.

(l) Order that the hearing be conducted in stages in cases where the number of parties is large or the issues are numerous and complex.

(m) Waive, suspend, or modify any rule in this subpart pursuant to § 2.25 if he determines that no party will be prejudiced, the ends of justice will be thereby served, and such action is in accordance with law.

(n) Strike the appearance of any person pursuant to § 2.131(g) or exclude any person from the hearing pursuant to § 2.156 or otherwise take reasonable disciplinary action.

(o) Take any action permitted to the presiding officer as authorized by this Subpart B or in conformance with law for the maintenance of order at the hearing and for the expeditious, fair, and impartial conduct of the proceeding.

§ 2.143 Disqualification of presiding officer.

(a) Any participant in the proceeding may, by motion made to the presiding officer, request that the presiding officer disqualify himself and withdraw from the proceeding. The presiding officer shall rule upon any such motion and shall promptly certify the motion and his ruling thereon to the Commissioner for interlocutory review.

(b) A presiding officer shall withdraw from any proceeding in which he deems himself disqualified for any reason.

§ 2.144 Unavailability of presiding officer.

(a) In the event that the presiding officer is unable to act for any reason whatever, the powers and duties to be performed by him in connection with any proceeding shall be assigned by the Commissioner to another presiding officer. Such substitution shall have no effect on any aspect of the hearing, except as the new presiding officer may order pursuant to the provisions of this subpart.

(b) Any motion predicated upon such substitution shall be made within 10 days thereafter.

HEARING PROCEDURES

§ 2.150 Filing and service of submissions.

(a) All submissions, including pleadings, relating to a formal evidentiary public hearing shall be filed with the Hearing Clerk pursuant to § 2.5.

(b) A copy of each such submission shall be served by the person making the submission upon each other participant in the proceeding, except that submissions of documentary data and information may but are not required to be served upon each participant. Any transmittal letter, pleading, summary, statement of position, certification pursuant to paragraph (d) of this section, or other similar document accompanying a submission of documentary data and information shall be served upon each participant pursuant to this paragraph.

(c) Service pursuant to this section shall be accomplished by mailing it to the address shown in the notice of appearance or by personal delivery.

(d) All submissions pursuant to this section shall be accompanied by a signed certification stating the extent to which the submission has been served on each participant, or is exempt from such service, pursuant to paragraph (b) of this section.

(e) No written submission or other portion of the administrative record shall be held in confidence, except as provided in § 2.171.

§ 2.151 Petition to participate in forma pauperis.

(a) Any participant who believes that compliance with the filing and service requirements of this section constitutes an unreasonable financial burden shall submit to the Commissioner a petition to participate in forma pauperis.

(b) Such petition shall be pursuant to § 2.7, except that the heading shall be "REQUEST TO PARTICIPATE IN FORMA PAUPERIS, DOCKET NO. _____." Pursuant to the guidelines established in § 4.43 (b) and (c) of this chapter, such petition shall demonstrate that either (i) the person is indigent and his participation has a strong public interest justification, or (ii) such participation is in the public interest because it can be considered primarily as benefiting the general public.

(c) The Commissioner may, in his discretion, grant or deny such petition. If such petition is granted, the participant may file only one copy of each submission with the Hearing Clerk, and it shall be the responsibility of the Hearing Clerk, at agency expense, to make sufficient additional copies for the administrative record and to serve a copy upon each other participant.

§ 2.152 Advisory opinions.

Prior to or during the pendency of any formal evidentiary public hearing any person may request the Commissioner for an advisory opinion as to the applicability to a specific situation of any regulation or order under consideration in an administrative proceeding. Requests for such opinions shall be made pursuant to § 2.19.

§ 2.153 Disclosure of data and information by the participants.

(a) Before the notice of hearing is published pursuant to § 2.118, the director of the bureau responsible for the matters involved in the hearing shall submit to the Hearing Clerk:

(1) The relevant portions of the administrative record of the proceeding up to that time. Those portions of the administrative record of the proceeding which are not relevant to the issues to be considered at the public hearing shall not be placed on public display and shall not be part of the administrative record of that proceeding.

(2) All documents in his files containing factual data and information, whether favorable or unfavorable to his position, which relate to the issues involved in the hearing.

(3) All other documentary data and information on which he relies.

(4) A narrative statement of his position on the factual issues stated in the notice of hearing and the type of evidence he intends to introduce in the hearing in support of his position.

(5) A signed statement that, to the best of his knowledge and belief, the submission complies with the requirements of this section.

(b) Within 60 days after the notice of hearing is published in the FEDERAL REGISTER pursuant to § 2.118, each participant shall submit to the Hearing Clerk all data and information specified in paragraphs (a)(2) through (5) of this section, and any objections with respect to the completeness of the administrative record filed pursuant to paragraph (a)(1) of this section.

(c) The submissions required by paragraphs (a) and (b) of this section may be supplemented later in the proceeding, with the approval of the presiding officer, upon a showing that the material contained in the supplement was not reasonably known or available when the submission was made or that the relevance of the material contained in the supplement could not reasonably have been foreseen at that time.

(d) The failure to comply with the provisions of this section in the case of a participant shall constitute a waiver of the right to participate further in the hearing and in the case of a party shall also constitute a waiver of the right to a hearing.

(e) Any documentary data and information submitted by one participant may be referenced by another. Participants are encouraged to exchange and consolidate lists of documentary evidence prior to reproducing it for submission to the Hearing Clerk in order to reduce duplicative submissions. If a particular document is bulky or is in limited supply and cannot reasonably be reproduced, and it constitutes relevant evidence, a participant may request the presiding officer for permission to submit a reduced number of copies to the Hearing Clerk.

(f) The presiding officer shall rule on questions relating to this section.

§ 2.154 Purpose; oral and written testimony; burden of proof.

(a) A formal evidentiary public hearing is held for the purpose of receiving evidence relating to an issue of fact determining the validity of a regulation or order subject to such a hearing. The objective of such a hearing is the fair determination of facts in a manner consistent with the right of all interested persons to participate and the public interest in expeditiously concluding controversies over matters affecting the public health and welfare.

(b) To achieve this objective, the evidence at a formal evidentiary public hearing shall be developed to the maximum feasible extent through written submissions, including written direct testimony which may be in narrative or in question-and-answer form, written cross-examination, and such other methods for the testing and proper evaluation of factual propositions as the presiding officer determines are necessary for a full and true disclosure of relevant evidentiary facts.

(1) In a hearing held pursuant to section 409(f), 502(n), 507(f), 512(n), 701(e), or 706(d) of the act or section 4 or 5 of the Fair Packaging and Labeling Act involving the issuance, amendment, or revocation of a regulation:

(i) All direct testimony shall be submitted in writing, except upon a showing that written direct testimony is insufficient to adduce testimony for a full and true disclosure of relevant evidentiary facts and that the participant will be prejudiced by denial of a request to present oral direct testimony.

(ii) Oral cross-examination of witnesses shall be permitted only upon a showing that the cross-examination requested is necessary because alternative means of developing relevant evidentiary facts are insufficient to adduce testimony required for a full and true disclosure of relevant evidentiary facts, and that the party requesting an opportunity for oral cross-examination will be prejudiced by denial of the request.

(2) In a hearing held pursuant to section 505 (d) or (e) or 512 (d), (e), (m) (3), or (4) of the act, or section 351 (a) of the Public Health Service Act, involving the issuance, amendment, or revocation of an order, the issues may have general applicability and depend upon general facts that do not concern any particular action of a specific party, e.g., the safety or effectiveness of a class of drug products, or may have specific applicability to part action and depend upon particular facts concerning only that party, e.g., the applicability of a grandfather clause to a particular brand of a drug or the failure of a particular manufacturer to meet required manufacturing and processing specifications or other general standards.

(i) Where the proceeding involves general issues, all direct testimony shall be submitted in writing, except upon a showing that written direct testimony is insufficient to adduce testimony for a full and true disclosure of relevant evidentiary facts and that the participant will be prejudiced by denial of a request to present oral direct testimony. Where the proceeding involves particular issues, each party shall determine whether, and the extent to which, he wishes to present his direct testimony orally or in writing.

(ii) Oral cross-examination of witnesses shall be permitted only upon a showing that the cross-examination requested is necessary because alternative means of developing relevant evidentiary facts are insufficient to adduce testimony required for a full and true disclosure of relevant evidentiary facts, and that the party requesting opportunity for oral cross-examination will be prejudiced by denial of the request.

(3) All oral and written testimony of witnesses shall be under oath.

(c) In considering whether a request for cross-examination of a particular witness has been justified, the presiding officer shall take into account the following factors:

(1) The extent to which a full and true disclosure with respect to any disputed issue of fact can be achieved through the presentation of additional direct evidence.

(2) The extent to which there are circumstantial guarantees of the trustworthiness of the direct evidence sought to be made the subject of cross-examination.

(3) Whether the particular person's testimony sought to be made the subject of cross-examination is required for the resolution of any disputed issue of fact.

(4) Whether a dispute concerns facts in contrast to the inferences and conclusions to be drawn from the facts.

(5) Whether the direct evidence sought to be made the subject of cross-examination is relevant and material to the issues of fact as to which the hearing has been justified.

(d) Except as provided in paragraph (e) of this section, in any formal evidentiary public hearing involving the issuance, amendment, or revocation of a regulation or order, the originator of the proposal or petition or of any significant modification thereof shall be, within the meaning of 5 U.S.C. 556(d), the proponent of the regulation or order, and accordingly shall have the burden of proof. Any participant who proposes the substitution of a new provision for a provision objected to shall have the burden of proof in relation to the new provision so proposed.

(e) At any formal evidentiary public hearing involving the issuance, amendment, or revocation of a regulation or order relating to the safety or effectiveness of a drug, food additive, or color additive, the participant who is contending that the product is safe or effective or both and who is requesting approval or contesting withdrawal of approval shall have the burden of proof in establishing safety or effectiveness or both and thus the right to approval. The burden of proof remains on such participant in an amendment or revocation proceeding.

§ 2.155 Participation of nonparties.

(a) A nonparty participant shall have the right:

(1) To attend all conferences (including the prehearing conference), oral proceedings, and arguments held in connection with or as part of a formal evidentiary public hearing.

(2) To submit written testimony and documentary evidence for inclusion in the record.

(3) To file written objections, briefs, and other pleadings.

(4) To present oral argument.

(b) A nonparty participant shall not have the right:

(1) To submit written interrogatories.

(2) To conduct cross-examination.

(c) Any person whose petition is the subject of the hearing shall have the same rights as a party.

(d) The presiding officer may, in his discretion, permit a nonparty participant additional rights when he concludes that the participant's interests would not be adequately protected otherwise or that broader participation is required for a full and true disclosure of relevant evidentiary facts, but the rights of a nonparty participant shall in no event exceed the rights of a party.

§ 2.156 Conduct at oral hearings or conferences.

All participants in a formal evidentiary public hearing shall conduct themselves with dignity and observe judicial standards of practice and ethics. They shall not indulge in personal attacks, unseemly wrangling, or intemperate accusations or characterizations. A representative of any party shall use his best efforts to restrain his client from improprieties in connection with any proceeding. Disrespectful, disorderly, or contumacious language or contemptuous conduct, refusal to comply with directions, continued use of dilatory tactics, or refusal to adhere to reasonable standards of orderly and ethical conduct during any such hearing, shall constitute grounds for immediate exclusion from the proceeding at the direction of the presiding officer.

§ 2.157 Time and place of prehearing conference.

A prehearing conference shall commence at the date, time, and place announced in the notice of hearing or in a later notice, published in the FEDERAL REGISTER pursuant to § 2.118(a)(8). At that conference the presiding officer shall establish the methods and procedures to be used in developing the evidence,

determine reasonable time periods for the conduct of the hearing, and designate the times and places for the production of witnesses for direct and cross-examination if leave to conduct oral examination is granted on any issue, insofar as is practicable at that time.

§ 2.158 Prehearing conference procedure.

(a) All participants in a formal evidentiary hearing shall appear at the prehearing conference, which shall not commence until after the time for disclosure of data and information specified in § 2.153 has expired, fully prepared to discuss in detail and resolve all matters specified in paragraph (b) of this agenda as may be issued by the Commissioner or the presiding officer.

(1) All participants shall cooperate fully at all stages of the proceeding to achieve the objective of a fair and expeditious hearing, through advance preparation for the prehearing conference, including communications between the participants, requests for information at the earliest possible time, and the commencement of preparation of testimony. The failure of any participant to appear at the prehearing conference or to raise any matters that could reasonably be anticipated and resolved at the prehearing conference shall not be permitted to delay the progress of the hearing and shall constitute a waiver of the rights of the participant with regard thereto, including all objections to the agreements reached, actions taken, or rulings issued by the presiding officer with regard thereto, and may be grounds for striking his appearance pursuant to § 2.131.

(2) Each participant shall bring to the prehearing conference the following specific information, which shall be filed with the Hearing Clerk pursuant to § 2.151:

(i) Any additional data or information to supplement the submission filed pursuant to § 2.153, which may be filed if approved pursuant to § 2.153(c).

(ii) A list of all witnesses whose testimony will be offered, orally or in writing, at the hearing, together with a full curriculum vitae for each such witness. Additional witnesses may later be identified, with the approval of the presiding officer, upon a showing that the witness was not reasonably available at the time of the prehearing conference or that the relevance of his views could not reasonably have been foreseen at that time.

(iii) All prior written statements, which shall include articles and any written statement signed or adopted, or a recording or transcription of an oral statement made, by the persons who have been identified as witnesses if all of the following conditions apply:

(*a*) The statement is available without making request of the witness or any other person.

(*b*) The statement relates to the subject matter of the witness's testimony.

(*c*) The statement either was made before the time the person agreed to become a witness or has been made publicly available by the person.

(b) The presiding officer shall conduct a prehearing conference for the following purposes:

(1) To determine and reduce to writing the areas of factual disagreement which are to be considered at the formal evidentiary hearing. The presiding officer may:

(i) Require each participant to prepare and file written statements of position on the areas of disagreement described in the notice of hearing.

(ii) Require each participant to summarize the testimony which he proposes to present in support of his position, and to describe and justify any additional documentary evidence not included with the submission pursuant to § 2.153 and expected to be introduced.

(iii) Consider oral or written argument with respect to the areas of disagreement described in the notice of hearing or with respect to objections thereto.

(iv) Hold conferences off the record in an effort to reach agreement as to factual questions on which disagreement exists, except that all statements as to areas of disagreement shall be reduced to writing or be the subject of a verbatim transcript approved by the participants.

(2) To identify the most appropriate techniques for the development of the evidence on issues in controversy in addition to the submissions pursuant to § 2.153, and the manner and sequence in which they will be used, including, where oral examination is to be conducted, the sequence in which witnesses will be produced for, and the time and place of, the oral examination. The methods and procedures which the presiding officer may consider for use in developing the evidence include but are not limited to:

(i) Submission of narrative statements of position on each factual issue in controversy.

(ii) Submission of evidence or identification of previously submitted evidence in support of such statements, such as affidavits, verified statements of fact, data, studies, reports, and any other type of written material.

(iii) Identification of all witnesses and submission of testimony of such witnesses.

(iv) Exchange of written interrogatories directed to particular witnesses for the purpose of developing the evidence on particular disputed facts.

(v) Written requests to any party for the production of additional documentation, data, or other information relevant and material to the facts in issue.

(vi) Submission of written questions to be orally propounded by the presiding officer to a specific witness.

(vii) Isolation of disputed facts as to which oral examination and/or cross-examination is appropriate pursuant to § 2.154(b).

(3) To group participants with substantially like interests for purposes of eliminating duplicative or repetitive development of the evidence, making and arguing motions and objections, including motions for summary decision, filing briefs, and presenting oral argument.

(4) To hear and determine objections to the admission into evidence of data and information submitted pursuant to § 2.153.

(5) To investigate the possibility of obtaining stipulations and admissions of facts.

(6) To consider such other matters and take such other action as may aid in the expeditious disposition of the proceeding.

(c) The presiding officer shall prepare a written prehearing order reciting the actions taken at the prehearing conference and setting forth the schedule for the hearing. Such order shall include a written statement of the areas of factual agreement and disagreement and of the methods and procedures to be used in developing the evidence and the respective duties of the parties in connection therewith. Such order shall control the subsequent course of the hearing unless modified by the presiding officer for good cause shown.

§ 2.159 Summary decisions.

(a) Any participant in a formal evidentiary public hearing may, after commencement of the hearing, submit to the Hearing Clerk pursuant to § 2.150 a motion with or without supporting affidavits for a summary decision in his favor with respect to any issue under consideration. Any other participant may, within 10 days after service of the motion, which time may be extended for an additional 10 days by the presiding officer for good cause shown, serve opposing affidavits or countermove for summary decision. The presiding officer may, in his discretion, set the matter for argument and call for the submission of briefs.

(b) The presiding officer shall grant such motion if the objections, requests for hearing, other pleadings, affidavits, and any material filed in connection with the hearing, or matters officially noticed, show that there is no genuine issue as to any material fact and that a participant is entitled to summary decision.

(c) Affidavits shall set forth such facts as would be admissible in evidence and shall show affirmatively that the affiant is competent to testify to the matters stated therein. When a motion for summary decision is made and supported as provided in this section, a participant opposing the motion may not rest upon mere allegations or denials or general descriptions of positions and contentions. His response, by affidavits or as otherwise provided in this section, must set forth specific facts showing that there is a genuine issue of fact for the hearing.

(d) Should it appear from the affidavits of a participant opposing the motion that he cannot, for sound reasons stated, present by affidavit facts essential to justify his opposition, the presiding officer may deny the motion for summary decision or may order a continuance to permit affidavits or additional evidence to be obtained or may make such order as is just.

(e) If on motion under this section a summary decision is not rendered upon the whole case or for all the relief asked, and development of evidentiary facts is

found necessary, the presiding officer shall make an order specifying the facts that appear without substantial controversy and directing further evidentiary proceedings. The facts so specified shall be deemed established.

(f) Any participant may obtain interlocutory review by the Commissioner of a summary decision of the presiding officer.

§ 2.160 Receipt of evidence.

(a) A formal evidentiary public hearing consists of the development of evidence and the resolution of factual issues in the manner set forth in the procedures established in this subpart and in the order issued by the presiding officer after the prehearing conference.

(b) All orders issued by the presiding officer, transcripts of oral hearings or arguments, written statements of position, written direct testimony, written interrogatories and the responses thereto, and any other data, studies, reports, documentation, information, and other written material of any kind submitted in the proceeding shall be a part of the administrative record of the hearing, and shall be placed on public display in the office of the Hearing Clerk promptly upon receipt in that office, except as provided in § 2.171.

(c) A written submission to the record shall be admissible as evidence unless a participant objects and the presiding officer excludes it as inadmissible.

(1) The presiding officer shall exclude written evidence as inadmissible only on the following grounds:

(i) The evidence is a document that is not authentic, or

(ii) Exclusion of part or all of the written evidence of a participant is necessary or appropriate to enforce the requirements of this subpart.

(2) The presiding officer shall not exclude any written evidence as inadmissible on the ground that it is irrelevant, immaterial, or repetitive. All such written evidence shall be admitted even if it is of no probative value. Irrelevant or immaterial written evidence shall be regarded as such and shall not be given weight or probative value because of its admission.

(3) Any written evidence excluded by the presiding officer as inadmissible shall remain a part of the administrative record, as an offer of proof, for purposes of judicial review.

(d) Oral testimony, whether on direct or on cross-examination, shall be admissible as evidence unless a participant objects and the presiding officer excludes it as inadmissible.

(1) The presiding officer shall exclude oral evidence as inadmissible only on the following grounds:

(i) The oral evidence is irrelevant, immaterial, or repetitive, or

(ii) Exclusion of part or all of the oral evidence of a participant is necessary or appropriate to enforce the requirements of this subpart.

(2) Whenever oral evidence is excluded by the presiding officer as inadmissible, the participant offering such evidence may make an offer of proof, which shall be part of the record. The offer of proof shall consist of a brief statement, which the presiding officer may require to be in writing, describing the evidence excluded. Upon review, the Commissioner may reopen the hearing to permit such evidence to be admitted if he determines that its exclusion was erroneous and prejudicial.

(e) All participants shall be responsible for apprising themselves of the contents of the administrative record in timely fashion for purposes of formulating objections to the admissibility of any item into evidence and evaluating the need for the submission of additional evidence.

(f) The presiding officer shall, on his own initiative as the circumstances warrant, or upon the motion of any participant for good cause shown, schedule conferences to monitor the progress of the hearing, narrow and simplify the issues, and consider and rule on motions, requests, and other matters concerning the development of the evidence.

(g) The presiding officer shall conduct such proceedings as are necessary for the taking of oral testimony, for the oral examination of witnesses by the presiding officer on the basis of written questions previously submitted to him by the parties, and for the conduct of cross-examination of witnesses by the parties. The presiding officer shall screen written questions submitted to him to be asked orally of witnesses in order to exclude irrelevant or repetitious questions. The presiding officer shall limit oral cross-examination to prevent irrelevant or repetitious examination.

(h) The presiding officer shall order that the proceedings be closed for the taking of oral testimony relating to matters specified in § 2.5(j)(3). Participation in such closed proceedings shall be limited to the witness, his counsel, and Federal Government Executive Branch employees and special government employees. Such closed proceedings shall be permitted only for such oral testimony as directly relates to matters specified in § 2.5(j)(3) and shall not include other matters.

(i) Any party may at any time move for an order that the taking of evidence be concluded. Such motion shall be granted unless within 10 days of service thereof a participant files an opposition to such motion, supported by an affidavit stating that he wishes to submit, or by specified means adduce, additional evidence on facts relevant to the issues at the hearing, describing the nature of such evidence, and estimating the time necessary to submit or adduce it. In the event that such an opposition is filed, the presiding officer may (1) grant the motion if it appears that the evidence described in the affidavit filed in support of the opposition does not relate to relevant facts or is duplicative or cumulative of evidence already on record at the hearing, (2) deny the motion, or (3) grant the motion but postpone its effect to a specified date in order that the participant opposing it may submit or adduce the evidence described in the affidavit. Upon the denial of a motion made under this paragraph, or the granting of a motion with a postponed effective date, no participant may submit additional evidence unless he has filed an opposition to the motion, and any participant who has filed an opposition shall confine the submission of additional evidence to the matters set forth in the affidavit in support of the opposition.

§ 2.161 Official notice.

(a) Upon motion of any participant, the presiding officer shall take official notice of official publications of the Food and Drug Administration and other Federal agencies and of any technical, scientific, or other fact that is not subject to reasonable dispute in that it is capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned.

(b) The presiding officer may take official notice of matters whether requested to do so or not.

(c) Where official notice is requested to be taken or is taken of a material fact not appearing in the evidence of record, any participant, on timely request, shall be afforded an opportunity to show the contrary.

§ 2.162 Briefs and argument.

(a) As soon as possible after the completion of the taking of evidence, the presiding officer shall announce a schedule for the filing of briefs. Briefs shall include a statement of position on each issue as supported by the evidence of record, with specific and complete citations to the evidence, together with citations of points of law relied upon. Briefs shall contain proposed findings of fact and conclusions of law.

(b) The presiding officer may permit the presentation of oral argument at his discretion and in such manner as he believes is both practical and fair.

(c) Briefs and oral argument shall attempt to refrain from disclosing specific details of written and oral testimony and documents relating to matters specified in § 2.5(j)(3), but any reference essential to resolution of the issues involved shall be permitted.

§ 2.163 Interlocutory appeal from ruling of presiding officer.

(a) Except as provided in paragraph (b) of this section and in §§ 2.131(g), 2.143(a), 2.159(f), and 2.165(e), where an interlocutory appeal is specifically authorized by this subpart, rulings of the presiding officer may not be appealed to the Commissioner prior to his consideration of the entire administrative record of the hearing.

(b) Any ruling of the presiding officer shall be the subject of an interlocutory appeal to the Commissioner where the presiding officer certifies on the record or in writing that such an interlocutory appeal is necessary to prevent exceptional delay, expense, or prejudice to any participant, or substantial harm to the public interest.

(c) Where an interlocutory appeal is made to the Commissioner, any partici-

pant may file a brief with the Commissioner within such period as the Commissioner directs. Oral argument will be heard only at the discretion of the Commissioner.

§ 2.164 Official transcript.

(a) Any oral testimony given at a formal evidentiary public hearing shall be reported verbatim. The presiding officer will make provision for a stenographic record of the testimony and for such copies of the transcript thereof as he requires for his own purpose.

(b) One copy of such transcript shall be placed on public display in the office of the Hearing Clerk upon receipt, where it may be reviewed by any interested person.

(c) Any person desiring a copy of the transcript of the testimony taken at the hearing or of any part thereof shall be entitled to the same, except as provided in § 2.171, upon application to the official reporter and payment of the costs thereof or pursuant to the provisions of Part 4 of this chapter.

§ 2.165 Motions.

(a) Any participant may make a motion, including any request, to the presiding officer with respect to any matter relating to the proceeding. All motions shall be filed pursuant to § 2.150, except those made in the course of an oral hearing before the presiding officer.

(b) Within 10 days after service of any such motion, which may be shortened to 3 days or extended for an additional 10 days by the presiding officer for good cause shown, any participant in the proceeding may file a response to the motion.

(c) The presiding officer shall rule upon such motion and may certify such motion, together with his ruling, to the Commissioner for interlocutory review.

ADMINISTRATIVE RECORD

§ 2.170 Administrative record of a formal evidentiary public hearing.

(a) The record of the administrative proceeding shall consist of the following:

(1) The order or regulation which gave rise to the hearing.

(2) All objections and requests for hearing filed by the Hearing Clerk pursuant to §§ 2.110 through 2.112.

(3) The notice of hearing published pursuant to § 2.118.

(4) All notices of appearance filed pursuant to § 2.131.

(5) All FEDERAL REGISTER notices pertinent to the proceeding.

(6) All submissions filed pursuant to § 2.151, e.g., the submissions required by § 2.153, all other documentary evidence and written testimony, pleadings, statements of position, briefs, and other similar documents.

(7) The transcript, written order, and all other documents relating to the prehearing conference, prepared pursuant to § 2.158.

(8) All documents relating to any motion for summary decision pursuant to § 2.159.

(9) All documents of which official notice is taken pursuant to § 2.161.

(10) All pleadings filed pursuant to § 2.162.

(11) All documents relating to any interlocutory appeal pursuant to § 2.163.

(12) All transcripts prepared pursuant to § 2.164.

(13) Any other documents relating to the hearing and filed with the Hearing Clerk by the presiding officer or any participant.

(b) The record of the administrative proceeding shall be closed:

(1) With respect to the taking of evidence, at the time specified in § 2.160 (g).

(2) With respect to pleadings, at the time specified in § 2.162(a) for the filing of briefs.

(c) The presiding officer may, in his discretion, reopen the record to receive further evidence at any time prior to the filing of a recommended or initial decision.

§ 2.171 Examination of administrative record.

The availability for public examination and copying of each document which is a part of the administrative record of the hearing shall be governed by the provisions of § 2.5(j). Each document which is available for public examination or copying shall be placed on public display in the office of the Hearing Clerk promptly upon receipt in that office.

§ 2.172 Correction of administrative record.

After the close of the taking of evidence, the presiding officer shall afford witnesses, participants, and their counsel time, not longer than 30 days except in unusual cases, in which to submit written proposed corrections of the transcript of any oral testimony taken at the hearing, pointing out errors that may have been made in transcribing the testimony. The presiding officer shall promptly thereafter order such corrections made as in his judgment are required to make the transcript conform to the testimony.

§ 2.173 Record for administrative decision.

The administrative record of the hearing specified in § 2.170 shall constitute the exclusive record for decision.

RECOMMENDED, INITIAL, TENTATIVE, AND FINAL DECISIONS

§ 2.180 Recommended decision or initial decision.

(a) Within 90 days after the filing of briefs and any oral argument pursuant to § 2.162, the presiding officer shall prepare and file a recommended decision or initial decision based solely upon the administrative record of the hearing.

(1) The presiding officer shall prepare a recommended decision if the notice of hearing so states pursuant to § 2.118 (a)(10).

(2) The presiding officer shall prepare an initial decision if the notice of hearing so states pursuant to § 2.118(a)(10) or if the notice of hearing is silent on the matter.

(b) The recommended decision or initial decision shall contain:

(1) Findings of fact based upon relevant, material, and reliable evidence of record.

(2) Conclusions of law.

(3) A full articulation of the reasons for the findings and conclusions, including a discussion of the significant factual and legal contentions made by any participant.

(4) Full citations to the administrative record supporting the findings and conclusions.

(5) An appropriate regulation or order supported by substantial evidence of record and based upon the findings of fact and conclusions of law.

(6) An effective date for the regulation or order.

(c) The recommended decision or initial decision shall attempt to refrain from disclosing specific details of written and oral testimony and documents relating to matters specified in § 2.5(j)(3), but any reference essential to resolution of the issues involved shall be permitted.

(d) If the presiding officer prepares a recommended decision he shall forward it, together with the certified record of the hearing, to the Commissioner.

(e) If the presiding officer prepares an initial decision:

(1) It shall be filed with the Hearing Clerk and served upon all participants.

(2) The initial decision shall become the decision of the Commissioner unless within 30 days after it is filed with the Hearing Clerk a participant in the proceeding files with the Hearing Clerk a notice of appeal to the Commissioner pursuant to § 2.182(a) or the Commissioner, on his own initiative, files with the Hearing Clerk a notice of review pursuant to § 2.182(d).

§ 2.181 Tentative order.

(a) If the presiding officer prepares a recommended decision, as soon as practicable after it is received the Commissioner either shall adopt it as his tentative order or shall prepare a different tentative order. The tentative order shall contain findings of fact and conclusions of law as set forth in § 2.180 (b) and (c), and shall be filed with the Hearing Clerk and served upon all participants.

(b) The tentative order shall specify a reasonable time, ordinarily not to exceed 60 days, within which any participant may file exceptions. The exceptions shall point out with particularity the alleged errors in the tentative order and shall contain a specific reference to the items in the record on which exceptions are based. Such exceptions may be accompanied by a memorandum or brief in support thereof. If oral argument on the exceptions is desired, such a request shall be made with the exceptions.

(c) After the exceptions are filed the Commissioner shall determine whether he wishes to hear oral argument on the matter. If the Commissioner concludes that he should hear oral argument on

the matter, the participants shall be informed of the date, time, and place for such oral argument, the amount of time that will be allotted to each participant for such oral argument, and the issues to be addressed.

§ 2.182 Appeal from or review of initial decision.

(a) If the presiding officer files an initial decision, any participant in a proceeding may appeal it to the Commissioner by filing a notice of appeal with the Hearing Clerk within 30 days after the initial decision is filed. If any participant appeals the initial decision, all participants shall have an equal opportunity to participate in the appeal.

(b) Promptly after a notice of appeal is filed with the Hearing Clerk, the Commissioner shall inform all participants of the date by which they may file briefs, stating exceptions to or agreement with the initial decision and supporting reasons therefor, the time for which shall be not less than 30 nor more than 60 days following such notice. Reply briefs may be filed only with the express permission of the Commissioner.

(c) If oral argument on the appeal is desired, such a request shall be made with the briefs. After the briefs are filed the Commissioner shall determine whether he wishes to hear oral argument on the matter. If the Commissioner concludes that he should hear oral argument on the matter, the participants shall be informed of the date, time, and place for such oral argument, the amount of time that will be allotted to each participant for such oral argument, and the issues to be addressed.

(d) Within 40 days after the initial decision is filed, the Commissioner may file with the Hearing Clerk a notice stating that he will review the initial decision on his own initiative. Such review shall proceed pursuant to the provisions of paragraph (b) of this section.

§ 2.183 Decision by Commissioner after exceptions to the tentative order.

If the presiding officer prepares a recommended decision and the Commissioner files a tentative order, as soon as practicable after the time for filing exceptions to the tentative order has passed, the Commissioner shall publish in the FEDERAL REGISTER his final order in the proceeding. The final order shall meet the requirements established in § 2.180 (b) and (c).

§ 2.184 Decision by Commissioner on appeal or review of initial decision.

(a) If the presiding officer files an initial decision and a notice of appeal or review is filed pursuant to § 2.182, the presiding officer shall certify to the Commissioner the full administrative record of the proceeding, which shall include all briefs filed pursuant to § 2.162 and the initial decision.

(b) On appeal from or review of the initial decision, the Commissioner shall have all the powers he would have in making the initial decision. The Commissioner may, on his own initiative or on the motion of any participant, remand the proceeding to the presiding officer with specific directions, e.g., to receive further evidence relating to a particular issue, where he concludes that such action is necessary for a proper decision in the matter.

(c) The scope of the issues on appeal shall be the same as the scope of the issues at the public hearing unless the Commissioner specifies otherwise.

(d) As soon as practicable after the filing of briefs and any oral argument, the Commissioner shall issue in the FEDERAL REGISTER his final decision in the proceeding based solely upon the administrative record of the hearing. Such final decision shall meet the requirements established in § 2.180 (b) and (c).

(e) The Commissioner may adopt the initial decision as the final decision, in whole or in part, if he concludes, after reviewing the administrative record, that it meets all the requirements specified in § 2.180 (b and (c) and represents a sound, reasonable, and fair decision based upon all relevant factual, legal, and policy considerations.

§ 2.185 Reconsideration and stay of action.

Following publication of the final decision, any participant may petition the Commissioner for reconsideration of any part or all of such decision pursuant to § 2.8 or may petition for a stay of such decision pursuant to § 2.9.

JUDICIAL REVIEW

§ 2.190 Review by the courts.

(a) The Commissioner's final decision constitutes final agency action from which any participant may petition for judicial review pursuant to the statutory provisions governing the matter involved. Before requesting an order from a court for relief pending review, any participant seeking court review shall first submit a petition for a stay of action pursuant to § 2.9.

(b) The Food and and Drug Administration will request consolidation in a single court of all petitions for judicial review related to a particular matter pursuant to 28 U.S.C. 2112(a).

§ 2.191 Copies of petitions for judicial review.

The Chief Counsel for the Food and Drug Administration has been designated by the Secretary as the officer upon whom copies of petitions for judicial review shall be served. Such officer shall be responsible for filing in the court the record of the proceedings on which the final decision is based. The record of the proceeding shall be certified by the Commissioner.

Subpart C—Public Hearing Before a Public Board of Inquiry

§ 2.200 Scope of subpart.

Subpart C governs the practices and procedures applicable whenever:

(a) The Commissioner concludes, in his discretion, that it is in the public interest to hold a public hearing before a Public Board of Inquiry, hereinafter referred to as a "Board," with respect to any matter, or class of matters, of importance pending before the Food and Drug Administration.

(b) Pursuant to specific provisions in other sections of this chapter, a matter pending before the Food and Drug Administration is subject to a public hearing before a Board.

(c) A person who has a right to an opportunity for a formal evidentiary public hearing under Subpart B of this Part waives that opportunity and in lieu thereof requests pursuant to § 2.117 of this Part the establishment of a Board to act as an administrative law tribunal with respect to the matters involved, and the Commissioner, in his discretion, accepts this request.

§ 2.201 Notice of a public hearing before a Public Board of Inquiry.

If the Commissioner determines that a Board should be established to conduct a public hearing on any matter, he shall publish in the FEDERAL REGISTER a notice of hearing setting forth the following information:

(a) If the hearing is pursuant to § 2.200 (a) or (b), all applicable information described in § 2.117(e).

(1) If any written document is to be the subject matter of the hearing, it shall be published as part of the notice, or reference shall be made to it if it has already been published in the FEDERAL REGISTER, or the notice shall state that the document is available from the Hearing clerk or an agency employee designated in the notice.

(2) For purposes of any such hearing, all participants who file a notice of appearance pursuant to § 2.117(e)(6)(ii) shall be deemed to be parties and shall be entitled to participate in selection of the Board pursuant to § 2.203(b).

(b) If the hearing is in lieu of a formal evidentiary hearing as provided in § 2.200(c), all of the information described in § 2.117(e).

§ 2.202 Members of a Public Board of Inquiry.

(a) All members of a Board shall have medical, technical, scientific, or other qualifications relevant to the issues to be considered at the hearing, shall be subject to the conflict of interest rules applicable to special government employees, and shall be free from bias or prejudice with respect to the issues involved. A member of a Board may be a full-time or part-time Federal government employee or may serve on a Food and Drug Administration advisory committee but except with the agreement of all parties shall not currently be a full-time or part-time employee of the Food and Drug Administration or otherwise act as a special government employee of the Food and Drug Administration.

(b) The director of the bureau of the Food and Drug Administration responsible for the matter which is the subject of a public hearing before a Board, the other parties to the proceeding, and any person whose petition is the subject of the hearing, shall, within 30 days after publication of the notice of hearing in the FEDERAL REGISTER, each submit to

the Hearing Clerk the names and full curricula vitae of five nominees for members of the Board. Nominations shall state that the nominee is aware of the nomination, is interested in becoming a member of the Board, and appears to have no conflict of interest.

(1) All such persons may in consultation with each other agree upon a single list of five qualified nominees.

(2) Within 10 days after receipt of such names of nominees, such persons may submit comments to the Hearing Clerk on whether the nominees of the other persons meet the criteria established in paragraph (a) of this section.

(3) In addition to being filed with the Hearing Clerk, the lists of nominees and comments thereon shall be submitted to the persons who have the right to submit a list of nominees pursuant to this paragraph but not to all participants. They shall be held in confidence by the Hearing Clerk as part of the administrative record of the proceeding and shall not be available for public disclosure, and shall similarily be held in confidence by all persons who submit or receive them. This portion of the administrative record shall remain confidential but shall be available for judicial review in the event that it becomes relevant to any issue before a court.

(c) After reviewing the lists of nominees and any comments thereon, the Commissioner shall choose three qualified persons as members of a Board. One member shall be chosen from the lists of nominees submitted by the director of the bureau and any person who is not a party and whose petition is the subject of the hearing. The second member shall be chosen from the lists of nominees submitted by the other parties. The Commissioner shall then choose the third member from any source, who shall be the Chairman of the Board.

(1) If the Commissioner is unable to find a qualified person with no conflict of interest from among a list of nominees submitted, or if additional information is needed, the Commissioner shall request from the party involved the submission of such additional nominees or information as is necessary to choose a qualified person nominated by that person.

(2) If a person fails to submit a list of nominees as required by paragraph (b) of this section, the Commissioner may choose a qualified person in lieu of a person nominated by that person without further consultation with that person.

(3) The Commissioner shall announce the members of a Board by filing a memorandum in the record of the proceeding and sending a copy to each participant who has filed a notice of appearance.

(d) In lieu of the procedure for selection of the members of a Board specified in paragraphs (b) and (c) of this section, the director of the bureau, the other party or parties to the proceeding, and any person whose petition is the subject of the hearing, may agree that any standing advisory committee listed in § 2.330 shall constitute the Board for a particular proceeding, or may mutually agree on any other procedure for selection of the members of the Board, or the number of members of the Board, subject to the approval of the Commissioner.

(e) The members of a Board shall serve as consultants to the Commissioner and shall be special government employees or government employees. A Board shall function as an administrative law tribunal with the consent of the parties involved in the proceeding and is not an advisory committee subject to the requirements of the Federal Advisory Committee Act or Subpart D of this Part.

(f) The chairman of a Board shall have the authority of a presiding officer set out in § 2.142.

§ 2.203 Separation of functions; ex parte communications; administrative support.

(a) All proceedings of a Board shall be subject to the provisions of § 2.13, relating to separation of functions and ex parte communications. Representatives of the participants in any proceeding before a Board shall have no contact with the members of the Board, except as participants in such proceeding, and shall not participate in the deliberations of the Board.

(b) Administrative support for a Board shall be provided only by the office of the Commissioner and the Chief Counsel for the Food and Drug Administration.

§ 2.204 Submissions to a Public Board of Inquiry.

(a) All submissions relating to a hearing before a Board shall be filed with the Hearing Clerk pursuant to § 2.5.

(b) A copy of any such submission shall be sent by the person making the submission to each participant in the proceeding, except as provided in §§ 2.202 (b) (3) and 2.207(c) and except that submissions of documentary data and information may but are not required to be sent to each participant. Any transmittal letter, summary, statement of position, certification pursuant to paragraph (d) of this section, or similar document accompanying a submission of documentary data and information shall be sent to each participant pursuant to this paragraph.

(c) Any such submission shall be sent as required by paragraph (b) of this section by mailing it to the address shown in the notice of appearance or by personal delivery.

(d) All submissions pursuant to this section shall be accompanied by a signed certification stating the extent to which the submission has been served on each participant, or is exempt from such service, pursuant to paragraph (b) of this section.

(e) No written submission or other portion of the administrative record shall be held in confidence, except as provided in §§ 2.202(b) (3) and 2.207(c).

(f) Any participant who believes that compliance with the requirements of this section constitutes an unreasonable financial burden shall submit to the Commissioner a petition to participate in forma pauperis.

(1) Such petition shall be pursuant to § 2.7, except that the heading shall be "REQUEST TO PARTICIPATE IN FORMA PAUPERIS, DOCKET NO. ------." Pursuant to the guidelines established in § 4.43 (b) and (c) of this chapter, such petition shall demonstrate that either (i) the person is indigent and his participation has a strong public interest justification, or (ii) such participation is in the public interest because it can be considered primarily as benefiting the general public.

(2) If the Commissioner grants such petition, the participant may file only one copy of each submission with the Hearing Clerk, and it shall be the responsibility of the Hearing Clerk to make sufficient additional copies for the administrative record and to serve a copy upon each other participant.

§ 2.205 Disclosure of data and information by the participants.

(a) Before the notice of hearing is published pursuant to § 2.201, the director of the bureau responsible for the matters involved in the hearing shall submit to the Hearing Clerk:

(1) The relevant portions of the existing administrative record of the proceeding. Those portions of the administrative record of the proceeding which are not relevant to the issues to be considered at the public hearing shall not be submitted to the Hearing Clerk or placed on public display and shall not be part of the administrative record of the proceeding.

(2) A list of all persons whose views will be presented orally or in writing at the hearing.

(3) All documents in his files containing factual data and information, whether favorable or unfavorable to his position, which relate to the issues involved in the hearing.

(4) All other documentary data and information on which he relies.

(5) A signed statement that, to the best of his knowledge and belief, the submission complies with the requirements of this section.

(b) Within 60 days after the notice of hearing is published pursuant to § 2.201, each participant shall submit to the Hearing Clerk all data and information specified in paragraph (a) (2) through (5) of this section, and any objections with respect to the completeness of the administrative record filed pursuant to paragraph (a) (1) of this section.

(c) The submissions required by paragraphs (a) and (b) of this section may be supplemented later in the proceeding, with the approval of the Board, upon a showing that the views of the persons or the material contained in the supplement were not known or reasonably available when the initial submission was made or that the relevance of the views of the persons or the material contained in the supplement could not reasonably have been foreseen.

(d) The failure to comply with the provisions of this section in the case of a participant shall constitute a waiver of the right to participate further in the hearing and in the case of a party shall

constitute a waiver of the right to a hearing.

(e) The Chairman of the Board shall rule on questions relating to this section. Any participant dissatisfied with any such ruling may request the Commissioner for an interlocutory review of that ruling.

§ 2.206 Proceedings of a Public Board of Inquiry.

(a) The purpose of a Board is to review medical, scientific, and technical issues fairly and expeditiously in order to reach a reasonable decision that is sound from a medical, scientific, and technical standpoint. The proceedings of a Board shall be conducted in the manner of a scientific inquiry rather than as a legal trial.

(b) Prior to the first hearing of a Board, all participants in the hearing shall have submitted to the Hearing Clerk the data and information required to be disclosed pursuant to § 2.205, subject to the sanctions specified in § 2.205(d).

(c) The Chairman of a Board shall call the first hearing of the Board at a reasonable time subsequent to receipt of the data and information specified in paragraph (b) of this section. Notice of the time and location of such hearing shall be published in the FEDERAL REGISTER at least 15 days in advance and the hearing shall be open to the public. The director of the bureau, the other parties, and all other participants shall have an opportunity at the first hearing to make an oral presentation of the data, information, and views which in their opinion are pertinent to resolution of the issues being considered by a Board. The Chairman shall determine the order in which these presentations shall be made. Each initial presentation shall be made without interruption from other participants, but members of the Board may ask any questions that they wish. At the conclusion of each presentation, each of the other participants may briefly state questions and criticism of the presentation and may request that the Board conduct further questioning with respect to specified matters. The Chairman and members of the Board may then ask further questions, and the Chairman may permit any other participant in the proceeding to ask questions if he determines this will facilitate resolution of the issues.

(d) The hearing shall be informal in nature, and the rules of evidence shall not apply. No motions or objections relating to the admissibility of data, information, and views shall be made or considered, but other participants may comment upon or rebut all such data, information, and views. No participant may interrupt the presentation of another participant for any reason.

(e) Within 30 days after the first hearing of a Board is concluded, each participant in the proceeding may submit in writing such rebuttal data, information, and views as he believes relevant to the issues, in accordance with the requirements of § 2.206. The Chairman shall thereafter schedule a second hearing of a Board if requested and justified by any participant. A second hearing, and any subsequent hearing, shall be called only if the Chairman concludes that it is necessary for the full and fair presentation of information that cannot otherwise adequately be considered and for the proper resolution of the issues involved. Notice of the time and location of any such subsequent hearings shall be published in the FEDERAL REGISTER at least 15 days in advance of the date of such hearing and the hearings shall be open to the public.

(f) A Board may consult with any person who it concludes may have data, information, or views relevant to resolution of the issues involved.

(1) Such consultation shall occur only at an announced hearing of a Board, and all participants shall have the right to be present and to suggest or, with the permission of the Chairman, conduct questioning of such consultants and to present rebuttal data, information, and views, as provided in paragraphs (c) and (d) of this section, except that written statements may be submitted to the Board with the consent of all participants.

(2) Any participant may submit to the Board a request that it consult with specific persons who may have data, information, or views relevant to the resolution of the issues. Such requests shall state the reasons why the person named should be consulted and why the views of that person cannot reasonably be furnished to the Board by any means other than having the Food and Drug Administration arrange for his appearance at a hearing of the Board. The Board may, in its discretion, grant or deny such a request.

(g) All hearings of a Board at which presentations of data, information, and views are made shall be transcribed. All such hearings shall be open to the public, except that the presentation of data and information which are prohibited from public disclosure pursuant to the provisions of § 2.5(j)(3) shall be closed to all persons except the persons making and participating in the presentation and Federal Government Executive Branch employees and special government employees. At least a majority of the members of the Board shall be present at every hearing. The executive sessions of a Board, during which a Board deliberates on the issues, shall be closed and shall not be transcribed. The report of the Board shall be voted upon by all members of the Board.

(h) All legal issues shall be referred to the Chief Counsel for the Food and Drug Administration for resolution.

(i) After the conclusion of all public hearings a Board shall announce that the record is closed with respect to the gathering of data and information. The Board shall provide an opportunity for all participants to submit a written statement of their positions, with proposed findings and conclusions, and may, in its discretion, provide an opportunity for participants to summarize their positions orally to assist the Board in its deliberations on the issues involved.

(j) At the conclusion of its deliberations, a Board shall prepare its decision on the issues, which shall include specific findings and references supporting and explaining its conclusions, and a detailed statement of the reasoning on which the conclusions are based. Any member of the Board may file a separate report with additional or dissenting views.

§ 2.207 Administrative record of a Public Board of Inquiry.

(a) The administrative record of a hearing before a Board shall consist of the following:

(1) All relevant FEDERAL REGISTER notices.

(2) All written submissions pursuant to § 2.204.

(3) The transcripts of all hearings of the Board.

(4) The recommended or initial decision of the Board.

(b) The record of the administrative proceeding shall be closed:

(1) With respect to the gathering of information and data, at the time specified in § 2.206(i).

(2) With respect to pleadings, at the time specified in § 2.206(i) for the filing of a written statement of position with proposed findings and conclusions.

(c) The Board may, in its discretion, reopen the record to receive further evidence at any time prior to the filing of a recommended or initial decision.

§ 2.208 Examination of administrative record.

(a) The availability for public examination and copying of each document which is a part of the administrative record of the hearing shall be governed by the provisions of § 2.5(j). Each document which is available for public examination or copying shall be placed on public display in the office of the Hearing Clerk promptly upon receipt in that office.

(b) Lists of nominees and comments thereon submitted pursuant to § 2.202(b)(3) shall be subject to the provisions of § 2.5(j)(3).

§ 2.209 Record for administrative decision.

The administrative record of the hearing specified in § 2.207(a) shall constitute the exclusive record for decision.

Subpart D—Public Hearing Before a Public Advisory Committee

GENERAL

§ 2.300 Scope of subpart.

(a) Subpart D governs the practices and procedures applicable whenever:

(1) The Commissioner concludes, in his discretion, that it is in the public interest for a standing or ad hoc policy or technical public advisory committee, hereinafter an "advisory committee" or "committee," to hold a public hearing and to review and make recommendations with respect to any matter or class of matters of importance pending before the Food and Drug Administration, and for interested persons to present data, information, and views at an oral public

hearing before the advisory committee.

(2) Pursuant to specific provisions in other sections of this chapter, a matter pending before the Food and Drug Administration is subject to a public hearing before an advisory committee. Such specific provisions are:

(i) Section 2.350 relating to review of a performance standard for an electronic product by the Technical Electronic Product Radiation Safety Standards Committee.

(ii) Section 2.360 relating to review of the safety of color additives.

(iii) Section 2.370 relating to review of the safety and effectiveness of human prescription drugs.

(iv) Section 330.10 of this chapter relating to review of the safety and effectiveness of over-the-counter drugs.

(v) Section 601.25 of this chapter relating to review of the safety and effectiveness of biological drugs.

(3) A person who has a right to an opportunity for a formal evidentiary public hearing under Subpart B of this Part waives that opportunity and in lieu thereof requests pursuant to § 2.117 a public hearing before a public advisory committee pursuant to this subpart, and the Commissioner, in his discretion, accepts this request.

(b) In determining whether a group is a "public advisory committee" as defined in § 2.3(a)(14) and thus subject to the requirements of this subpart and of the Federal Advisory Committee Act, the following guidelines shall be used:

(1) An advisory committee may be a standing advisory committee or an ad hoc advisory committee. All standing advisory committees shall be listed in § 2.340.

(2) An advisory committee may be a policy advisory committee or a technical advisory committee. A policy advisory committee advises on broad and general matters. A technical advisory committee advises on specific regulatory issues.

(3) An advisory committee includes any subgroup thereof when it is working on behalf of the committee. An advisory committee may have members and consultants.

(4) A committee composed entirely of full-time Federal government employees is not an advisory committee.

(5) An advisory committee shall ordinarily have a fixed membership, a defined purpose of providing advice to the agency on a particular subject, regular or periodic meetings, and an organizational structure, e.g., a chairman and staff, and shall serve as a source of independent expertise and advice rather than as a representative of or advocate for any particular interest.

(i) A group of persons convened on an ad hoc basis to discuss a matter of current interest to the agency, but which has no continuing function or organization, does not involve substantial special preparation, and does not as a group issue a report to or advise the agency, is not an advisory committee.

(ii) A group of two or more agency consultants meeting with the agency on an ad hoc basis is not an advisory committee.

(iii) A group of experts who are employed by a private company or a trade association which has been requested by the agency to provide its views on a regulatory matter pending before the agency is not an advisory committee.

(iv) A consulting firm hired by the agency to provide advice regarding a matter is not an advisory committee.

(6) An advisory committee which is utilized by the agency is subject to the requirements of this subpart even though it was not established by the agency. In general, a committee is "utilized" by the agency when the agency requests advice or recommendations from the committee on a specific matter in order to obtain an independent review and consideration of the matter, and not when the agency is merely seeking the comments of all interested persons or of persons who have a specific interest in the matter involved.

(i) A committee formed by an independent scientific or technical organization is utilized by the agency if the agency requests the advice of that committee rather than of the parent organization, or if the circumstances show that the advice given is that of the committee and not of the parent organization. A committee formed by an independent scientific or technical organization is not utilized by the agency if the agency requests advice of the organization rather than of a committee and if the recommendations of any committee formed in response to the agency's request for advice are subject to substantial independent policy and factual review by the governing body of the parent organization.

(ii) A committee is not utilized by the agency if it provides only data and information, as contrasted with advice or opinions or recommendations.

(iii) The Food and Drug Administration is charged with seeking out the views of all segments of the public on enforcement of the laws administered by the Commissioner. The fact that a group of individuals or a committee meets regularly with the agency, e.g., a monthly meeting with consumer representatives, does not make that group or committee an advisory committee. Thus, the provisions of this subpart are not applicable to routine meetings, discussions, and other dealings, including exchanges of views, between the agency and any committee representing or advocating the particular interests of consumers, industry, professional organizations, or others.

(7) The inclusion of one or two agency consultants who are special government employees on an internal agency committee does not make that committee an advisory committee.

(8) A Public Board of Inquiry established under Subpart C of this Part or other similar group convened by agreement between the parties to a regulatory proceeding pending before the Food and Drug Administration, to review and prepare an initial decision on the issue in lieu of a formal evidentiary public hearing, is acting as an administrative law tribunal and is not an advisory committee.

(9) An open public conference or meeting conducted pursuant to § 2.15(b) is not an advisory committee meeting.

(c) The provisions of this subpart apply only when a committee convenes to conduct committee business. Site visits, social gatherings, informal discussions by telephone or during meals or while traveling or at other professional functions, or other similar activities do not constitute a meeting.

(d) An advisory committee which is utilized but not established by the Food and Drug Administration shall be subject to the provisions of this subpart only to the extent of such utilization, and not with respect to any other activities of such committee.

(e) Any conference or meeting between an employee of the Food and Drug Administration and a committee or group which is not an advisory committee shall be subject to the provisions of § 2.15 or other provisions specifically applicable to such committee or group, e.g., Subpart C of this Part for a Public Board of Inquiry.

(f) The provisions of this subpart shall apply to all Food and Drug Administration advisory committees, except to the extent that specific stautory requirements provide otherwise for a particular committee, e.g., the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) and the Board of Tea Experts.

§ 2.301 Establishment and renewal of public advisory committees.

(a) A public advisory committee may be established or renewed whenever it is necessary or appropriate for such an advisory committee to hold a public hearing and to review and make recommendations on any matter pending before the Food and Drug Administration. Before an advisory committee is established or renewed it shall first be approved by the Department pursuant to 45 CFR Part 11 and the Office of Management and Budget pursuant to duly promulgated procedures.

(b) Upon the establishment or renewal of an advisory committee, the Commissioner shall issue in the FEDERAL REGISTER a notice certifying that the establishment or renewal of the advisory committee is in the public interest and stating the structure, function, and purposes of the advisory committee and, if it is a standing advisory committee, shall amend § 2.340 to add it to the list of standing advisory committees. The notice shall be published in the FEDERAL REGISTER at least 15 days prior to the filing of the advisory committee charter pursuant to paragraph (c) of this section.

(c) No advisory committee shall meet or take any action until its charter is prepared and filed as required by section 9(c) of the Federal Advisory Committee Act. This requirement shall be met by an advisory committee utilized by the Food and Drug Administration, even though

it is not established by the agency, prior to such utilization.

(d) An advisory committee not required by law will be established or utilized only if it is in the public interest and only if its functions could not reasonably be performed by other existing advisory committees or by the Food and Drug Administration directly.

(e) An advisory committee shall:

(1) Have a clearly defined purpose.

(2) Have a membership that is balanced fairly in terms of the points of view represented in light of the functions to be performed. Although proportional representation is not required, there shall be no discrimination on the basis of race, color, national origin, religion, age, or sex in the selection of advisory committee members.

(3) Be constituted and utilized procedures designed to assure that its advice and recommendations are not inappropriately influenced by any special interest or by the Food and Drug Administration, and are the result of the advisory committee's independent judgment.

(4) Have an adequate staff. The Commissioner shall designate an executive secretary and alternate for every advisory committee, who shall be employees of the Food and Drug Administration. The executive secretary shall be responsible for all staff support for the advisory committee unless other agency employees are specifically designated for this function with respect to particular advisory committees.

(5) Whenever feasible, include representatives of the public interest.

§ 2.302 Termination of public advisory committees.

(a) A standing advisory committee shall be terminated when it is no longer needed and in any event shall terminate not later than 2 years following its date of establishment unless it is renewed for an additional 2-year period. An advisory committee may be renewed for as many 2-year periods as the public interest requires. The requirements for establishment of an advisory committee pursuant to § 2.301 shall also apply to renewal of an advisory committee.

(b) Upon termination of any advisory committee the Commissioner shall issue in the FEDERAL REGISTER a notice announcing the termination and the reasons therefor and, if it is a standing advisory committee, amending § 2.340 to delete it from the list of standing advisory committees.

(c) The Technical Electronic Product Radiation Safety Standards Committee is a permanent statutory advisory committee established by section 358(f)(1)(A) of the Public Health Service Act (42 U.S.C. 263f(f)(1)(A)), as added by the Radiation Control for Health and Safety Act of 1968, and is not subject to the termination and renewal provisions of paragraph (a) of this section, except that a new charter shall be prepared and filed at the end of each 2-year period as provided in § 2.301(c).

(d) The Board of Tea Experts is a permanent statutory advisory committee established by the Tea Importation Act (21 U.S.C. 42), and is not subject to the termination and renewal provisions of paragraph (a) of this section, except that a new charter shall be prepared and filed at the end of each 2-year period as provided in § 2.301(c).

(e) Color additive advisory committees are required to be established under the circumstances specified in section 706(b)(5)(C) and (D) of the act. A color additive advisory committee is subject to the termination and renewal requirements of the Federal Advisory Committee Act and of this subpart.

§ 2.303 Purpose of proceedings before a public advisory committee.

(a) An advisory committee shall be utilized to conduct public hearings on matters of importance that come before the Food and Drug Administration, to review the issues involved, and to provide advice and recommendations to the Commissioner on such matters.

(b) The Commissioner shall have sole discretion with respect to action to be taken and policy to be expressed on any matter considered by an advisory committee.

§ 2.304 Portions of public advisory committee meetings.

An advisory committee meeting shall have the following separable portions:

(a) *The open public hearing.* Every advisory committee meeting shall include an open portion which shall constitute a public hearing during which any interested person may present data, information, or views, orally or in writing, relevant to the advisory committee's agenda or other work. Such hearing shall be conducted in accordance with § 2.312.

(b) *The open committee discussion.* An advisory committee shall discuss any matter pending before it in an open portion of its meeting unless the meeting has been closed with respect to that matter pursuant to § 2.318. To the maximum extent feasible, consistent with the policy expressed in § 2.318, an advisory committee shall conduct its discussion of pending matters in an open portion. No public participation is permissible during this portion of the meeting except with the consent of the chairman of the advisory committee.

(c) *The closed presentation of data.* Data and information which are prohibited from public disclosure pursuant to the provisions of Part 4 of this chapter and the regulations referenced therein shall be presented to the advisory committee in a closed portion of its meeting. If such data and information are presented in the form of a summary which is not prohibited from public disclosure, such presentation shall not be made in a closed portion of its meeting.

(d) *The closed committee deliberations.* Deliberations with respect to matters pending before an advisory committee may be made in a closed portion of its meeting upon an appropriate determination by the Commissioner pursuant to § 2.318.

§ 2.305 Notice of public hearing before a public advisory committee.

(a) Before the first day of each month, and at least 15 days before any meeting so announced, the Commissioner shall publish a notice in the FEDERAL REGISTER containing information on all advisory committee meetings to be held during the subsequent month. Any advisory committee meetings for that month called subsequent to the publication of the general monthly notice shall be announced in the FEDERAL REGISTER on an individual basis at least 15 days in advance. The Commissioner may authorize an exception to the notice requirements of this section in an emergency or for other reasons requiring an immediate meeting of an advisory committee, in which case public notice shall be given at the earliest time and in the most accessible form feasible including, whenever possible, publication in the FEDERAL REGISTER.

(b) The FEDERAL REGISTER notice shall include:

(1) The name of the advisory committee.

(2) The date, time, and place of the meeting.

(3) The general function of the advisory committee.

(4) A list of all agenda items, showing whether each will be discussed in an open or closed portion of the meeting.

(5) If any portion of the meeting is closed, a statement of the time of the open and closed portions.

(6) The nature of the subjects to be discussed during, and the reasons for closing, any closed portion of the meeting.

(7) The time specifically set aside for oral statements by interested persons and for other public participation.

(8) The name, address, and telephone number of the advisory committee executive secretary and any other agency employee designated as responsible for the administrative support for the advisory committee.

(9) A statement that written submissions may be made to the advisory committee at any time. Such submissions shall be made pursuant to § 2.311(c).

(10) Where a notice is published in the FEDERAL REGISTER less than 15 days before a meeting, an explanation for the lateness of the notice.

(c) If a public hearing before a public advisory committee is being used in lieu of a formal evidentiary public hearing as provided in § 2.300(a)(3), an initial notice of hearing shall be published separately in the FEDERAL REGISTER containing all the information described in § 2.117(e). Such a separate notice may also be published in the FEDERAL REGISTER with respect to any other public hearing before a public advisory committee when the Commissioner concludes, in his discretion, that it would be informative to the public.

(d) A list of public advisory committee meetings shall be distributed to the press by the Assistant Commissioner for Public Affairs.

(e) All public advisory committee meetings shall be included on the public calendar described in § 2.21(a).

§ 2.306 Chairman of a public advisory committee.

(a) The advisory committee chairman shall have the authority to conduct hearings and meetings, including the authority to adjourn any hearing or meeting whenever he determines adjournment to be in the public interest, to discontinue discussion of a particular matter, to conclude the open portion of a meeting, or to take any other action in furtherance of a fair and expeditious hearing or meeting.

(b) If the chairman is not a full-time employee of the Food and Drug Administration, the executive secretary of the advisory committee or other designated agency employee, or his alternate, shall be the designated Federal employee who is assigned to the advisory committee. The designated Federal employee is also authorized to adjourn any hearing or meeting whenever he determines adjournment to be in the public interest.

§ 2.307 Meetings of a public advisory committee.

(a) No advisory committee may conduct a meeting except at the call or with the advance approval of, and with an agenda approved by, the designated Federal employee or his alternate. No such meeting shall be held in the absence of such designated Federal employee.

(1) If any matter is added to the agenda after its publication in the FEDERAL REGISTER pursuant to § 2.303(b)(4), an attempt shall be made to so inform any person known to be interested in such matter, and the addition of such matter shall be announced at the beginning of the open portion of the meeting.

(2) The advisory committee meeting shall be conducted in accordance with the approved final agenda insofar as is practical.

(b) Advisory committee meetings shall be held at places that are reasonably accessible to members of the public. All advisory committee meetings shall be held in Washington, DC, or Rockville, MD, or the immediate vicinity, unless the Commissioner receives a written request from the advisory committee for, and approves, a different location. A different location may be approved when one or more of the following applies:

(1) The total cost of the meeting to the government will be reduced.

(2) A substantial number of the advisory committee members will be at the location at no expense to the Food and Drug Administration for other reasons, e.g., for a meeting of a professional association.

(3) It is a central location which is more readily accessible to advisory committee members.

(4) There is a need for increased participation available at that location.

(5) The advisory committee wishes to review work or facilities in a specific location.

(c) Advisory committee members may, with the approval of the Food and Drug Administration, conduct onsite visits relevant to the work of the advisory committee.

(d) A quorum for an advisory committee shall be a majority of the current voting members of the advisory committee, except as provided in § 2.352(c) for TEPRSSC. Any matter before the advisory committee shall be decided by a majority vote of the voting members present at the time, except that the designated Federal official may require that any final report be voted upon by all current voting members of the advisory committee. Any current voting member of the advisory committee may file a separate report with additional or minority views.

(e) Subject to availability of space, any interested person may attend any portion of any advisory committee meeting which is not closed.

(f) Whenever feasible, meetings shall be held in government facilities or other facilities involving the least expense to the public. The size of the meeting room shall be reasonable, considering such factors as the size of the advisory committee, the number of members of the public who could be expected to attend a particular meeting, the number of persons who attended or sought to attend similar meetings in the past, and the resources and facilities available.

(g) Any portion of a meeting shall be closed by the advisory committee chairman when matters which have been determined by the Commissioner to be closed in accordance with § 2.318 are to be discussed. Where a portion of the meeting is closed, the closed portion shall be held after the conclusion of the open portion whenever practicable.

(h) Any advisory committee member may take notes during advisory committee meetings and report and discuss advisory committee deliberations after a meeting is completed and before official minutes or a report are available, within such rules and regulations as are adopted by the Food and Drug Administration and by the advisory committee with the concurrence of the Food and Drug Administration, including all of the following:

(1) There shall be no attribution of individual views expressed in a closed session or revealing of numerical votes.

(2) There shall be no reporting or discussion with respect to any particular matter where the advisory committee or the Food and Drug Administration specifically so directs, e.g., where deliberations are incomplete or involve a sensitive regulatory decision which requires preparation for implementation.

(3) There shall be no reporting or discussion with respect to data or information prohibited from public disclosure pursuant to § 2.316.

(4) Any notes or minutes kept or report prepared by any advisory committee member shall have no status or effect whatever unless adopted as or incorporated into the official minutes or report by the advisory committee. It shall be the responsibility of each advisory committee member to make certain that the official minutes and reports are complete and accurate and fully reflect what happened at any meeting he attended.

§ 2.308 Consultation by a public advisory committee with other persons.

(a) An advisory committee may consult with any person who may have data, information, or views relevant to any matter pending before the advisory committee.

(b) Any interested person may submit to the advisory committee a written request that it consult with specific persons who may have data, information, or views relevant to any matter pending before the advisory committee. Such request shall state why the specified person should be consulted and why the views of that person cannot reasonably be furnished to the advisory committee by any other means. The advisory committee may, in its discretion, grant or deny such a request.

§ 2.309 Additional rules for a particular public advisory committee.

(a) In addition to the rules established for all Food and Drug Administration advisory committees in this subpart, any advisory committee may, with the concurrence of the designated Federal official, adopt additional rules which are not inconsistent with this subpart or with applicable legal requirements.

(b) Such additional rules shall be included in the minutes of the meeting when adopted and in the materials compiled pursuant to § 2.310 and shall be available for public disclosure pursuant to § 2.317(c).

§ 2.310 Compilation of materials for members of a public advisory committee.

The Commissioner shall prepare and provide to all advisory committee members a compilation of materials bearing upon an advisory committee member's duties and responsibilities, including:

(a) All applicable conflict of interest laws and regulations and a summary of their principal provisions.

(b) All applicable laws and regulations relating to trade secrets and confidential commercial or financial information that may not be disclosed publicly and a summary of their principal provisions.

(c) All applicable laws, regulations, and guidelines relating to the subject matter covered by the advisory committee and a summary of their principal provisions.

(d) All applicable laws, regulations, advisory committee charters, FEDERAL REGISTER notices, curricula vitae, rules adopted by the advisory committee, and other material relating to the formation, composition, and operation of the advisory committee, and a summary of their principal provisions.

(e) Instructions on whom to contact when any questions arise.

(f) Such other material relating to the Food and Drug Administration and the subject matter covered by the committee as may facilitate the work of the advisory committee.

§ 2.311 Written submissions to a public advisory committee.

(a) Ten copies of all written submissions for an advisory committee shall be sent to the executive secretary of the advisory committee, unless an applicable FEDERAL REGISTER notice or other regulations in this chapter specify otherwise. All such submissions shall be subject to the provisions of § 2.5, except that no copies need be sent to the Hearing Clerk.

(b) At the request of an advisory committee, or on his own initiative, the Commissioner may at any time issue in the FEDERAL REGISTER a notice requesting the submission to the advisory committee of written data, information, and views pertinent to any matter being reviewed by an advisory committee. Such notice may specify the format in which the submission shall be made, the number of copies to be submitted, and the time within which submission shall be made.

(c) Any interested person may submit to an advisory committee written data, information, or views on any matter being reviewed by that advisory committee. Voluminous data shall be accompanied by a summary.

(1) Any such submission shall be distributed to each advisory committee member, either by mail or at the next advisory committee meeting, and shall be considered by the advisory committee in its review of the matter.

(2) An advisory committee may establish, and shall give public notice of, a cut-off date after which submissions relating to any matter shall no longer be received or considered.

(d) The Commissioner shall provide to an advisory committee all data and information he concludes to be relevant to any matter being reviewed by the advisory committee. Any member of the advisory committee shall, upon request, also be provided any additional material available to the Food and Drug Administration which he believes appropriate for an independent judgment on the matter, e.g., raw data underlying any summary or report, or a briefing on the legal aspects of the matter.

§ 2.312 Conduct of a public hearing before a public advisory committee.

(a) For each advisory committee meeting, the open portion for public participation which constitutes a public hearing pursuant to § 2.304(a) shall be at least 1 hour long unless the public participation does not last that long, and may last for whatever longer time the advisory committee chairman determines will facilitate the work of the advisory committee. The FEDERAL REGISTER notice published pursuant to § 2.303 shall designate the time specifically reserved for such public hearing, which shall ordinarily be the first portion of the meeting. Further public participation in any open portion of the meeting pursuant to § 2.304(b) shall be solely at the discretion of the advisory committee chairman.

(b) Any interested person who wishes to be assured of the right to make an oral presentation at a particular advisory committee hearing shall so inform the executive secretary of the advisory committee or other designated agency employee, orally or in writing, prior to the advisory committee meeting.

(1) Such person shall state the general nature of the presentation and the approximate time requested. Whenever possible, all written data and information to be discussed by that person at the advisory committee hearing shall be furnished in advance to the executive secretary or other designated agency employee. Such written material shall be mailed to the advisory committee members in advance of the committee meeting if time permits, and otherwise will be distributed to the advisory committee members when they arrive for the meeting. Such mailing or distribution shall be undertaken only by the agency unless the agency specifically permits the person making the presentation to mail or distribute such material.

(2) Prior to the advisory committee hearing, the executive secretary or other designated agency employee shall determine the amount of time allocated to each person for his oral presentation and the time that oral presentation is scheduled to begin. Each such person shall be so informed in writing, or if the time prior to the hearing is short, by telephone. Joint presentations may be required by persons with common interests.

(c) The chairman of the advisory committee shall preside at the hearing pursuant to § 2.306 and shall be accompanied by other advisory committee members who shall serve as a panel in conducting the hearing.

(d) Each person may use his allotted time in whatever way he wishes, consistent with a reasonable and orderly hearing. A person may be accompanied by any number of additional persons, and may present any written data, information, or views for inclusion in the record of the hearing, subject to the requirements of § 2.311(c).

(e) If a person is not present at the time specified for his presentation, the persons following will appear in order. An attempt will be made to hear any such person at the conclusion of the hearing. Any interested persons attending the hearing who did not request an opportunity to make an oral presentation shall be given an opportunity to make an oral presentation at the conclusion of the hearing, in the discretion of the chairman of the advisory committee, to the extent that time permits.

(f) The chairman and other members of the advisory committee may question any person during or at the conclusion of his presentation. No other person attending the hearing may question a person making a presentation. The chairman may allot additional time to any person when he concludes that it is in the public interest, but may not reduce the time allotted for any person without his consent.

(g) Public participants may question an advisory committee member only with that advisory committee member's permission and only about matters before the advisory committee.

(h) The hearing shall be informal in nature, and the rules of evidence shall not apply. No motions or objections relating to the admissibility of data, information, and views shall be made or considered, but other participants may comment upon or rebut all such data, information, and views. No participant may interrupt the presentation of another participant at any hearing for any reason.

§ 2.313 Minutes and reports of public advisory committee meetings.

(a) The executive secretary or other designated agency employee shall prepare detailed minutes of all advisory committee meetings, except that less detailed minutes may be prepared for open portions of meetings which are transcribed or recorded by the agency. Their accuracy shall be approved by the advisory committee and certified by the advisory committee chairman. Such approval and certification may be accomplished by mail and by telephone.

(b) The minutes shall include:

(1) The time and place of the meeting.

(2) The advisory committee members, committee staff, and agency employees present, and the names and affiliations or interests of public participants in the meeting.

(3) A copy of or reference to all written information made available for consideration by the advisory committee at such proceedings.

(4) A complete and accurate description of matters discussed and conclusions reached. Such description shall be kept separately for the following portions of the meeting to facilitate their public disclosure: The open portions specified in § 2.304 (a) and (b), any closed portion during which a presentation is made pursuant to § 2.304(c), and any closed deliberative portion pursuant to § 2.304(d). The minutes of a closed deliberative portion of a meeting shall not refer to advisory committee members by name, except upon their request, or to data or information described in § 2.316(b). Any such inadvertent references which do occur shall be deleted prior to public disclosure.

(5) A copy of or reference to all reports received, issued, or approved by the advisory committee.

(6) The extent to which the meeting was open and closed to the public.

(7) The extent of public participation, including a list of members of the public who presented oral or written statements.

(c) For all advisory committee meetings any portion of which is closed, either (1) the minutes of the closed portion shall be available for public disclosure pursuant to § 2.316(a)(6)(i), or (2) if pursuant to § 2.316(a)(6)(ii) such minutes are not promptly available, the executive secretary or other designated

agency employee shall prepare a brief summary of the matters considered in such manner as is informative to the public, consistent with the policy of 5 U.S.C. 522(b).

(d) Where a significant portion of the meetings of an advisory committee is closed, the advisory committee shall issue a report at least annually setting forth a summary of its activities and such related matters as would be informative to the public consistent with the policy of 5 U.S.C. 552(b). Such report shall be a compilation of or be prepared from the individual reports on closed portions of meetings prepared pursuant to paragraph (c) of this section.

(e) The executive secretary of each advisory committee or other designated agency employee shall, with the approval of the advisory committee, prepare an annual report describing its membership, functions, recommendations, and other actions.

§ 2.314 Transcripts of public advisory committee meetings.

(a) A transcript or recording is not required for any portion of an advisory committee meeting.

(b) Each advisory committee shall decide whether any portion or all of its meetings shall be transcribed or recorded and, if so, by what means. Any such transcription or recording shall be arranged by the agency.

(c) If a transcript or recording of an open portion of an advisory committee meeting is made by the Food and Drug Administration, or is made by any interested person and is submitted to the Food and Drug Administration, it shall be included in the record of the advisory committee proceedings.

(d) If a transcript or recording of any closed portion of an advisory committee meeting is made by the Food and Drug Administration, it shall not be included in the administrative record of the advisory committee proceedings. Any such transcript or recording shall be retained as confidential by the Food and Drug Administration and shall not be discarded or erased. The chairman of the advisory committee may, in his discretion, permit discussion without transcription or recording during any closed portion of an advisory committee meeting that is otherwise being transcribed or recorded.

(e) Any transcript or recording of an advisory committee meeting or portion thereof which is publicly available pursuant to this section shall be available at actual cost of duplication, which shall be, where applicable, the fees established in § 4.42 of this chapter. The Food and Drug Administration may furnish the requested transcript or recording for copying to a private contractor who shall charge directly for the cost of copying pursuant to § 4.51 of this chapter.

(f) Any person attending any open portion of an advisory committee meeting may, consistent with the orderly conduct of the meeting, record or otherwise take his own transcript of the meeting. No person attending any closed portion of any advisory committee meeting may record or otherwise take his own transcript of the meeting, except for an official transcript or recording arranged by the Food and Drug Administration.

§ 2.315 Administrative record of a public hearing before a public advisory committee.

(a) Advice or recommendations of an advisory committee shall be given only on matters covered in the administrative record of the advisory committee's proceedings. Except as specified otherwise in regulations in this chapter, such administrative record shall consist of all of the following:

(1) Any transcript or recording that was made of any open portion of a meeting relating to the matter.

(2) The minutes of all portions of all advisory committee meetings relating to the matter, after any deletions pursuant to § 2.313(b)(4).

(3) All written submissions made to and data and information considered by the advisory committee relating to the matter.

(4) All reports made by the advisory committee relating to the matter.

(b) The record of the administrative proceeding shall be closed at the time the advisory committee renders its advice or recommendations or at any earlier time specified by the advisory committee or in other sections in this chapter.

§ 2.316 Examination of administrative record and other advisory committee records.

(a) The administrative record and other advisory committee records shall be available for public disclosure pursuant to the provisions of Part 4 of this chapter, except as provided in paragraph (b) of this section, at the following time:

(1) The written information made available for consideration by the advisory committee at any meeting, at the same time.

(2) The transcript or recording of any open portion of a meeting, as soon as it is available.

(3) The minutes of any open portion of a meeting, after they have been approved by the advisory committee and certified by the advisory committee chairman.

(4) The brief summary of any closed portion of a meeting prepared pursuant to § 2.313(c), as soon as it is available.

(5) All written data, information, or views submitted to the advisory committee at any open portion of a meeting, as soon as they are so submitted.

(6) The minutes or portions thereof of any closed executive portion of a meeting:

(i) For any matter not directed to be maintained as confidential pursuant to § 2.307(h)(2), after they have been approved by the advisory committee and certified by the advisory committee chairman.

(ii) For any matter directed to be maintained as confidential pursuant to § 2.307(h)(2), after the advice or report of the advisory committee relevant to those minutes or portions thereof is acted upon by the Commissioner, or upon a determination by the Commissioner that such minutes or portions thereof may be made available for public disclosure without undue interference with agency or advisory committee operations.

(7) Any formal advice or report of the advisory committee, after it has been acted upon, i.e., approved, disapproved, or rejected as inadequate, by the Commissioner, or upon a determination by the Commissioner that such formal advice or report may be made available for public disclosure without undue interference with agency and/or advisory committee operations. Such formal advice or report may be retained as confidential while it is under active advisement.

(8) Any other advisory committee records relating to the matter involved, except transcripts and recordings of closed portions of advisory committee meetings, after the advice or report of the advisory committee relevent to those records is acted upon by the Commissioner, or upon a determination by the Commissioner that such records may be made available for public disclosure without undue interference with agency or advisory committee operations.

(b) The following data and information contained in the administrative record shall not be available for public examination or copying except as provided in § 2.117(g):

(1) Material provided to the advisory committee by the Food and Drug Administration which is exempt from public disclosure pursuant to the provisions of Part 4 of this chapter and the regulations referenced therein.

(2) Material provided to the advisory committee by a person making a presentation described in § 2.304(c) and which is prohibited from public disclosure pursuant to the provisions of Part 4 of this chapter and the regulations referenced therein.

(c) The Public Records and Documents Center shall maintain a file for each advisory committee containing the following principal records of that advisory committee for ready access by the public: The advisory committee charter, a list of advisory committee members and their curricula vitae, the minutes of advisory committee meetings, and any formal advice or report of the advisory committee.

§ 2.317 Public inquiries and requests for public advisory committee records.

(a) Public inquiries on general advisory committee matters, except requests for records, shall be directed to: Committee Management Officer (HFS-20), Office of the Associate Commissioner for Science, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852.

(b) Public inquiries on matters relating to a specific advisory committee, except requests for records, shall be directed to the executive secretary of the advisory committee or other designated agency employee as listed in the FEDERAL REGISTER notices published pursuant to § 2.303.

(c) All requests for public advisory committee records, including minutes, shall be made to the Food and Drug Administration Public Records and Documents Center pursuant to § 4.40 and the related provisions of Part 4 of this chapter.

§ 2.318 Determination to close portions of public advisory committee meetings.

(a) No advisory committee meeting shall be entirely closed. A portion of an advisory committee meeting may be closed only pursuant to a determination made in writing by the Commissioner, stating the reasons therefor, in accordance with this section.

(b) The executive secretary of an advisory committee or other designated agency employee shall prepare the initial request for a determination to close a portion of an advisory committee meeting, specifying the matter(s) to be discussed during the closed portion and the reasons why the portion should be closed. The Commissioner, based upon this request and with the concurrence of the Chief Counsel, shall determine whether to close a portion of an advisory committee meeting. Such a determination may be made with respect to a single meeting or, where appropriate, a series of meetings. The reasons for closing a portion of a meeting shall be made in the FEDERAL REGISTER notice of the meeting published pursuant to § 2.305 in accordance with the following rules:

(1) Any determination to close a portion of a meeting shall restrict such closing to the shortest possible time consistent with the policy established in this section.

(2) Portions of meetings devoted to the review, discussion, evaluation, or ranking of grant applications, contract proposals, or performance by grantees and contractors shall be closed.

(3) Portions of meetings during which matters are considered that are prohibited from public disclosure pursuant to the provisions of Part 4 of this chapter and the regulations reference therein shall be closed.

(4) Portions of meetings during which matters are considered that are exempt from public disclosure pursuant to 5 U.S.C. 552(b) may be closed if the Commissioner determines that:

(i) It involves discussion of existing documents falling within 5 U.S.C. 552 (b) (1) through (4) and (6) through (9) or matters that, if in writing, would fall within 5 U.S.C. 552(b) (1) through (4) and (6) through (9).

(ii) It involves discussion of existing documents falling within 5 U.S.C. 552 (b)(5) and § 4.62 of this chapter (interagency or intragency memoranda or letters which would not be available by law to a party other than an agency in litigation with the agency) or matters that, if in writing, would fall within 5 U.S.C. 552 (b)(5) and § 4.62 of this chapter, and it is essential to close such portion of such meeting to protect the free exchange of internal views and to avoid undue interference with agency or advisory committee operations.

(5) Examples of portions of advisory committee meetings which ordinarily may be closed include the review, discussion, and evaluation of specific investigational or marketed drugs and devices which are intended to result in recommendations for regulatory decisions under the laws administered by the Commissioner, deliberative sessions to formulate advice and recommendations to the agency, review of confidential data and information, consideration of matters involving investigatory files compiled for law enforcement purposes, and review of matters involving personal privacy.

(6) Examples of advisory committee meetings which ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices, consideration of labeling requirements for a class of marketed drugs and devices, review of data and information on specific investigational or marketed drugs and devices which have previously been made public, and presentation of any other data or information which is not exempt from public disclosure pursuant to the provisions of Part 4 of this chapter and the regulations referenced therein.

(7) No portion of an advisory committee meeting devoted to matters other than those designated in paragraph (b) (1) through (4) of this section may be closed, and no portion of a meeting of the Technical Electronic Product Radiation Safety Standards Committee may be closed, except in accordance with § 2.354.

(8) A matter which is properly considered in an open portion of an advisory committee meeting may instead be considered in a closed portion only if it is so inextricably intertwined with matters to be discussed in a closed portion that it is not feasible to separate them or discussion of the matter in an open portion would compromise or impinge upon the matters to be discussed in the closed portion.

(c) A closed portion of an advisory committee meeting shall be attended only by advisory committee members and Federal Government Executive Branch employees and consultants, except as provided in § 2.304(c) for presentation of data and information which are prohibited from public disclosure pursuant to the provisions of Part 4 of this chapter and the regulations referenced therein. Any person making a presentation described in § 2.304(c) may be accompanied by a reasonable number of employees, consultants, or other persons with whom he has a commercial arrangement within the meaning of § 4.81(a) of this chapter. If any person other than an advisory committee member or a Federal Government Executive Branch employee or special government employee or a person making a presentation described in § 2.304(c) attends a portion of an advisory committee meeting, that portion shall be open to attendance by any interested person.

§ 2.319 Administrative remedies.

Any person who alleges noncompliance by the Commissioner or an advisory committee with any provision of this subpart or the Federal Advisory Committee Act may pursue the following administrative remedies.

(a) If the person objects to any action, including a failure to act, other than denial of access to an advisory committee document, he shall submit a petition in the form and pursuant to the requirements specified in § 2.7. The provisions of § 2.11 relating to exhaustion of administrative remedies shall be applicable.

(1) If the person objects to past action, the petition shall be submitted within 30 days after the action objected to. If the Commissioner determines that there was noncompliance with any provision of this subpart or of the Federal Advisory Committee Act, he shall grant any appropriate relief and shall take appropriate steps to prevent its recurrence in the future.

(2) If the person objects to proposed future action, the Commissioner shall expedite his review of the petition and shall make a reasonable effort to render a decision prior to the action which is the subject of the petition.

(3) If the person objects to action that is imminent or is occurring and which could not reasonably have been anticipated in advance, e.g., the closing of a portion of a meeting which is made known for the first time on the day of the meeting, the matter may be handled by an oral petition in lieu of a written petition.

(b) If the person objects to a denial of access to an advisory committee document, administrative review shall be pursued in accordance with the procedures established by the Department of Health, Education, and Welfare under 45 CFR 5.82.

§ 2.320 Applicability to Congress.

The provisions of this subpart shall apply to Congress, individual members of Congress, and other employees or representatives of Congress, in the same way that they apply to any other member of the public, except that disclosure of advisory committee records to Congress shall be governed by the provisions of § 4.87 of this chapter.

§ 2.321 Committees working pursuant to a contract with the Food and Drug Administration.

(a) The Food and Drug Administration may enter into contracts with independent scientific or technical organizations to obtain advice and recommendations on particular matters, and such organizations may in turn undertake such work through existing or new committees. Whether a particular committee working pursuant to such a contract is a public advisory committee and thus subject to all of the provisions of the Federal Advisory Committee Act and this subpart will depend upon application of the criteria and principles established in § 2.300(b).

(b) The following minimum standards shall apply to any committee of an independent scientific or technical organization which is working pursuant to a contract initially executed with the Food and Drug Administration subsequent to July 1, 1975, but which is determined not to be a public advisory committee:

(1) The committee shall give public notice of its meetings and agenda, and shall provide any interested person an opportunity to submit data, information, and views, in writing at any time, and orally at specified times, relevant to the matter which is the subject of the contract. Such notice may be published in the FEDERAL REGISTER or disseminated by any other reasonable means, and shall in any event be filed with the Hearing Clerk not less than 15 days before the meeting. The length of time permitted for oral presentations and the extent to which the committee meets in open session other than for such oral presentations is in the discretion of the committee.

(2) Minutes of all open sessions shall be maintained, to which shall be attached all written submissions made to the committee in open session. After approval, such minutes shall be forwarded to the Hearing Clerk and placed on public display. The extent to which the committee maintains minutes of closed sessions is at the discretion of the committee.

(3) In selecting the members of the Committee, the organization involved shall apply the same principles relating to conflicts of interest as the Food and Drug Administration does in establishing a public advisory committee. Such principles are set out or cross-referenced in this subpart and in Subpart G of this Part. Upon request, the Food and Drug Administration will assist or provide guidance to any such organization in meeting this requirement.

§ 2.322 Application of anticancer clauses.

Whenever the Commissioner concludes that it is appropriate to obtain an independent review of any scientific issue involving application of the anticancer clauses in section 409(c)(3)(A), 512(d)(1)(H), or 706(b)(5)(B) of the act, including whether a substance has been found to induce cancer when ingested by man or animal, and whether a substance has been found, after appropriate tests other than ingestion, to induce cancer in man or animal, he shall ordinarily refer such matter to the Toxicology Advisory Committee which shall hold a public hearing and provide advice and recommendations to the Commissioner on such matter, except as specifically required by the provisions of section 706(b)(5)(C) of the act and § 2.363(a)(2) relating to color additives.

MEMBERS OF PUBLIC ADVISORY COMMITTEES

§ 2.330 Qualifications for members of standing policy and technical advisory committees.

(a) Members of policy advisory committees, which advise the Commissioner on broad and general matters, shall possess the following qualifications:

(1) Policy advisory committee members shall possess diverse interests, education, training, and experience. Technical expertise in the subject matter with which the advisory committee is involved shall not be a requirement.

(2) Policy advisory committee members are special government employees and are subject to the conflict of interest laws and regulations. The Commissioner has determined that, because members representing particular interests, e.g., a representative of labor, industry, consumers, or agriculture, are included on advisory committees specifically for the purpose of representing such interests, any financial interest covered by 18 U.S.C. 208(a) in the class which the member represents is irrelevant to the services which the government expects from them and thus is hereby exempted pursuant to 18 U.S.C. 208(b) as too remote and inconsequential to affect the integrity of their services.

(3) All members of policy advisory committees shall be voting members.

(b) Members of technical advisory committees, which advise on specific regulatory issues, shall possess the following qualifications:

(1) Voting members of technical advisory committees:

(i) Shall possess expertise in the particular subject matter with which the committee is concerned. Members shall have diverse professional education, training, and experience so that the committee will reflect a balanced composition of sufficient scientific expertise to handle the problems that come before it.

(ii) Are special government employees, subject to the conflict of interest laws and regulations.

(2) The Commissioner may, in his discretion, provide for nonvoting members of a technical advisory committee to serve as representatives of and liaison with interested organizations. Nonvoting members of technical advisory committees:

(i) Shall be selected by the interested organizations, as provided in § 2.332. Technical expertise in the subject matter with which the advisory committee is involved shall not be a requirement.

(ii) Are special government employees subject to the conflict of interest laws and regulations, except as provided in § 2.332(e).

(c) No person may serve as a voting or nonvoting member on more than one Food and Drug Administration advisory committee unless the Commissioner determines in writing that such dual membership will facilitate the work of the committees involved and is in the public interest.

(d) Members of Food and Drug Administration advisory committees and the chairman thereof shall be appointed from among those nominated pursuant to §§ 2.331 and 2.333 and from any other sources by the Secretary, the Assistant Secretary for Health, or the Commissioner, pursuant to duly promulgated procedures and delegations of authority.

(e) Members appointed to an advisory committee shall continue to serve for the duration of the advisory committee, or until their terms of appointment expire, they resign, or are removed from membership by the Commissioner.

(f) An advisory committee member may be removed from membership by the Commissioner for good cause. Good cause shall include excessive unjustified absenteeism from advisory committee meetings, a demonstrated bias which interferes with the ability to render objective advice, failure to abide by the procedures established in this subpart, or violation of other applicable rules and regulations, e.g., for nonvoting members, the provisions of § 2.333(c).

§ 2.331 Nominations of voting members of standing advisory committees.

(a) The Commissioner shall publish one or more notices in the FEDERAL REGISTER each year requesting nominations for voting members of all existing standing advisory committees. Each such notice shall list separately the standing advisory committees covered by the notice in which it is known that vacancies will occur during the next 12 months and in which vacancies are not expected but may occur. The notice shall invite the submission of nominations for voting members for any vacancies from any interested individual as well as from consumer, industry, and professional organizations for the advisory committees listed.

(b) The notice published in the FEDERAL REGISTER announcing the establishment of a new standing advisory committee pursuant to § 2.301(b) shall invite the submission of nominations for voting members for such advisory committee.

(c) Any interested person may nominate one or more qualified persons as a member of a particular advisory committee. Nominations shall specify the advisory committee for which the nominee is recommended. A complete curriculum vitae of the nominee shall be included. Nominations shall state that the nominee is aware of the nomination, is willing to serve as a member of the advisory committee, and appears to have no conflict of interest which would preclude committee membership.

(d) Voting members of standing technical advisory committees shall serve as individuals and not as representatives of any group or organization which nominated them or with which they may be affiliated.

§ 2.332 Nominations and selection of nonvoting members of standing technical advisory committees.

(a) The provisions of this section shall apply whenever the Commissioner concludes, in his discretion, that a standing technical advisory committee should include nonvoting members in order to represent and serve as a liaison with interested individuals and organizations.

(b) Except where the Commissioner determines otherwise, non-voting members of a standing technical advisory committee shall be limited to one member selected by consumer groups and organizations and one person selected by industry groups and organizations.

(c) With respect to any nonvoting member representing consumer interests, the Commissioner shall publish a notice in the FEDERAL REGISTER requesting nominations for each specific standing technical advisory committee for which he has determined that nonvoting members are appropriate.

(1) A period of 60 days shall be permitted for submission of such nominations for that particular advisory committee. Any interested person may nominate one or more qualified persons as a nonvoting member of a particular advisory committee to represent consumer interests. Interested persons may, in addition, nominate one or more qualified persons for general consideration as a nonvoting member of any advisory committee to represent consumer interests. All nominations shall be submitted in writing to Director, Office of Consumer Programs (HFG–1), Office of Assistant Commissioner for Professional and Consumer Programs, Food and Drug Administration, Rm. 15B–41, 5600 Fishers Lane, Rockville, MD 20852.

(2) A complete curriculum vitae of any nominee shall be included. Nominations shall state that the nominee is aware of the nomination, is willing to serve as a member of an advisory committee, and appears to have no conflict of interest. If a nominee is interested only in a particular advisory committee, the nomination shall so state. If a nominee is interested in becoming a member of any advisory committee, the nomination shall so state. Nominations which do not comply with the requirements of this paragraph shall not be considered.

(3) The Director, Office of Consumer Affairs, shall compile a list of organizations representing consumers or otherwise involved in consumer affairs, who shall be entitled to vote upon the nominees. Any organization which qualifies as a consumer organization may be included on such list upon request.

(4) After the time for nominations has expired, the curriculum vitae for each of the nominees shall be sent to each of the organizations on the list compiled pursuant to paragraph (c)(3) of this section and to any other person submitting a nomination, together with a ballot to be filled out and returned within 30 days. After the time for return of the ballots has expired, the ballots shall be counted and the nominee who has received the highest number of votes shall be selected as the nonvoting member representing consumer interests for that particular advisory committee. In the event of a tie, the Commissioner shall select the winner by lot from among those tied for the highest number of votes.

(d) With respect to any nonvoting member representing industry interests, the Commissioner shall issue in the FEDERAL REGISTER, for each specific standing technical advisory committee for which he has determined that nonvoting members are appropriate, a notice requesting that any industry organization interested in participating in the selection of an appropriate nonvoting member representing industry interests send a letter stating that interest to the Food and Drug Administration employee designated in the notice within 30 days. After the time for such expression of interest has expired, a letter shall be sent to each organization which has expressed such an interest, attaching a complete list of all such organizations, and stating that it is their responsibility to consult with each other in selecting a single nonvoting member representing industry interests for that particular advisory committee within 60 days after receipt of the letter. If no such individual is so selected within that period of time, the Commissioner shall select the nonvoting member representing industry interests to serve on that advisory committee.

(e) The Commissioner has determined that, because nonvoting members representing consumer and industry interests are included on advisory committees specifically for the purpose of representing such interests and have no vote, any financial interest covered by 18 U.S.C. 208(a) in the class which the member represents is irrelevant to the services which the government expects from them and thus is hereby exempted pursuant to 18 U.S.C. 208(b) as too remote and inconsequential to affect the integrity of their services.

§ 2.333 Rights and responsibilities of nonvoting members of advisory committees.

(a) A nonvoting member of an advisory committee selected to represent and serve as a liaison with interested individuals, associations, and organizations, shall have the same rights as any other advisory committee member except that:

(1) A nonvoting member shall not vote on any matter before the advisory committee except such procedural matters as additional rules adopted pursuant to § 2.309(a), approval of minutes pursuant to § 2.313(a), decisions relating to transcripts pursuant to § 2.314(b), and future meeting dates.

(2) A nonvoting member shall not have access to data and information that constitute a trade secret or confidential commercial or financial information as defined in § 4.61 of this chapter.

(b) A nonvoting member of an advisory committee is subject to, and shall abide by, all rules and regulations adopted by the Food and Drug Administration and the advisory committee.

(c) It is the responsibility of the nonvoting consumer and industry members of an advisory committee to represent the consumer and industry interests in all deliberations.

(1) A nonvoting member does not represent any particular organization or group, but rather represents all interested persons within the class which he is selected to represent. Accordingly, any interested person within the class represented by that nonvoting member shall have access to all written statements or oral briefings related to the committee prepared by the nonvoting member for distribution to any person outside the advisory committee.

(2) The nonvoting member shall review all official advisory committee minutes to assure their completeness and accuracy.

(3) The nonvoting member shall act as a liasion and conduit between the advisory committee and the interested persons whom he represents, and shall transmit requests for information from the committee and relevant data, information, and views to the committee. He shall take the initiative in contacting interested persons whom he represents, to seek out relevant data, information, and views, and to relate the progress of the advisory committee.

(4) A nonvoting industry member shall represent all members of the industry, and not any particular association, company, product, or ingredient. If a matter comes before the committee that directly or indirectly affects the company which employs the nonvoting industry member, he shall so inform the committee but need not absent himself during the discussion or decline to participate in the discussion. A nonvoting industry member shall not discuss his company's position as such, but may discuss any matter in general terms. All presentations and discussions of scientific data and their interpretation on behalf of a company shall occur in open session, except as provided in § 2.305(c).

(5) A nonvoting member of an advisory committee shall not make any presentation to that advisory committee during a hearing conducted by that advisory committee.

(6) Although a nonvoting member is serving in a representative capacity, he shall exercise restraint in performing his functions and shall not engage in unseemly advocacy or attempt to exert undue influence over the other members of the committee.

(d) A nonvoting member of an advisory committee may be removed by the Commissioner for failure to comply with the provisions of this section as well as § 2.330(f).

§ 2.334 Ad hoc advisory committee members.

In selecting members of an ad hoc advisory committee, the Commissioner may utilize the procedures established in §§ 2.331 and 2.332 or any other procedure he concludes to be appropriate under the circumstances.

§ 2.335 Compensation of public advisory committee members.

(a) All voting and nonvoting advisory committee members shall (1) be appointed as special government employees, except for members of the Technical Electronic Product Radiation Safety Standards Committee, and (2) receive a consultant fee and be reimbursed for their travel expenses, including per diem in lieu of subsistence, unless such compensation and reimbursement is waived.

(b) An advisory committee member, notwithstanding his primary residence, while in attendance at meetings of the full committee, or of a subcommittee,

will be paid whether the meetings are held in the Washington, DC area or elsewhere.

(c) An advisory committee member who participates in any agency-directed assignment will be paid at an hourly rate when he performs his work at his home, place of business, or in a Food and Drug Administration facility located within his commuting area, and at a daily rate when he is required to travel outside of his commuting area to perform his assignment. An advisory committee member will not be paid for time spent on normal preparation for a committee meeting.

(1) An agency-directed assignment is an assignment which meets the following criteria:

(i) An activity which requires undertaking a definitive study. The activity must produce a tangible end product, usually a written report. Examples are (*a*) an analysis of the risks and benefits of the use of a class of drugs or a report on a specific problem generated by an IND or NDA; (*b*) the performance of similar investigations or analysis of complex industry submissions to support advisory committee deliberations other than normal meeting preparation; (*c*) the preparation of a statistical analysis leading to an estimate of toxicologically safe dose levels; and (*d*) the design or analysis of animal studies of toxicity, mutagenicity, teratogenicity, or carcinogenicity.

(ii) The performance of an IND or NDA review or similar review.

(2) An advisory committee member who undertakes a special assignment, the end product of which does not represent the end product of the advisory committee, but rather of his own assignment, can be compensated. Should such preparatory work by advisory committee members collectively result in an end product of the advisory committee, this is to be considered normal meeting preparation and advisory committee members are not to be compensated for this work.

(d) Salary while in travel status is authorized when an advisory committee member has his ordinary pursuits interrupted for the substantial portion of an additional day beyond the day or days on which he performs services, and as a consequence he sustains a loss in his regular compensation. This applies on weekends and holidays if the special government employee suffers a loss in income he would otherwise earn on that day. For travel purposes, a substantial portion of a day is defined as 50 percent of the working day, and the traveler will be paid at a daily rate.

STANDING ADVISORY COMMITTEES

§ 2.340 List of standing advisory committees.

The following standing advisory committees have been established for the Food and Drug Administration.

(a) *Office of the Commissioner*—(1) *Board of Tea Experts.* (i) Date established: March 2, 1897.

(ii) Function: Advises on establishment of uniform standards of purity, quality, and fitness for consumption of all tea imported into the United States pursuant to 21 U.S.C. 42.

(2) *National Advisory Food and Drug Committee.* (i) Date established: November 15, 1974.

(ii) Function: Reviews and evaluates agency programs and advises on policy matters of national significance as they relate to the statutory mission of the Food and Drug Administration in the areas of foods, drugs, cosmetics, medical devices, biological products, and electronic products. Reviews and makes recommendations on applications for grants-in-aid for research projects relevant to the mission of the Food and Drug Administration as required by law.

(3) *Toxicology Advisory Committee.* (i) Date established: December 9, 1974.

(ii) Function: Reviews and evaluates available data relating to the evaluation of the safety of chemicals present in foods, drugs, cosmetics, and medical devices. Advises on the safety of specific human drugs, animal drugs, color and food additives, cosmetic components, and components of devices. Recommends the development of standardized methodologies for the toxicity testing of such materials.

(b) *Bureau of Biologics.* (1) Advisory review panels for biological products, and dates established. (i) *Bacterial Vaccines and Bacterial Antigens Panel.* Established December 22, 1972.

(ii) *Bacterial Vaccines and Toxoids Panel.* Established April 16, 1973.

(iii) *Viral Vaccines and Rickettsial Vaccines Panel.* Established April 16, 1973.

(iv) *Skin Test Antigens Panel.* Established August 24, 1973.

(v) *Allergenic Extracts Panel.* Established August 24, 1973.

(vi) *Blood and Blood Derivatives Panel.* Established August 24, 1973.

(2) Function: Reviews and evaluates available data concerning the safety and effectiveness of biological products.

(c) *Bureau of Drugs*—(1) *Anti-Infective Agents Advisory Committee.* (i) Date established: August 30, 1967.

(ii) Function: Reviews and evaluates available data concerning safety and effectiveness of marketed and investigational prescription drugs for use in infectious diseases.

(2) *Arthritis Advisory Committee.* (i) Date established: April 5, 1974.

(ii) Function: Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational prescription drugs for use in arthritic conditions.

(3) *Biometric and Epidemiological Methodology Advisory Committee.* (i) Date established: March 7, 1968.

(ii) Function: Reviews and evaluates scientific studies and data with respect to, and otherwise advises the Commissioner on, epidemiological and biometrical methodology.

(4) *Cardiovascular and Renal Advisory Committee.* (i) Date established: August 27, 1970.

(ii) Function: Reviews and evaluates available data concerning safety and effectiveness of marketed and investigational prescription drugs for use in cardiovascular and renal disorders.

(5) *Controlled Substances Advisory Committee.* (i) Date established: September 27, 1973.

(ii) Function: Advises the Commissioner regarding the scientific and medical evaluation of all information gathered by the Department of Justice and the Department of Health, Education, and Welfare with regard to safety, effectiveness, and abuse potential of drugs or other substances classified as stimulants, sedatives, hypnotics, or analgesics, and recommends actions to be taken with regard to control of such substances.

(6) *Dental Drug Products Advisory Committee.* (i) Date established: June 6, 1972.

(ii) Function: Reviews and evaluates available data concerning safety and effectiveness of marketed and investigational prescription drugs for use in the practice of dentistry.

(7) *FDA/NIDA Drug Abuse Research Advisory Committee.* (i) Date established: March 9, 1967.

(ii) Function: Advises the Food and Drug Administration on action to be taken with respect to investigational use of substances with abuse potential. Advises the National Institute on Drug Abuse on supplies of substances for clinical studies and on quantities of substances for animal and in vitro studies. Advises FDA and NIDA on development of broad outlines for studies of substances with abuse potential and on new methods and tests in animals and man by which the dependence liability of investigational drugs may be estimated.

(8) *Endocrinology and Metabolism Advisory Committee.* (i) Date established: August 27, 1970.

(ii) Function: Reviews and evaluates available data concerning safety and effectiveness of marketed and investigational prescription drugs for use in endocrine and metabolic disorders.

(9) *Gastrointestinal Drugs Advisory Committee.* (i) Date established: January 3, 1974.

(ii) Function: Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational prescription drugs for use in gastrointestinal diseases.

(10) *Neurologic Drugs Advisory Committee.* (i) Date established: June 4, 1974.

(ii) Function: Reviews and evaluates available data concerning safety and effectiveness of marketed and investigational prescription drugs for use in neurologic disease.

(11) *Obstetrics and Gynecology Advisory Committee.* (i) Date established: August 31, 1965.

(ii) Function: Reviews and evaluates available data concerning safety and effectiveness of marketed and investigational prescription drugs for use in the practice of obstetrics and gynecology.

(12) *Oncologic Drugs Advisory Committee.* (i) Date established: October 24, 1973.

(ii) Function: Reviews and evaluates available data concerning the safety and

effectiveness of marketed and investigational prescription drugs for use in the treatment of cancer.

(13) *Ophthalmic Drugs Advisory Committee.* (i) Date established: September 20, 1971.

(ii) Function: Reviews and evaluates available data concerning safety and effectiveness of marketed and investigational prescription drugs for use in diseases and disorders of the eye.

(14) *Psychopharmacological Agents Advisory Committee.* (i) Date established: June 4, 1974.

(ii) Function: Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational prescription drugs for use in the practice of psychiatry and related fields.

(15) *Pulmonary-Allergy and Clinical Immunology Advisory Committee.* (i) Date established: February 17, 1972.

(ii) Function: Reviews and evaluates available data concerning safety and effectiveness of marketed and investigational prescription drugs for use in the treatment of pulmonary disease and diseases with allegeric and/or immunologic mechanisms.

(16) *Radioactive Pharmaceuticals Advisory Committee.* (i) Date established: August 30, 1967.

(ii) Function: Reviews and evaluates available data concerning safety and effectiveness of marketed and investigational prescription drugs for use in the practice of nuclear medicine.

(17) *Respiratory and Anesthetic Drugs Advisory Committee.* (i) Date established: March 23, 1966.

(ii) Function: Reviews and evaluates available data concerning safety and effectiveness of marketed and investigational prescription drugs for use in the field of anethesiology.

(18) *Surgical Drugs Advisory Committee.* (i) Date established: September 14, 1971.

(ii) Function: Reviews and evaluates available data concerning safety and effectiveness of marketed and investigational prescription drugs for use in the field of surgery.

(19) *Advisory review panels for over-the-counter (OTC) drugs.* (i) Dates established.

(*a*) *Antimicrobial Panel.* Established March 16, 1972.

(*b*) *Internal Analgesic Panel.* Established August 31, 1972.

(*c*) *Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Panel.* Established September 19, 1972.

(*d*) *Sedative, Tranquilizer, and Sleep Aid Panel.* Established September 19, 1972.

(*e*) *Laxative, Antidiarrheal, Antiemetic, and Emetic Panel.* Established December 27, 1972.

(*f*) *Topical Analgesic Panel.* Established December 27, 1972.

(*g*) *Dentifrice and Dental Care Panel.* Established December 27, 1972.

(*h*) *Hemorrhoidal Panel.* Established April 16, 1973.

(*i*) *Ophthalmic Panel.* Established April 16, 1973.

(*j*) *Contraceptive and Other Vaginal Drug Products Panel.* Established June 27, 1973.

(*k*) *Oral Cavity Panel.* Established July 16, 1973.

(*l*) *Antiperspirant Panel.* Established July 16, 1973.

(*m*) *Miscellaneous Internal Drug Products Panel.* Established July 16, 1973.

(*n*) *Miscellaneous External Drug Products Panel.* Established July 16, 1973.

(*o*) *Vitamin, Mineral, and Hematinic Panel.* Established July 16, 1973.

(ii) Function: Reviews and evaluates available data concerning the safety and effectiveness of nonprescription drug products.

(d) *Bureau of Medical Devices and Diagnostic Products.* (1) Advisory review panels for medical devices, and dates established.

(i) *Cardiovascular Panel.* Established March 22, 1972.

(ii) *Orthopaedic Panel.* Established April 25, 1972.

(iii) *Diagnostic Products Advisory Committee.* Established August 9, 1972.

(iv) *Dental Panel.* Established October 3, 1972.

(v) *Anesthesiology Panel.* Established October 3, 1972.

(vi) *Gastroenterology and Urological Panel.* Established April 16, 1973.

(vii) *Obstetrical and Gynecological Panel.* Established April 16, 1973.

(viii), *Radiology Panel.* Established October 15, 1973.

(ix) *Neurology Panel.* Established October 15, 1973.

(x) *General Hospital Panel.* Established October 15, 1973.

(xi) *Physiatry Panel.* Established October 15, 1973.

(xii) *General and Plastic Surgery Panel.* Established October 15, 1973.

(xiii) *Ear, Nose, and Throat Panel.* Established October 15, 1973.

(xiv) *Ophthalmic Panel.* Established October 15, 1973.

(2) Function: Reviews and evaluates available data concerning the safety and effectiveness of devices currently in use and makes recommendations for their regulation.

(e) *Bureau of Radiological Health*— (1) *Medical Radiation Advisory Committee.* (i) Date established: October 31, 1963.

(ii) Function: Advises on the formulation of policy and development of a coordinated program related to the application of ionizing radiation in the healing arts.

(2) *Technical Electronic Product Radiation Safety Standards Committee.* (i) Date established: October 18, 1968.

(ii) Function: Advises on technical feasibility, reasonableness, and practicability of performance standards for electronic products to control the emission of radiation pursuant to 42 U.S.C. 263 (f) (1) (A).

(f) *National Center for Toxicological Research, Science Advisory Board.* (1) Date established: June 2, 1973.

(2) Function: Advises on establishment and implementation of a research program that will assist the Commissioner of Food and Drugs and the Administrator, Environmental Protection Agency, in fulfilling their regulatory responsibilities.

TECHNICAL ELECTRONIC PRODUCTS RADIATION SAFETY STANDARDS COMMITTEE

§ 2.350 Establishment of the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC).

The Technical Electronic Product Radiation Standards Committee (TEPRSSC), consisting of 15 members, is established pursuant to the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263f (f) (1) (A)). The purpose of TEPRSSC is to provide consultation with the Commissioner before he prescribes any performance standard for an electronic product, as required by law.

§ 2.351 Functions of TEPRSSC.

(a) In performing its function of advising the Commissioner, TEPRSSC:

(1) May propose electronic product radiation safety standards to the Commissioner for his consideration.

(2) Shall provide consultation to the Commissioner on all performance standards proposed for consideration under 42 U.S.C. 263f.

(3) May make recommendations to the Commissioner on any other matters it deems necessary or appropriate in fulfilling the purposes of the act.

(b) Responsibility for action with respect to performance standards under 42 U.S.C. 263f rests with the Commissioner, after receiving the advice of TEPRSSC.

§ 2.352 Procedures of TEPRSSC.

(a) When the Commissioner is considering promulgation of a performance standard for an electronic product, or any amendment of an existing standard, he shall, prior to issuance of a proposed regulation in the FEDERAL REGISTER, submit to TEPRSSC the proposed standard or amendment under consideration, together with other relevant information to aid TEPRSSC in its deliberations.

(b) The agenda and other material to be considered at any meeting shall be sent to members whenever possible at least 2 weeks prior to the meeting.

(c) Ten members shall constitute a quorum, provided at least three members from each group specified in 42 U.S.C. 263f (f) (1) (A) and in § 2.353(a), i.e., government, industry, and the public, are present.

(d) The chairman of TEPRSSC shall ordinarily submit to the Commissioner a report of the committee's consideration of any proposed performance standard for an electronic product within 60 days after such consideration. If the chairman believes that more time is needed, he shall so inform the Director of the Bureau of Radiological Health in writing, in which case an additional 30 days will be allowed to make the report.

(e) The provisions of §§ 2.300 through 2.319 shall be applicable to TEPRSSC, except where other provisions are specifically included in §§ 2.350 through 2.354.

§ 2.353 Membership of TEPRSSC.

(a) The members shall be appointed by the Commissioner after consultation with public and private associations and organizations concerned with the technical aspect of electronic product radiation safety. TEPRSSC shall consist of fifteen members, each of whom shall be technically qualified by training and experience in one or more fields of science or engineering applicable to electronic product radiation safety, as follows:

(1) Five members shall be selected from government agencies, including State and Federal governments.

(2) Five members shall be selected from the affected industries after consultation with industry representatives.

(3) Five members shall be selected from the general public, of whom at least one shall be a representative of organized labor.

(b) The Commissioner shall appoint a committee member as chairman of TEPRSSC.

(c) Appointments of members shall be for a term of 3 years or as specified by the Commissioner.

(1) The chairman shall be appointed for a term concurrent with his term as a member of TEPRSSC. If the chairmanship becomes vacant without adequate notice, the executive secretary may appoint a committee member as temporary chairman pending appointment of a new chairman by the Commissioner.

(2) Members shall not be reappointed for a second consecutive full term.

(d) A person otherwise qualified for membership shall not be eligible for selection as a member of TEPRSSC from government agencies or the general public if the Commissioner determines that he does not meet the requirements of the conflict of interest laws and regulations.

(e) Retention of membership is conditioned upon:

(1) The member's continued status as a member of the group from which he was selected as specified in paragraph (a) of this section.

(2) The absence of any conflict of interest during the term of membership as specified in paragraph (d) of this section.

(3) Active participation in TEPRSSC activities.

(f) Appointment as a member of TEPRSSC shall be conditioned upon a certification from the prospective member that he:

(1) Agrees to the procedures and criteria as specified in this subpart.

(2) Has no conflict of interest as specified in paragraph (d) of this section.

(3) Will notify the executive secretary of TEPRSSC prior to any change in his representative status on TEPRSSC which may be contrary to the conditions of his appointment.

(g) Members of TEPRSSC who are not full-time officers or employees of the United States shall, in accordance with 42 U.S.C. 210(c), receive compensation pursuant to the provisions of § 2.335.

§ 2.354 Conduct of TEPRSSC meetings; availability of TEPRSSC records.

(a) In accordance with 42 U.S.C. 263 (f)(1)(B), all proceedings of TEPRSSC shall be open, except as provided in paragraph (b) of this section, and shall be recorded, and the record of each such proceeding shall be available for public inspection.

(b) The provisions of paragraph (a) of this section with respect to open meetings shall not apply where TEPRSSC:

(1) Considers any information which contains or relates to a trade secret or other matter referred to in 18 U.S.C. 1905 and thus in accordance with 42 U.S.C. 263i(e) may not be publicly disclosed.

(2) Meets in executive session to formulate and vote on its recommendations or to consider administrative matters.

COLOR ADDITIVE ADVISORY COMMITTEES

§ 2.360 Establishment of a color additive advisory committee.

The Commissioner shall establish a color additive advisory committee whenever:

(a) The Commissioner concludes, in his discretion, that it would be in the public interest for a color additive advisory committee to review and make recommendations with respect to the safety of any color additive on which important issues are pending before the Food and Drug Administration, and for interested persons to present data, information, and views at an oral public hearing before a color additive advisory committee.

(b) Any person who would be adversely affected by the issuance, amendment, or repeal of a regulation listing a color additive requests that any issue relating to the safety of the color additive arising under section 706(b)(5)(B) of the act because of the color additive's potential or actual carcinogenicity and requiring the exercise of scientific judgment be referred to a color additive advisory committee.

(1) The provisions of paragraph (b) of this section are inapplicable to any issue arising under the transitional provisions in section 203 of the Color Additive Amendments of 1960 relating to provisional listing of commercially established colors. Any color additive advisory committee to consider any such matter shall be established pursuant to the provisions of paragraph (a) of this section.

(2) A request for establishment of a color additive advisory committee shall be pursuant to § 2.7. The Commissioner may deny any such petition if inadequate grounds are stated for establishment of a color additive advisory committee. A request for establishment of a color additive advisory committee may not rest on mere allegations or denials, but must set forth specific facts showing there is a genuine and substantial issue of fact that requires scientific judgment and justifies a hearing before a color additive advisory committee. When it conclusively appears from the request for a color additive advisory committee that the matter is premature or that it does not involve an issue arising under section 706(b)(5)(B) of the act or there is no genuine and substantial issue of fact requiring scientific judgment or for any other reason a color additive advisory committee is not justified, the Commissioner may deny the establishment of a color additive advisory committee.

(3) Establishment of a color additive advisory committee on the request of an interested person shall be conditioned upon receipt of the applicable fee specified in § 2.364.

(4) Any person so adversely affected may request referral of such a matter to a color additive advisory committee at any time before, or within 30 days after, publication of an order of the Commissioner acting upon a color additive petition or proposal.

§ 2.361 Functions of a color additive advisory committee.

(a) A color additive advisory committee shall review all available information relating to the matter referred to it, including all data and information contained in any pertinent color additive petition and in Food and Drug Administration files. All such data and information so reviewed shall be placed on public display and available for review at the office of the Hearing Clerk.

(b) The Commissioner shall specify to the color additive advisory committee, in writing, the issues on which review and recommendations are requested.

(c) The date of the first meeting of a color additive advisory committee, following receipt of the administrative record by each of the committee members, shall be designated as the beginning of the period allowed for consideration of the matter by the color additive advisory committee. Within 60 days after that first meeting, unless the time is extended as provided in paragraph (d) of this section, the chairman of the color additive advisory committee shall certify to the Commissioner the report containing the recommendations of the color additive advisory committee, including any minority report. The report shall state the recommendations of the color additive advisory committee and the reasons or basis for such recommendations. The report shall include copies of all material considered by the color additive advisory committee in addition to the administrative record furnished to it.

(d) If the chairman concludes that the color additive advisory committee needs additional time, he shall so inform the Commissioner in writing and may certify the report of the color additive advisory committee to the Commissioner within 90 days instead of 60 days.

(e) More than one matter may be handled by a color additive advisory committee concurrently.

§ 2.362 Procedures of a color additive advisory committee.

(a) A color additive advisory committee shall be subject to all the requirements of the Federal Advisory Committee Act and this subpart.

(b) All interested persons shall have a right to consult with the color additive advisory committee reviewing a matter, and to submit data, information, and views to a color additive advisory committee, in accordance with the procedures established in this subpart.

§ 2.363 Membership of a color additive advisory committee.

(a) The members of a color additive advisory committee shall be selected in the following manner:

(1) If a color additive advisory committee is established for purposes that do not include review of an issue arising under section 706(b)(5)(B) of the act, or is established on the initiative of the Commissioner, the Commissioner may utilize the procedure established in paragraph (a)(2) of this section to select the members, or may utilize an existing standing advisory committee listed in § 2.340, or may establish a new advisory committee pursuant to the provisions of this subpart. Once the Commissioner has established a color additive advisory committee pursuant to this paragraph and has referred to it a matter relating to a color additive, no interested person may subsequently request that an additional or different color additive advisory committee be established to review and make recommendations with respect to that color additive.

(2) If the Commissioner establishes a color additive advisory committee to review an issue arising under section 706(b)(5)(B) of the act on the request of an interested person, it shall be established pursuant to the following requirements.

(i) Except as provided in paragraph (a)(2)(ii) and (iii) of this section, the Commissioner shall request the National Academy of Sciences to select the members of a color additive advisory committee from among experts qualified in the subject matter to be reviewed by the committee, and of adequately diversified professional backgrounds. The Commissioner shall appoint one of the members so selected as the chairman.

(ii) If the National Academy of Sciences is unable or refuses to select the members of a color additive advisory committee, the Commissioner shall select such members, who shall ordinarily be the Toxicology Advisory Committee in accordance with § 2.322.

(iii) If the Commissioner and the requesting party agree, the provisions of section 706(b)(5)(D) of the act may be waived and the matter may be referred to any standing advisory committee listed under § 2.340 or to any advisory committee established pursuant to any other procedure that is mutually agreeable, which shall ordinarily be the Toxicology Advisory Committee in accordance with § 2.322. Once the Commissioner has so established a color additive advisory committee and has referred to it a matter relating to a color additive, no interested person may subsequently request that an additional or different color additive advisory committee be established to review and make recommendations with respect to that color additive.

(b) Members of a color additive advisory committee shall be subject to the requirements of the Federal Advisory Committee Act and this subpart, except that no member of a color additive advisory committee shall by reason of such membership alone be a special government employee or be subject to the conflict of interest laws and regulations.

§ 2.364 Fees and compensation pertaining to a color additive advisory committee.

(a) In the event of a referral of any matter to a color additive advisory committee, all costs related thereto, including personal compensation of committee members, travel, materials, and other costs, shall be borne by the person requesting the referral, such costs to be assessed on the basis of actual cost to the government. The compensation of such costs shall include personal compensation of color additive advisory committee members at a rate not to exceed $128.80 per member per day.

(b) In the case of a request for referral to a color additive advisory committee, a special advance deposit shall be made in the amount of $2,500.00. Where required, further advances in increments of $2,500.00 each shall be made upon request of the Commissioner. All deposits for referrals to a color additive advisory committee in excess of actual expenses shall be refunded to the depositor.

(c) All deposits and fees required by the regulations in this section shall be paid by money order, bank draft or certified check drawn to the order of the Food and Drug Administration, collectable at par in Washington, DC. All deposits and fees shall be forwarded to the Associate Commissioner for Administration, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852, whereupon after making appropriate record thereof they will be transmitted to the Treasurer of the United States for deposit in the special account "Salaries and Expenses, Certification, Inspection, and Other Services, Food and Drug Administration."

(d) The Commissioner may waive or refund such fees in whole or in part when, in his judgment, such action will promote the public interest. Any person who believes that payment of these fees will work a hardship on him may petition the Commissioner pursuant to § 2.7 to waive or refund the fees.

Public Advisory Committees for Human Prescription Drugs

§ 2.370 Establishment of standing technical public advisory committees for human prescription drugs.

The standing technical advisory committees for human prescription drugs are established to advise the Commissioner:

(a) Generally on the safety and effectiveness, including the labeling and advertising, and regulatory control of any of the human prescription drugs falling within the pharmacologic class covered by the advisory committee and on the scientific standards appropriate for a determination of safety and effectiveness in that class of drugs.

(b) Specifically on any particular matter involving a human prescription drug pending before the Food and Drug Administration, including whether the available data and information are adequate to support a determination that:

(1) A particular IND study may properly be conducted.

(2) A particular drug meets the statutory standard for proof of safety and effectiveness necessary for approval or continued approval for marketing.

(3) A particular drug is properly classified as a new drug, an old drug, or a banned drug.

§ 2.371 Utilization of a public advisory committee on the initiative of the Food and Drug Administration.

(a) Any matter involving a human prescription drug under review within the agency may, in the discretion of the Commissioner, be the subject of a public hearing and continuing or periodic review by the appropriate standing technical advisory committee for human prescription drugs. The Commissioner's determinations with respect to the agenda of such an advisory committee shall be based upon the priorities of the various matters pending before the agency which fall within the pharmacologic class covered by that advisory committee.

(b) High priority for such hearing and review by the appropriate standing technical advisory committee for human prescription drugs shall be given to the following types of human prescription drugs:

(1) Investigational drugs which are potential therapeutic advances over currently marketed products from the standpoint of safety or effectiveness, or which pose significant safety hazards, or which present narrow benefit-risk considerations requiring a close judgmental decision in regard to approval for marketing, or which have a novel delivery system or formulation, or which are the subject of major scientific or public controversy, or which may be subject to special regulatory requirements such as a limitation on clinical trials, a patient followup requirement, post-marketing Phase IV studies, distributional controls, or boxed warnings.

(2) Marketed drugs for which an important new use has been discovered, or which pose newly discovered safety hazards, or which are the subject of major scientific or public controversy, or which may be subject to important regulatory actions such as withdrawal of approval for marketing, boxed warnings, distributional controls, or newly required scientific studies.

(c) The advisory committee may request the Commissioner for an opportunity to hold a public hearing and to review any matter involving a human prescription drug which falls within the pharmacologic class covered by the advisory committee. The Commissioner shall, after consulting with the advisory committee on such request, grant or deny

the request in light of the priorities of the other matters pending before the advisory committee. Whenever feasible, consistent with the other work of the advisory committee, such a request shall be granted.

(d) For any drug which meets any of the criteria established in paragraph (b) of this section, one or more members of or consultants to the appropriate advisory committee may be selected for more detailed monitoring of the matter and consultation with the Food and Drug Administration on behalf of the committee. Such member or consultant may be invited by the agency to attend appropriate meetings and shall assist the bureau in any briefing of the committee with respect to that matter.

(e) An advisory committee may obtain advice and recommendations from the Toxicology Advisory Committee, the Biometric and Epidemiological Methodology Advisory Committee, and from such other agency advisory committees, consultants and experts as the advisory committee and the bureau conclude would facilitate the work of the advisory committee.

(f) Presentation of all relevant data and information relating to any such matter shall be made in open session unless it relates to an IND the existence of which has not previously been disclosed to the public as defined in § 4.81 of this chapter or is otherwise prohibited from public disclosure pursuant to the provisions of Part 4 of this chapter and the regulations referenced therein. The provisions of §§ 314.14, 431.71, and 601.51 of this chapter shall determine whether, and the extent to which, relevant data and information shall be made available for public disclosure, summarized and discussed in open session but not otherwise made available for public disclosure, or not in any way discussed or disclosed in open session or otherwise disclosed to the public.

§ 2.372 Advice and recommendations in writing.

Advice and recommendations given by an advisory committee with respect to a specific drug or a class of drugs shall ordinarily be in the form of a written report. Such written report may consist of the approved minutes of the meeting or a separate written report. Such written report shall respond to the specific issues or questions which the Commissioner has addressed to the advisory committee, and shall state the basis of the advice and recommendations of the advisory committee.

§ 2.373 Utilization of a public advisory committee at the request of an interested person.

Any interested person may request, pursuant to § 2.7 of this Part, that a specific matter relating to a particular human prescription drug be submitted to an appropriate advisory committee for a hearing and review and recommendations. Any such request shall demonstrate the importance of the matter and the reasons why it should be submitted for a hearing and at that time. The Commissioner may, in his discretion, grant or deny any such request.

Subpart E—Public Hearing Before the Commissioner

§ 2.400 Scope of subpart.

Subpart E governs the practices and procedures applicable whenever:

(a) The Commissioner concludes, in his discretion, that it is in the public interest to permit interested persons to present data, information, and views at a public hearing on any particular matter, or class of matters, of importance pending before the Food and Drug Administration.

(b) Pursuant to specific provisions in other sections of this chapter, a matter pending before the Food and Drug Administration is subject to a public hearing before the Commissioner. Such specific provisions are in § 330.10(a)(8) of this chapter relating to review of the safety, effectiveness, and labeling of over-the-counter drugs.

(c) A person who has right to an opportunity for a formal evidentiary public hearing under Subpart B of this Part waives that opportunity and in lieu thereof requests pursuant to § 2.117 of this Part a public hearing before the Commissioner pursuant to this Subpart E, and the Commissioner, in his discretion, accepts this request.

§ 2.401 Notice of a public hearing before the Commissioner.

(a) If the Commissioner determines that a public hearing before the Commissioner should be held on any matter, he shall publish in the FEDERAL REGISTER a notice of hearing setting forth the following information:

(1) If the hearing is pursuant to § 2.400 (a) or (b):

(i) The purpose of the hearing and the subject matter to be considered. If any written document is to be the subject matter of the hearing, it shall be published as part of the notice, or reference shall be made to it if it has already been published in the FEDERAL REGISTER, or the notice shall state that the document is available from the Hearing Clerk or an agency employee designated in the notice.

(ii) The time, date, and place of the hearing, or a statement that such information shall be contained in a subsequent notice published in the FEDERAL REGISTER.

(2) If the hearing is in lieu of a formal evidentiary hearing pursuant to § 2.400 (c), all of the information described in § 2.117(e) of this Part.

(b) The scope of the hearing shall be determined by the notice of hearing and any specific provisions in other sections of this chapter. If any such specific provision, e.g., § 330.10(a)(10) of this chapter, limits a hearing to review of an existing administrative record, data and information not already included in the record shall not be submitted or considered at the hearing.

§ 2.402 Notice of appearance; schedule for hearing.

(a) The notice of hearing shall provide interested persons an opportunity to file a written notice of appearance with the Hearing Clerk within a specified period of time in the form and pursuant to the requirements specified in § 2.131. If the public interest requires that such a hearing be conducted within a short period of time, the notice may name a specific Food and Drug Administration employee, together with his telephone number, to whom an oral notice of appearance shall be given. A written or oral notice of appearance shall be received by the Hearing Clerk, or other designated person, by the close of business of the day specified in the notice.

(b) A notice of appearance shall state the approximate amount of time requested by the person for his presentation. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations.

(c) Promptly after expiration of the time specified in the notice for the filing of a notice of appearance, the Commissioner shall determine the amount of time allocated to each such person for his oral presentation and the time that oral presentation is scheduled to begin. Each such person shall be so informed in writing or, if the time prior to the hearing is short, by telephone. The Commissioner may require joint presentations by persons with common interests.

(d) The Commissioner shall prepare a hearing schedule showing the persons making oral presentations and the time allotted to each such person, which shall be filed with the Hearing Clerk and mailed or telephoned to each such person and, if time permits, published in the FEDERAL REGISTER.

§ 2.403 Conduct of a public hearing before the Commissioner.

(a) The Commissioner or his designee shall preside at the hearing, except where specific provisions in other sections of this chapter require that the Commissioner preside personally. The presiding officer may be accompanied by other Food and Drug Administration employees or other Federal government employees designated by the Commissioner, who may serve as a panel in conducting the hearing.

(b) The hearing shall be transcribed.

(c) Each person may use his allotted time in whatever way he wishes, consistent with a reasonable and orderly hearing. A person may be accompanied by any number of additional persons, and may present any written data, information, or views for inclusion in the record of the hearing, subject to the requirements of § 2.404.

(d) If a person is not present at the time, specified for his presentation, the persons following will appear in order. An attempt will be made to hear any such person at the conclusion of the hearing. Any other interested persons attending the hearing who did not request an opportunity to make an oral

presentation shall be given an opportunity to make an oral presentation at the conclusion of the hearing, in the discretion of the presiding officer, to the extent that time permits.

(e) The presiding officer and any other persons serving with him as a panel may question any person during or at the conclusion of his presentation. No other person attending the hearing may question a person making a presentation. The presiding officer may allot additional time to any person when he concludes that it is in the public interest, but may not reduce the time allotted for any person without their consent.

(f) The hearing shall be informal in nature, and the rules of evidence shall not apply. No motions or objections relating to the admissibility of data, information, and views shall be made or considered, but other participants may comment upon or rebut all such data, information, and views. No participant may interrupt the presentation of another participant at any hearing for any reason.

§ 2.404 Written submissions pertaining to a public hearing before the Commissioner.

Any interested person may submit data, information, or views on the matter that is the subject of the hearing in writing to the Hearing Clerk, pursuant to § 2.5. The record of the hearing shall remain open for 15 days after the hearing is held for any additional written submissions, unless the notice of the hearing specifies otherwise or the presiding officer rules otherwise at the hearing.

§ 2.405 Administrative record of a public hearing before the Commissioner.

(a) The administrative record of a public hearing before the Commissioner shall consist of the following:

(1) All relevant FEDERAL REGISTER notices, including any documents to which they refer.

(2) All written submissions pursuant to § 2.404.

(3) The transcript of the oral hearing.

(b) The record of the administrative proceeding shall be closed at the time specified in § 2.404.

§ 2.406 Examination of administrative record.

The availability for public examination and copying of each document which is a part of the administrative record of the hearing shall be governed by the provisions of § 2.5(j). Each document which is available for public examination or copying shall be placed on public display in the office of the Hearing Clerk promptly upon receipt in that office.

Subpart F—Regulatory Hearing Before the Food and Drug Administration

§ 2.500 Scope of subpart.

Subpart F governs the practices and procedures applicable whenever:

(a) The Commissioner is considering any regulatory action, including a refusal to act, and concludes, in his discretion, on his own initiative or at the suggestion of any person, to offer an opportunity for a regulatory hearing to obtain additional information before he makes a decision or takes action.

(b) Any provision in any regulation of this chapter provides any person with an opportunity for a hearing with respect to any regulatory action, including proposed action, and such regulation either specifically provides an opportunity for a regulatory hearing pursuant to this subpart or provides an opportunity for a hearing but does not specify the procedures for such hearing and such procedures are not specified in other provisions of this chapter. Such sections are:

(1) Section 202.1(j)(5), relating to approval of prescription drug advertisements.

(2) Section 8.27(b), relating to refusal to certify a batch of a color additive.

(3) Section 8.28(b), relating to suspension of certification service for a color additive.

(4) Section 8.33(a), relating to use of food containing a new color additive.

(5) Section 10.5(l), relating to a temporary permit to vary from a food standard.

(6) Section 121.75(b), relating to use of food containing an investigational food additive.

(7) Section 511.1(b)(5), relating to use of food containing an investigational new animal drug.

(8) Section 511.1(c)(1), relating to termination of an INAD for an investigator.

(9) Section 511.1 (c)(4) and (d), relating to termination of an INAD for a sponsor.

(10) Section 514.210, relating to suspension of certification service for a veterinary antibiotic drug.

(11) Section 312.1(c)(1), relating to whether an investigator is entitled to receive investigational new drugs.

(12) Sections 312.1 (c)(4) and (d), relating to termination of an IND for a sponsor.

(13) Section 312.9(c), relating to termination of an IND for tests in vitro and in laboratory research animals for a sponsor.

(14) Section 429.50, relating to suspension of certification service for an insulin drug.

(15) Section 431.52, relating to suspension of certification service for an antibiotic drug.

(16) Section 433.2(d), relating to exemption from certification for an antibiotic drug.

(17) Section 433.12(b)(5), relating to an exemption from labeling for a certifiable antibiotic drug.

(18) Section 433.13(b), relating to an exemption from manufacturing use for a certifiable antibiotic drug.

(19) Section 433.14(b), relating to an exemption for storage for a certifiable antibiotic drug.

(20) Section 433.15(b), relating to an exemption for processing for a certifiable antibiotic drug.

(21) Section 433.16(b), relating to an exemption for repacking for a certifiable antibiotic drug.

(22) Section 1003.11(a)(3), relating to the failure of an electronic product to comply with an applicable standard or to a defect in an electronic product.

(23) Section 1003.31(d), relating to denial of an exemption from notification requirements for an electronic product which fails to comply with an applicable standard.

(24) Section 1004.6, relating to plan for repurchase, repair, or replacement of an electronic product.

(25) Section 1210.30, relating to denial, suspension, or revocation of a permit under the Federal Import Milk Act.

(26) Any other provision in the regulations in this chapter under which a party who is adversely affected by regulatory action is entitled to an opportunity for a hearing, and no other procedural provisions in this part are by regulation applicable to such hearing.

§ 2.501 Inapplicability and limited applicability.

(a) The provisions of this subpart are inapplicable to the following:

(1) Informal presentation of views before reporting a criminal violation pursuant to section 305 of the act and § 1.6 of this chapter, and section 5 of the Federal Import Milk Act and § 1210.31 of this chapter.

(2) A hearing with respect to a refusal of admission of a food, drug, device, or cosmetic pursuant to section 801(a) of the act and § 1.318 of this chapter, or of an electronic product pursuant to section 360(a) of the Public Health Service Act and § 1005.20 of this chapter.

(b) The provisions of this subpart are applicable to hearings conducted pursuant to specific procedural provisions in other sections of this chapter to the extent that the provisions of this subpart are in addition to the provisions in such other sections and not in conflict with them, e.g., the right to counsel, public notice of the hearing, reconsideration and stay, and judicial review. Such other sections include Subpart A of Part 90 of this chapter, relating to emergency permit control.

§ 2.505 Presiding officer.

(a) Any Food and Drug Administration employee to whom the Commissioner delegates such authority, or any other agency employee designated by an employee to whom such authority is delegated, may serve as the presiding officer at and conduct a regulatory hearing pursuant to the provisions of this subpart.

(b) The presiding officer shall be free from bias or prejudice and shall not have participated in the investigation or action that is the subject of the hearing or be subordinate to a person who has participated in such investigation or action.

(c) A different presiding officer may be substituted for the one originally designated pursuant to §§ 2.510 and 2.511 without notice to the parties.

§ 2.506 Right to counsel.

Any party to a hearing pursuant to this subpart shall have the right at all times to be advised and accompanied by counsel.

§ 2.510 Regulatory hearing on the initiative of the Commissioner.

(a) A regulatory hearing on the initiative of the Commissioner pursuant to § 2.500(a) shall be initiated by a notice of opportunity for hearing from the Food and Drug Administration.

(1) Such notice shall be sent by registered mail, telegram, telex, personal delivery, or any other mode of written communication.

(2) Such notice shall specify the facts and the action that are the subject of the opportunity for a hearing.

(3) Such notice shall state that the notice of opportunity for hearing and the hearing are governed by the provisions of this subpart.

(4) Such notice shall state the time within which a hearing shall be requested, shall be signed by the Food and Drug Administration employee who will be the presiding officer in the event a hearing is held, and shall state the name, address, and telephone number of the presiding officer.

(b) Any person offered an opportunity for a hearing shall have the amount of time specified in the notice, which shall be not less than 3 working days after receipt of such notice, within which to request a hearing. Such request may be filed by registered mail, telegram, telex, personal delivery, or any other mode of written communication, addressed to the presiding officer. If no response is filed within such time, the offer shall be deemed to have been refused and no hearing shall be held.

(c) If a hearing is requested, such hearing shall take place at a time and location agreed upon by the party requesting the hearing and the presiding officer or, if such agreement cannot be reached, at a reasonable time and location designated by the presiding officer.

(d) A notice of opportunity for hearing under this section shall not operate to delay or stay any administrative action, including enforcement action of any kind, by the agency unless the Commissioner, in his discretion, determines that delay or a stay is in the public interest.

§ 2.511 Regulatory hearing pursuant to regulation.

(a) A regulatory hearing pursuant to a regulation listed in § 2.500(b) shall be initiated by a notice of opportunity for hearing from the Food and Drug Administration.

(1) Such notice shall be sent by registered mail, telegram, telex, personal delivery, or any other mode of written communication.

(2) Such notice shall specify the facts and the action that are the subject of the opportunity for hearing, and shall state whether the action is or is not being taken pending the hearing pursuant to paragraph (e) of this section.

(3) Such notice shall state that the notice of opportunity for hearing and the hearing are governed by the provisions of this subpart.

(4) Such notice shall state the time within which a hearing shall be requested, and shall state the name, address, and telephone number of the Food and Drug Administration employee to whom any request for hearing shall be addressed.

(b) Any person offered an opportunity for hearing shall have the amount of time specified in the notice, which shall be not less than 3 working days after receipt of such notice, within which to request a hearing. Such request may be filed by registered mail, telegram, telex, personal delivery, or any other mode of written communication, addressed to the presiding officer. If no response is filed within such time, the offer shall be deemed to have been refused and no hearing shall be held.

(c) If a hearing is requested, the Commissioner shall designate a presiding officer and such hearing shall take place at a time and location agreed upon by the party requesting the hearing and the presiding officer or, if such agreement cannot be reached, at a reasonable time and location designated by the presiding officer. The hearing may not be required to be held at a time less than two working days subsequent to receipt of the request for hearing.

(d) Before the hearing, the Food and Drug Administration shall give to the party requesting the hearing reasonable notice of the matters to be considered at the hearing, including a comprehensive statement of the basis for the decision or action taken or proposed that is the subject of the hearing and a general summary of the information that will be presented by the Food and Drug Administration at the hearing in support of such decision or action. Such information may be given orally or in writing, in the discretion of the Commissioner.

(e) The Commissioner may take such action pending a hearing pursuant to this section as he concludes is necessary to protect the public health, except where expressly prohibited by statute or regulation. A hearing to consider action already taken, and not stayed by the Commissioner, shall be conducted on an expedited basis.

(f) On the basis of the administrative record of the hearing specified in § 2.513 (a), the Commissioner shall issue a written decision stating the reasons for his administrative action and the basis in the record.

§ 2.512 Hearing procedure.

(a) A regulatory hearing may be conducted in private or may be a public hearing, as determined by the party requesting the hearing.

(1) The party requesting the hearing shall inform the presiding officer or other designated agency employee at the time that he requests the hearing, whether it will be a private or public hearing. If the party requesting the hearing fails to state whether the hearing shall be private or public, it shall be a private hearing.

(2) If the hearing is a private hearing, no persons other than the party requesting the hearing, his counsel and witnesses, and an employee or consultant or other person subject to a commercial arrangement as defined in § 4.81(a) of this chapter, and Food and Drug Administration representatives, shall be entitled to attend.

(3) If the hearing is a public hearing, it shall be announced on the public calendar described in § 2.21(a) whenever feasible, and any interested person who attends the hearing may participate to the extent of presenting relevant information.

(b) A regulatory hearing shall be conducted by a presiding officer. Employees of the Food and Drug Administration shall first give a full and complete statement of the action which is the subject of the hearing, together with the information and reasons supporting it, and may present any oral or written information relevant to the hearing. The party requesting the hearing shall then have the right to present any oral or written information relevant to the hearing. All parties may confront and conduct reasonable cross-examination of any person (except for the presiding officer and counsel for the parties) who makes any statement with respect to the matter at the hearing.

(c) The hearing shall be informal in nature, and the rules of evidence shall not apply. No motions or objections relating to the admissibility of data, information, and views shall be made or considered, but any other party may comment upon or rebut all such data, information, and views.

(d) The Commissioner may, in his discretion, order the hearing to be transcribed. The party requesting the hearing shall have the right to have the hearing transcribed, at his expense, in which case a copy of such transcription shall be furnished to the Food and Drug Administration and included with the presiding officer's report of the hearing. Any transcription of the hearing shall be included with the presiding officer's report of the hearing.

(e) The presiding officer shall prepare a written report of the hearing. All written material presented at the hearing shall be attached to the report. Whenever time permits, the parties to the hearing shall be given the opportunity to review and offer corrections to the presiding officer's report of the hearing.

§ 2.513 Administrative record of a regulatory hearing.

(a) The record of the administrative proceeding shall consist of the following:

(1) The notice of opportunity for hearing and the response thereto.

(2) All written data, information, and views submitted to the presiding officer at the hearing.

(3) Any transcript of the hearing.

(4) The presiding officer's report of the hearing.

(b) The record of the administrative proceeding shall be closed with respect to the submission of data, information, and views, at the close of the hearing, unless the presiding officer specifically permits additional time for a further submission.

§ 2.514 Examination of administrative record.

The availability for public disclosure of each document which is a part of the administrative record of a regulatory hearing shall be governed by the provisions of Part 4 of this chapter and the regulations referenced therein.

§ 2.515 Record for administrative decision.

(a) With respect to any matter which is subject to an opportunity for a hearing pursuant to §§ 2.500(a) and 2.510, the administrative record of the hearing specified in § 2.513(a) shall be considered by the Commissioner together with all other relevant data and information available to the Food and Drug Administration in determining whether regulatory action should be taken and, if so, what form of regulatory action should be taken.

(b) With respect to any matter which is subject to an opportunity for a hearing pursuant to §§ 2.500(b) and 2.511, the administrative record of the hearing specified in § 2.513(a) shall constitute the exclusive record for decision.

§ 2.516 Reconsideration and stay of action.

Following any final administrative action which is the subject of a hearing pursuant to this subpart or any provision referenced in § 2.501(b), any party may petition the Commissioner for reconsideration of any part or all of such decision or action pursuant to § 2.8 or may petition for a stay of such decision or action pursuant to § 2.9.

§ 2.520 Judicial review.

The availability of judicial review with respect to any regulatory action which is the subject of a hearing pursuant to this subpart shall be governed by the provisions of § 2.11.

Subpart G—Standards of Conduct and Conflicts of Interest

§ 2.600 Scope of subpart.

Subpart G governs the standards of conduct for, and establishes regulations to prevent conflicts of interest by, all Food and Drug Administration employees.

§ 2.610 Reference to Department regulations.

(a) The provisions of 45 CFR Part 73, establishing standards of conduct for all Department employees, are fully applicable to all Food and Drug Administration employees, except that such regulations shall be applicable to special government employees, i.e., consultants to the Food and Drug Administration, only to the extent stated in Subpart L of 45 CFR Part 73.

(b) The provisions of 45 CFR Part 73a supplement the Department standards of conduct and apply only to Food and Drug Administration employees except special government employees.

§ 2.611 Code of ethics for government service.

The following code of ethics, adopted by Congress on July 11, 1958, shall apply to all Food and Drug Administration employees:

CODE OF ETHICS FOR GOVERNMENT SERVICE

Any person in Government service should:

1. Put loyalty to the highest moral principles and to country above loyalty to persons, party, or Government department.
2. Uphold the Constitution, laws, and legal regulations of the United States and of all governments therein and never be a party to their evasion.
3. Give a full day's labor for a full day's pay; giving to the performance of his duties his earnest effort and best thought.
4. Seek to find and employ more efficient and economical ways of getting tasks accomplished.
5. Never discriminate unfairly by the dispensing of special favors or privileges to anyone, whether for remuneration or not; and never accept, for himself or his family, favors or benefits under circumstances which might be construed by reasonable persons as influencing the performance of his governmental duties.
6. Make no private promises of any kind binding upon the duties of office, since a Government employee has no private word which can be binding on public duty.
7. Engage in no business with the Government, either directly or indirectly, which is inconsistent with the conscientious performance of his governmental duties.
8. Never use any information coming to him confidentially in the performance of governmental duties as a means for making private profit.
9. Expose corruption wherever discovered.
10. Uphold these principles, ever conscious that public office is a public trust.

§ 2.612 Food and Drug Administration Conflict of Interest Review Board.

(a) The Commissioner shall establish a permanent five-member Conflict of Interest Review Board, which shall review and make recommendations to the Commissioner on all specific or policy matters relating to conflicts of interest arising within the Food and Drug Administration that are forwarded to it by (1) the Associate Commissioner for Administration or (2) anyone who is the subject of an adverse determination by the Associate Commissioner for Administration on any matter arising under the conflict of interest laws, except a determination of an apparent violation of law. The Director, Division of Personnel Management, Office of the Associate Commissioner for Administration, shall serve as executive secretary of the Review Board.

(b) It shall be the responsibility of every Food and Drug Administration employee with whom any specific or policy issue relating to conflicts of interest is raised, or who otherwise wishes to have any such matter resolved, to forward the matter to the Associate Commissioner for Administration for resolution, except that reporting of apparent violations of law are governed by § 2.613.

(c) All general policy relating to conflicts of interest shall be established in guidelines pursuant to the provisions of § 2.19(b) and whenever feasible shall be incorporated in regulations in this subpart.

(d) All decisions relating to specific individuals shall be placed in a public file established for this purpose by the Public Records and Documents Center, e.g., a determination that a consultant may serve on an advisory committee with specific limitations or with public disclosure of stock holdings, except that such determination shall be written in a way that does not identify the individual in the following situations:

(1) A determination that an employee must dispose of prohibited financial interests or refrain from incompatible outside activities in accordance with established Department or agency regulations.

(2) A determination that a proposed consultant is not eligible for employment by the agency.

(3) A determination that public disclosure of any information would constitute an unwarranted invasion of personal privacy in violation of § 4.63 of this chapter.

§ 2.613 Duty to report violations.

(a) The Policy Management Staff, Associate Commissioner for Administration, is responsible for obtaining factual information for the Food and Drug Administration on any matter relating to allegations of misconduct, impropriety, conflict of interest, or other violations of Federal statutes by agency personnel.

(b) Any Food and Drug Administration employee who has factual information showing or who otherwise believes that any present or former Food and Drug Administration employee has violated or is violating any provision of this subpart or of 45 CFR Parts 73 or 73a or of any statute listed in Appendix A to 45 CFR Part 73 should report such information directly to the Policy Management Staff. Any such reports shall be in writing or shall with the assistance of the Policy Management Staff be reduced to writing, and shall be promptly investigated.

(c) Any report pursuant to paragraph (b) of this section and any records relating to an investigation of such reports shall be maintained in strict confidence in the files of the Policy Management Staff, shall be exempt from public disclosure, and may be reviewed only by authorized Food and Drug Administration employees who are required to do so in the performance of their duties.

§ 2.620 Permanent disqualification of former employees.

No former Food and Drug Administration employee, including a special government employee, shall knowingly act as agent or attorney for anyone other than United States in connection with any judicial or other proceeding, application, request for a ruling or other determination, contract, claim, controversy,

charge, accusation, or other particular matter involving a specific party or parties in which the United States is a party or has a direct and substantial interest and in which he participated personally and substantially through decision, approval, disapproval, recommendation, rendering of advice, investigation, or otherwise as a Food and Drug Administration employee.

§ 2.621 Temporary disqualification of former employees.

Within 1 year after termination of employment with the Food and Drug Administration, no former Food and Drug Administration employee, including a special government employee, shall appear personally before the Food and Drug Administration or other federal agency or court as agent or attorney for any person other than the United States in connection with any proceeding or matter in which the United States is a party or has a direct and substantial interest and which was under his official responsibility at any time within one year preceding termination of such responsibility. The term "official responsibility" means the direct administrative or operating authority, whether intermediate or final, and either exercisable alone or with others, and either personally or through subordinates, to approve, disapprove, or otherwise direct government action.

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4. By establishing a new Part 5—Delegations of Authority and Organization, consisting of the redesignated Subparts H and M of Part 2, to read as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

Subpart A—Delegations of Authority to the Commissioner of Food and Drugs

Sec.
5.1 Delegations from the Secretary and Assistant Secretary.

Subpart B—Redelegations of Authority from the Commissioner of Food and Drugs

5.20 General redelegations of authority from the Commissioner to other officers of the Food and Drug Administration.
5.21 Delegations regarding hearings and review boards.
5.22 Delegations regarding imports.
5.23 Delegations regarding certification of true copies and use of Department seal.
5.24 Delegations regarding disclosure of official records.
5.25 Delegations regarding certification of color additives.
5.26 Delegations regarding certification of insulin.
5.27 Delegations regarding certification of antibiotic drugs.
5.28 Delegations regarding approved new animal drug applications and approved new animal drug application supplements for new animal drugs.
5.29 Delegations regarding approval of new-drug applications and new-drug application supplements for drugs for human use.
5.30 Delegations regarding issuance of notices relating to proposals to refuse approval or to withdraw approval of new drug applications and new drug application supplements for drugs for human use.
5.31 Delegation regarding designation of official master and working standards for antibiotic drugs.
5.32 Delegations regarding emergency functions.
5.33 Delegations regarding enforcement activities.
5.34 Delegations regarding certification following inspections.
5.35 Delegations regarding grants and fellowships.
5.36 Delegation regarding issuance, amendment, or repeal of regulations pertaining to antibiotic drugs for human use.
5.37 Delegation regarding issuance of notices of filing of petitions and notices of proposed rule making pertaining to food standards, food additives, and color additives.
5.38 Delegations regarding termination of exemptions for new drugs for investigational use in human beings or in animals.
5.39 Delegations regarding detention of meat, poultry, eggs, and related products.
5.40 Delegations regarding approval of schools providing food-processing instruction.
5.41 Delegations regarding issuance of reports of minor violations.
5.42 Delegations relating to granting and withdrawing variances from performance standards for electronic products.
5.43 Delegations relating to exemptions from performance standards for electronic products.
5.44 Delegations relating to testing programs and methods of certification and identification for electronic products.
5.45 Delegations relating to notification of defects in, and repair or replacement of, electronic products.
5.46 Delegations relating to manufacturer's resident import agents.
5.47 Delegations relating to requiring manufacturers to provide data to ultimate purchasers of electronic products.
5.48 Delegations relating to directing dealers and distributors of electronic products to provide data to manufacturers.
5.49 Delegations relating to acceptance of assistance from State and local authorities for enforcement of radiation control legislation and regulations.
5.50 Delegations regarding issuance and revocation of licenses for the propagation or manufacture and preparation of biological products.

Subpart C—Organization

5.100 Headquarters.
5.105 Chief Counsel for the Food and Drug Administration and Assistant General Counsel for Food and Drugs, Office of General Counsel, Department of Health, Education, and Welfare.
5.110 FDA Public Records and Documents Center.
5.111 FDA Hearing Clerk.
5.115 Field structure.

Subpart A—Delegations of Authority to the Commissioner of Food and Drugs

§ 5.1 Delegations from the Secretary and Assistant Secretary.

(a) The Assistant Secretary for Health has redelegated to the Commissioner of Food and Drugs with authority to redelegate (35 FR 606 as amended) all authority delegated to him by the Secretary of Health, Education, and Welfare as follows:

(1) Functions vested in the Secretary under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the Filled Milk Act (21 U.S.C. 61–63), the Federal Import Milk Act (21 U.S.C. 141 et seq.), the Tea Importation Act (21 U.S.C. 41 et seq.), the Federal Caustic Poison Act (44 Stat. 1406), and The Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.), pursuant to section 12 of Reorganization Plan No. IV and Reorganization Plan No. 1 of 1953, including authority to administer oaths vested in the Secretary of Agriculture by 7 U.S.C. 2217.

(2) Functions vested in the Secretary under section 301 (Research and Investigation); section 307 (International Cooperation); section 310 (Health Education and Information); section 311 (Federal-State Cooperation); and section 314(f) (Interchange of Personnel with States) of the Public Health Service Act (42 U.S.C. 241, 242l, 242o, 243, 246(f)) which relate to the functions of the Food and Drug Administration.

(3) Functions vested in the Secretary under sections 354 through 360F of the Public Health Service Act (42 U.S.C. 263b through 263n) which relate to electronic product radiation control.

(4) Functions vested in the Secretary under section 361 of the Public Health Service Act (42 U.S.C. 264) which relate to the law enforcement functions of the Food and Drug Administration concerning the following products and activities: biologicals (including blood and blood products); interstate travel sanitation (except interstate transportation of etiological agents under 42 CFR 72.25); food (including milk and food service sanitation and shellfish sanitation); and drugs, devices, cosmetics, and electronic products, and other items or products regulated by the Food and Drug Administration.

(5) Functions vested in the Secretary under sections 351 and 352 of the Public Health Service Act (42 U.S.C. 262 and 263) which relate to biological products.

(6) Functions vested in the Secretary pertaining to section 302(a) of the Public Health Service Act (42 U.S.C. 242(a)) which relate to the determination and reporting requirements with respect to the medicinal and scientific requirements of the United States for controlled substances.

(7) Functions vested in the Secretary pertaining to section 303 of the Public Health Service Act (42 U.S.C. 242a) which relate to the authorization of persons engaged in research on the use and

effect of drugs to protect the identity of their research subjects with respect to drugs scheduled under Public Law 91–513 for which a notice of claimed exemption for an investigational new drug is filed with the Food and Drug Administration and with respect to all drugs not scheduled under Public Law 91–513.

(8) Functions vested in the Secretary pertaining to section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (84 Stat. 1241) which relate to the determination of the safety and effectiveness of drugs or to approve new drugs to be used in the treatment of narcotic addicts.

(9) Functions vested in the Secretary pertaining to section 303(f) of the Controlled Substances Act (21 U.S.C. 823(f)) which relate to the determination of the qualifications and competency of practitioners wishing to conduct research with controlled substances listed in Schedule I of the Act, and the merits of the research protocol.

(10) Functions vested in the Secretary pertaining to provisions of the Controlled Substances Act (21 U.S.C. 801 et seq.) which relate to administration of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(11) Functions vested in the Secretary under section 409(b) of the Federal Meat Inspection Act (21 U.S.C. 679(b)) which relate to the detention of any carcass, part thereof, meat, or meat product of cattle, sheep, swine, goats, or equines.

(12) Functions vested in the Secretary under section 24(b) of the Poultry Products Inspection Act (21 U.S.C. 467f(b)) which relate to the detention of any poultry carcass, part thereof, or poultry product.

(13) Functions vested in the Secretary under the Egg Products Inspection Act (21 U.S.C. 1031 et seq.).

(14) Functions vested in the Secretary by amendments to the foregoing statutes subsequent to Reorganization Plan No. 1 of 1953.

(15) Function of issuing all regulations of the Food and Drug Administration. The reservation of authority contained in Chapter 2–000 of the Department Organization Manual shall not apply.

(16) Functions vested in the Secretary under Executive Order 11490, section 1103(5), and those portions of sections 1103(1), 1103(3), 1103(4), 3001(2), 3001(3), 3002(1), 3002(2), 3002(3), 3004, and 3009 which relate to food, drugs, and biologicals. In the performance of these emergency functions the Commissioner shall coordinate his activities with the Administrator, Health Services and Mental Health Administration, in order that preemergency plans shall be developed in consonance with postattack organization plans and structure of the Department for the Emergency Health Service.

(17) Function vested in the Secretary of authorizing and approving miscellaneous and emergency expenses of enforcement activities.

(18) Function vested in the Secretary under the Federal Advisory Committee Act, Public Law 92–463, to make determinations that advisory committee meetings are concerned with matters listed in section 552(b) of title 5, U.S.C. and therefore may be closed to the public for those committees under the administrative jurisdiction of the Commissioner of Food and Drugs. This authority may not be redelegated. This authority is to be exercised in accordance with the requirements of the Act and only with respect to the following:

(i) Meetings, to the extent that they directly involve review, discussion or consideration of records of the Department which are exempt from disclosure under 5 U.S.C. 552(b) (4), (6), and (7), namely, (*a*) records containing trade secrets and commercial or financial information obtained from a person and privileged or confidential; (*b*) personnel, medical and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy; and (*c*) investigatory files compiled for law enforcement purposes;

(ii) Meetings to the extent that they involve the review, discussion, and evaluation of specific drugs and devices regulated by FDA which are intended to result in recommendations for regulatory decisions under the Federal Food, Drug, and Cosmetic Act and which are concerned with matters listed in 5 U.S.C. 552(b)(4), (5), and (7);

(iii) Meetings held for the sole purpose of considering and formulating advice which the committee will give or any final report it will render, *Provided:*

(*a*) The meetings will involve solely the internal expression of views and judgments of the members and it is essential to close the meeting or portions thereof to protect the free exchange of such views and avoid undue interference with agency or committee operations, and such views if reduced to writing would be protected from mandatory disclosure under section 552(b)(5) of title 5 U.S.C.;

(*b*) The meeting is closed for the shortest time necessary, summarizing the work of the committee during the closed sessions, and a report, prepared by the executive secretary will be made available promptly to the public;

(*c*) When feasible, the public is given a timely opportunity to present relevant information and views to the committee; and

(*d*) Concurrence for closing the meetings for such purpose is obtained from the Office of the General Counsel and the Office of Public Affairs.

(19) Functions vested in the Secretary under the second sentence of section 309 (Health Conferences) of the Public Health Service Act (42 U.S.C. 242n) to call for a conference and invite as many health authorities and officials of State or local public or private agencies or organizations as deemed necessary or proper on subjects related to the functions of the Food and Drug Administration.

(20) Functions vested in the Secretary under section 501 (Gifts) of the Public Health Service Act (42 U.S.C. 219) to accept offers of unconditional gifts, of other than real property, provided such gifts are of $1,000 value or less and the total costs associated with acceptance of property will not exceed the cost of purchasing a similar item and the cost of normal care and maintenance.

(21) Functions vested in the Secretary under section 362 of the Public Health Service Act (42 U.S.C. 265) which relate to the prohibition of the introduction of foods, drugs, devices, cosmetics, and electronic products and other items or products regulated by the Food and Drug Administration into the United States when it is determined that it is required in the interest of public health when such functions relate to the law enforcement functions of the Food and Drug Administration.

(b) The Chief Counsel for the Food and Drug Administration and Assistant General Counsel in charge of the Division of Food and Drugs, Office of General Counsel, Department of Health, Education, and Welfare, has been authorized to report apparent violations to the Department of Justice for the institution of criminal proceedings, pursuant to section 305 of the Federal Food, Drug, and Cosmetic Act, section 4 of the Federal Import Milk Act, and section 9(b) of the Federal Caustic Poison Act.

(c) The Assistant Secretary for Health has redelegated to the Commissioner of Food and Drugs, with authority to redelegate, the authority delegated to him by the Assistant Secretary for Administration and Management: (1) To certify true copies of any books, records, papers, or other documents on file within the Department, or extracts from such; to certify that true copies are true copies of the entire file of the Department; to certify the complete original record or to certify the nonexistence of records on file within the Department; and to cause the Seal of the Department to be affixed to such certifications and to agreements, awards, citations, diplomas, and similar documents.

(2) To establish volunteer service programs and accept volunteer services for use in the operation of a health care facility or the provision of health care under section 223 of the Public Health Services Act (42 U.S.C. 217b).

Subpart B—Redelegations of Authority From the Commissioner of Food and Drugs

§ 5.20 General redelegations of authority from the Commissioner to other officers of the Administration.

(a) Final authority of the Commissioner of Food and Drugs is redelegated as set forth in this subpart. Further redelegation of the authority vested herein is not authorized. Authority redelegated herein to a position by title may be exercised by a person officially designated to serve in such position in an acting capacity or on a temporary basis, unless prohibited by a restriction written into the document designating him as "acting" or unless not legally permissible.

(b) The Deputy Commissioner of Food and Drugs and the Associate Commissioner for Compliance are authorized to perform all the functions of the Commissioner of Food and Drugs.

§ 5.21 Delegations regarding hearings and review boards.

(a) The Directors and Deputy Directors of Bureaus, Regional Food and Drug Directors, Deputy Regional Food and Drug Directors, and District Directors are authorized to designate officials to hold informal hearings which relate to their assigned functions under sections 305, 404(b), and 801(a) of the Federal Food, Drug, and Cosmetic Act, section 6 of the Fair Packaging and Labeling Act, section 9(b) of the Federal Caustic Poison Act, and section 5 of the Federal Import Milk Act. Officials so designated are delegated authority vested in the Secretary of Agriculture by 7 U.S.C. 2217 (43 Stat. 803) to administer or to take from any person an oath, affirmation, affidavit, or deposition for use in any prosecution or proceeding under or in enforcement of any law as cited in this section.

(b) The Director and Deputy Director of the Bureau of Radiological Health are authorized to hold hearings under section 360(a) of the Public Health Service Act, and to designate officials to hold informal hearings under section 360(a) of the act.

§ 5.22 Delegations regarding imports.

(a) The Regional Food and Drug Directors, Deputy Regional Food and Drug Directors, and District Directors are authorized to designate officials who may request, under section 801(a) of the Federal Food, Drug, and Cosmetic Act, from the Secretary of the Treasury samples of foods, drugs, devices or cosmetics imported, or offered for import, in order to determine whether such articles are in compliance with the act.

(b) The Director and Deputy Director of the Bureau of Radiological Health, and the Director of the Division of Compliance of that Bureau are authorized to request, under section 360(a) of the Public Health Service Act, from the Secretary of the Treasury samples of electronic products imported or offered for import in order to determine whether such articles are in compliance with that act.

(c) The Director and Deputy Director of the Bureau of Radiological Health, and the Director of the Division of Compliance of that Bureau may, under section 360B(b) of the Public Health Service Act, exempt persons from issuing a certification as required by section 358 (h) of the act, for electronic products imported into the United States for testing, evaluation, demonstration, or training, which will not be introduced into commerce and upon completion of their function, will be destroyed or exported in accord with Bureau of Customs regulations.

(d) The Regional Food and Drug Directors, Deputy Regional Food and Drug Directors, and District Directors are authorized to exercise all of the functions of the Commissioner of Food and Drugs under section 362 of the Public Health Service Act (42 U.S.C. 265) that relate to the prohibition of the introduction of foods, drugs, devices, cosmetics, and electronic products and other items or products regulated by the Food and Drug Administration into the United States when it is determined that it is required in the interest of public health, and such functions relate to the law enforcement functions of the Food and Drug Administration.

§ 5.23 Delegations regarding certification of true copies and use of Department seal.

(a) The following officials are authorized to certify true copies of or extracts from any books, records, papers, or other documents on file within the Food and Drug Administration, to certify that copies are true copies of the entire file, to certify the complete original record, or to certify the nonexistence of records on file within the Administration, and to cause the seal of the Department to be affixed to such certifications:

(1) Associate and Deputy Associate Commissioners.

(2) Assistant and Deputy Assistant Commissioners.

(3) Director of the Executive Secretariat.

(4) Director and Deputy Director of the Office of Legislative Services.

(5) The FDA Regulations Officer and the Federal Register Liaison Officer and their alternates of the Office of the Associate Commissioner for Compliance.

(6) Directors and Deputy Directors of Bureaus and Executive Director and Deputy Executive Director of Regional Operations.

(7) Director of the Office of Planning and Evaluation, the Associate Director and Deputy Associate Director for Compliance, and the Directors of the Divisions of: Methadone Monitoring; Drug Product Quality; Drug Labeling Compliance; and Drug Manufacturing of the Bureau of Drugs.

(8) Associate Director for Management, the Associate Director and Deputy Associate Director for Compliance, and the Directors of the Divisions of: Regulatory Guidance; Food Technology; and Food Service of the Bureau of Foods.

(9) Associate Director and the Director of the Division of Compliance of the Bureau of Biologics.

(10) Director and Deputy Director of the Division of Compliance of the Bureau of Veterinary Medicine.

(11) Associate Director for Administration of the Bureau of Radiological Health, and the Director of the Division of Compliance of that Bureau.

(12) Assistant Director for Program Operations and the Director of the Division of Compliance of the Bureau of Medical Devices and Diagnostic Products.

(b) The following officials are authorized to cause the seal of the Department to be affixed to agreements, awards, citations, diplomas, and similar documents.

(1) Associate and Deputy Associate Commissioners.

(2) The Director of the Division of Personnel Management of the Office of Administration and the Chief of the Career Development and Training Branch of that Division and Office.

(c) The FEDERAL REGISTER Writer and his alternates of the Office of Compliance are authorized to certify true copies of FEDERAL REGISTER documents.

§ 5.24 Delegations regarding disclosure of official records.

(a) The following officials are authorized to make determinations to disclose official records and information in accordance with § 4.1 of this chapter.

(1) The Director and Deputy Director of the Bureau of Drugs, and the Associate Director and Deputy Associate Director for Compliance and the Directors of the Divisions of: Methadone Monitoring; Drug Product Quality; Drug Labeling Compliance; and Drug Manufacturing of that Bureau.

(2) The Director and Deputy Director of the Bureau of Foods, and the Associate Director and Deputy Associate Director for Compliance and the Director of the Division of Regulatory Guidance of that Bureau.

(3) The Director and Deputy Director of the Bureau of Veterinary Medicine and the Director and Deputy Director of the Division of Compliance of that Bureau.

(4) The Director and Deputy Director, Bureau of Radiological Health, and the Director of the Division of Electronic Products and the Director of the Division of Compliance of that Bureau.

(5) The Director and Deputy Director of the Bureau of Biologics, and the Associate Director and the Director of the Division of Compliance of that Bureau.

(6) The Director and Deputy Director of the Bureau of Medical Devices and Diagnostic Products and the Director of the Division of Compliance of that Bureau.

(b) The Chief of the Drug Listing Branch of the Division of Drug Labeling Compliance of the Bureau of Drugs is authorized to sign affidavits regarding the presence or absence of records of Registration of Drug Establishments.

(c) The Chief of the Records Section of the Administrative Services Branch, Division of Management Services, Office of Administration, is authorized to sign affidavits regarding the presence or absence of records in the files of that section.

§ 5.25 Delegations regarding certification of color additives.

The Director and Deputy Director of the Bureau of Foods, the Associate Director and Deputy Associate Director for Technology, and the Director and Deputy Director of the Division of Color Technology of that Bureau are authorized to certify batches of color additives for use in foods, drugs, or cosmetics, under section 706 of the Federal Food, Drug, and Cosmetic Act.

§ 5.26 Delegations regarding certification of insulin.

The Director, Deputy Director, and the Associate Director and Deputy Associate Director for Compliance of the Bureau of Drugs, the Director and Deputy Director of the Division of Drug Product Quality of that Bureau, and the Chief

and Assistant Chief of the Certification Services Branch of that Division and Bureau are authorized to certify or reject batches of drugs containing insulin, pursuant to section 506(a) of the Federal, Food, Drug, and Cosmetic Act.

§ 5.27 Delegations regarding certification of antibiotic drugs.

The Director, Deputy Director, and the Associate Director and Deputy Associate Director for Compliance of the Bureau of Drugs, the Director and Deputy Director of the Division of Drug Product Quality of that Bureau, and the Chief and Assistant Chief of the Certification Services Branch of that Division and Bureau are authorized to certify or reject batches of antibiotic drugs, or any derivative of these drugs, pursuant to sections 507(a) and 512(n) of the Federal Food, Drug, and Cosmetic Act.

§ 5.28 Delegations regarding approved new animal drug applications and approved new animal drug application supplements for new animal drugs.

The Director of the Bureau of Veterinary Medicine is authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the approval of new animal drug applications, and new animal drug application supplements, for new animal drugs submitted pursuant to section 512 of the Federal Food, Drug, and Cosmetic Act. The Director of the Division of Veterinary Medical Review of the Bureau of Veterinary Medicine is authorized to perform for functions of the Commissioner with regard to the approval of applications for animal feeds containing new animal drugs.

§ 5.29 Delegations regarding approval of new-drug applications and new-drug application supplements for drugs for human use.

(a) The Director, Deputy Director, and Associate Director for New Drug Evaluation of the Bureau of Drugs are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the approval of new-drug applications and new-drug application supplements which are for drugs for human use and have been submitted pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act.

(b) The Directors of the Divisions of: Anti-Infective Drug Products; Cardio-Renal Drug Products; Surgical-Dental Drug Products; Metabolism and Endocrine Drug Products; Neuropharmacological Drug Products; Oncology and Radiopharmaceutical Drug Products; and Drug Advertising of the Bureau of Drugs are authorized to perform all the functions of the Commissioner with regard to the approval of new-drug application supplements which are for drugs for human use and have been submitted pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act.

§ 5.30 Delegations regarding issuance of notices relating to proposals to refuse approval or to withdraw approval of new drug applications and new drug application supplements for drugs for human use.

The Director of the Bureau of Drugs is authorized to issue notices of an opportunity for a hearing on proposals to refuse approval or to withdraw approval of new drug applications and new drug application supplements for drugs for human use submitted pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act and to issue notices of denial or withdrawal of approval when opportunity for hearing has been waived.

§ 5.31 Delegation regarding designation of official master and working standards for antibiotic drugs.

The Director, Deputy Director, and Associate Director for Pharmaceutical Research and Testing of the Bureau of Drugs, and the Director of the National Center for Antibiotics Analysis of that Bureau are authorized to designate official Food and Drug Administration master and working standards for antibiotic drugs under § 430.5 of this chapter.

§ 5.32 Delegations regarding emergency functions.

Each Regional Food and Drug Director is authorized, during any period when normal channels of direction are disrupted between the Food and Drug Administration headquarters and his region, to fully represent the Food and Drug Administration within his region in consonance with the Department of Health, Education, and Welfare regional emergency plans and to exercise the authority of the Commissioner for supervision of and direction to all Food and Drug Administration activities and use of resources within his region for continuity and for Federal Emergency Health Service operations. These same officials are authorized to provide in Regional Emergency Plans for the delegation of Food and Drug Administration regional authorities to heads of field activities when such activities are cut off from national and regional headquarters.

§ 5.33 Delegations regarding enforcement activities.

(a) Duly appointed and authorized inspectors, officers, and employees of the Food and Drug Administration who have been issued the Food and Drug Administration official credentials consisting of FD Form 200a entitled "Identification Record" and FD Form 200b entitled "Specification of General Authority" are designated by the Commissioner of Food and Drugs:

(1) To conduct examinations, inspections, and investigations; to collect and obtain samples; to have access to and to copy and verify records; and to supervise compliance operations, for the enforcement of the Federal Food, Drug, and Cosmetic Act, the Fair Packaging and Labeling Act, the Federal Caustic Poison Act, the Import Milk Act, the Filled Milk Act, the Tea Importation Act, the Radiation Control for Health and Safety Act of 1968, and section 361 of the Public Health Service Act.

(2) To administer oaths and affirmations under section 1 of the Act of January 31, 1925 (Ch. 124, 43 Stat. 803); sections 12 to 15 of Reorganization Plan No. IV, effective June 30, 1940; and Reorganization Plan No. 1 of 1953, effective April 11, 1953.

(b) Duly appointed and authorized inspectors, officers, and employees of the Food and Drug Administration who have been issued the Food and Drug Administration official credentials consisting of FD Form 200a entitled "Identification Record" and FD Form 200c entitled "Specification of General and Special Authority" are designated by the Commissioner of Food and Drugs:

(1) To perform the duties enumerated in paragraph (a) (1) and (2) of this section.

(2) As officers and employees having the authority to request and the authority to have access to and copy and verify records and reports required by sections 505 (i) and (j), 507 (d) and (g), and 512 (l) and (m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355 (i) and (j), 357 (d) and (g), and 360b (l) and (m)).

(c) The Food and Drug Administration official credentials referred to in paragraphs (a) and (b) of this section are described as follows:

(1) FD Form 200a entitled "Identification Record" bears a color photograph, description, and signature of the bearer, an identification number, an expiration date, the Department of Health, Education, and Welfare seal with blue imprint centered to the left of the photograph and the Food and Drug Administration symbol centered to the right of the photograph.

(2) FD Form 200b entitled "Specification of General Authority" bears the holder's name, his general authority, an identification number, an expiration date, and the Commissioner's signature.

(3) FD Form 200c entitled "Specification of General and Special Authority" bears the holder's name, his general and special authority, an identification number, an expiration date, and the Commissioner's signature and is superimposed in the lower right corner with a red, white, and blue stripe imprint.

(4) Both FD Form 200b and FD Form 200c bear the name of the Department of Health, Education, and Welfare, Public Health Service, and Food and Drug Administration and are superimposed with the Department seal with blue imprint.

(d) The Director and Deputy Director of the Bureau of Radiological Health are authorized to refuse admission of noncomplying electronic product imports and to notify the Secretary of the Treasury of such refusal under section 360(a) of the Public Health Service Act and are authorized to refuse or to grant per-

mission and time extensions to bring such products into compliance, and are authorized to supervise or designate an official to supervise such operations under section 360(b) of the act.

(e) The Director and Deputy Director of the Bureau of Radiological Health and the Director of the Division of Compliance of that Bureau are authorized to perform all of the functions of the Commissioner of Food and Drugs under section 360A(a) of the Public Health Service Act relating to electronic product safety and inspection of electronic product manufacturers' premises, and to perform all of the functions of the Commissioner of Food and Drugs under section 360A(b) of the act relating to the establishment, maintenance, and inspection of electronic product manufacturers' records.

(f) The Director and Deputy Director of the Bureau of Radiological Health are authorized to designate officials to make accident and investigation reports under section 360A(d) of the Public Health Service Act.

(g) The Director, Deputy Director, and Associate Director of the Bureau of Biologics and the Director of the Division of Compliance of that Bureau may authorize, pursuant to section 351(c) of the Public Health Service Act (42 U.S.C. 262 (c)), any officer, agent, or employee to enter and inspect any establishment which is subject to the provisions of section 351 of the act (42 U.S.C. 262).

§ 5.34 Delegations regarding certification following inspections.

Regional Food and Drug Directors, Deputy Regional Food and Drug Directors, and District Directors are authorized to issue certificates of sanitation under 21 CFR 1240.20.

§ 5.35 Delegations regarding grants and fellowships.

(a) The Associate and Deputy Associate Commissioner for Science are authorized to approve or disapprove all applications for grants and fellowships and to select officials to serve as program managers to exercise scientific oversight and to monitor grantee progress.

(b) The Associate and Deputy Associate Commissioner for Administration and the Director and Deputy Director of the Division of Contracts and Grants Management of the Office of the Associate Commissioner for Administration are authorized to execute grant awards upon approval by the Associate or Deputy Associate Commissioner for Science under sections 301, 308, 311, and 356 of the Public Health Service Act, and to notify grantees of officials who will serve as the FDA program manager for their grant.

§ 5.36 Delegation regarding issuance, amendment, or repeal of regulations pertaining to antibiotic drugs for human use.

The Director and Deputy Director of the Bureau of Drugs and the Assistant Director for Regulatory Affairs are authorized to perform all of the functions of the Commissioner of Food and Drugs under section 507 of the Federal Food, Drug, and Cosmetic Act regarding the issuance, amendment, or repeal of regulations pertaining to antibiotic drugs for human use.

§ 5.37 Delegation regarding issuance of notices of filing of petitions and notices of proposed rulemaking pertaining to food standards, food additives, and color additives.

The Director of the Bureau of Foods is authorized to perform all the functions of the Commissioner of Food and Drugs under sections 401, 409, and 706 of the Federal Food, Drug, and Cosmetic Act regarding the issuance of notices of filing of petitions and notices of proposed rulemaking pertaining to food standards, food additives, and color additives.

§ 5.38 Delegations regarding termination of exemptions for new drugs for investigational use in human beings, in laboratory research animals or in vitro tests, or in animals.

(a) The Director and Deputy Director of the Bureau of Drugs are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the termination of exemptions for new drugs for investigational use in human beings under § 312.1 and in laboratory research animals or in vitro tests under § 312.9 of this chapter, except those which pertain to a biological product subject to the licensing provisions of section 351 of the Public Health Service Act (42 U.S.C. 262). The Associate Director and Deputy Associate Director for New Drug Evaluation and the Directors of the Divisions of: Anti-Infective Drug Products; Cardio-Renal Drug Products; Surgical-Dental Drug Products; Metabolism and Endocrine Drug Products; Neuropharmacological Drug Products; and Oncology and Radiopharmaceutical Drug Products of the Bureau of Drugs are authorized to notify sponsors and invite correction prior to termination action on such exemptions.

(b) The Director, Deputy Director, and Associate Director of the Bureau of Biologics are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the termination of those exemptions for new drugs for investigational use in human beings under § 312.1 and in laboratory research animals or in vitro tests under § 312.9 of this chapter pertaining to a biological product subject to the licensing provisions of section 351 of the Public Health Service Act (42 U.S.C. 262).

(c) The Director and Deputy Director of the Bureau of Veterinary Medicine are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the termination of exemptions for new animal drugs for investigational use in animals under § 511.1 of this chapter.

§ 5.39 Delegations regarding detention of meat, poultry, eggs, and related products.

The Regional Food and Drug Directors, Deputy Regional Food and Drug Directors, and District Directors are authorized to perform and to designate other officials to perform all the functions of the Commissioner of Food and Drugs under:

(a) Section 409(b) of the Federal Meat Inspection Act (21 U.S.C. 679(b)) which relate to the detention of any carcass, part thereof, meat, or meat product of cattle, sheep, swine, goats, or equines.

(b) Section 24(b) of the Poultry Products Inspection Act (21 U.S.C. 467f(b)) which relate to the detention of any poultry carcass, part thereof, or poultry product.

(c) The Egg Products Inspection Act (21 U.S.C. 1031 et seq.).

§ 5.40 Delegations regarding approval of schools providing food-processing instruction.

The Director and Deputy Director of the Bureau of Foods are authorized to perform all of the functions of the Commissioner of Food and Drugs under § 128b.10 of this chapter regarding the approval of schools giving instruction in retort operations, processing systems operations, aseptic processing and packaging systems operations, and container closure inspections.

§ 5.41 Delegations regarding issuance of reports of minor violations.

(a) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under section 306 of the Federal Food, Drug, and Cosmetic Act regarding the issuance of written notices or warnings:

(1) The Director and Deputy Director of the Bureau of Drugs and the Associate Director and Deputy Associate Director for Compliance of that Bureau.

(2) The Director and Deputy Director of the Bureau of Foods and the Associate Director and Deputy Associate Director for Compliance of that Bureau.

(3) The Director and Deputy Director of the Bureau of Veterinary Medicine and the Director and Deputy Director of the Division of Compliance of that Bureau.

(4) The Director and Deputy Director of the Bureau of Medical Devices and Diagnostic Products and the Director of the Division of Compliance of that Bureau.

(5) The Director and Deputy Director of the Bureau of Biologics, and the Associate Director and the Director of the Division of Compliance of that Bureau.

(b) The Director and Deputy Director of the Bureau of Radiological Health are authorized to perform all the functions of the Commissioner of Food and Drugs under section 360C(d) of the Public Health Service Act regarding the issuance of written notices or warnings.

§ 5.42 Delegations relating to granting and withdrawing variances from performance standards for electronic products.

The Director and Deputy Director of the Bureau of Radiological Health are authorized to grant and withdraw variances from the provisions of performance standards for electronic products established in Subchapter J of this chapter.

§ 5.43 Delegations relating to exemptions from performance standards for electronic products.

The Director of the Bureau of Radiological Health is authorized to exempt from performance standards any electronic product intended solely or predominantly for departments or agencies of the United States under section 358(a)(5) of the Public Health Service Act.

§ 5.44 Delegations relating to testing programs and methods of certification and identification for electronic products.

The Director and Deputy Director of the Bureau of Radiological Health and the Director of the Division of Compliance of that Bureau are authorized to review and evaluate industry testing programs under section 358(g) of the Public Health Service Act, and to approve or disapprove alternate methods of certification and identification and to disapprove testing programs upon which certification is based under section 358(h) of the act.

§ 5.45 Delegations relating to notification of defects in, and repair or replacement of, electronic products.

The Director and Deputy Director of the Bureau of Radiological Health are authorized to perform all the functions of the Commissioner of Food and Drugs relating to notification of defects in, and repair or replacement of, electronic products under section 359 of the Public Health Service Act and under §§ 1003.11, 1003.22, 1003.31, 1004.2, 1004.3, 1004.4, and 1004.6 of this chapter. The Director of the Division of Compliance of the Bureau of Radiological Health is authorized to notify manufacturers of defects in, and noncompliance of, electronic products under section 359(e) of the Public Health Service Act.

§ 5.46 Delegations relating to manufacturer's resident import agents.

The Director and Deputy Director of the Bureau of Radiological Health are authorized to reject manufacturers' designations of resident import agents pursuant to § 1005.25(b) of this chapter.

§ 5.47 Delegations relating to requiring manufacturers to provide data to ultimate purchasers of electronic products.

The Director and Deputy Director of the Bureau of Radiological Health are authorized to require manufacturers to provide performance and technical data to the ultimate purchaser of electronic products under section 360A(c) of the Public Health Service Act.

§ 5.48 Delegations relating to directing dealers and distributors of electronic products to provide data to manufacturers.

The Director and Deputy Director of the Bureau of Radiological Health and the Director of the Division of Compliance of that Bureau and the Regional Food and Drug Directors are authorized to direct dealers and distributors of electronic products to furnish information on first purchasers of such products to the manufacturer of the product under section 360A(f) of the Public Health Service Act.

§ 5.49 Delegations relating to acceptance of assistance from State and local authorities for enforcement of radiation control legislation and regulations.

The Director and Deputy Director of the Bureau of Radiological Health are authorized to accept assistance from State and local authorities engaged in activities related to health or safety or consumer protection on a reimbursable basis or otherwise, under section 360E of the Public Health Service Act.

§ 5.50 Delegations regarding issuance and revocation of licenses for the propagation or manufacture and preparation of biological products.

The Director and Deputy Director of the Bureau of Biologics and the Associate Director of that Bureau are authorized to issue licenses under section 351 of the Public Health Service Act (42 U.S.C. 262) for propagation or manufacture and preparation of biological products as specified in the act, and to revoke such licenses at the manufacturer's request.

Subpart C—Organization

§ 5.100 Headquarters.

The central organization of the Food and Drug Administration consists of the following:

OFFICE OF THE COMMISSIONER [1]

Commissioner of Food and Drugs.
Deputy Commissioner.
  Administrative Law Judge.
Associate Commissioner for Compliance.
  Hearing Clerk.
Associate Commissioner for Medical Affairs.
Associate Commissioner for Science.
Associate Commissioner for Administration.
Assistant Commissioner for Public Affairs.
Assistant Commissioner for Planning and Evaluation.
Assistant Commissioner for Professional and Consumer Programs.

BUREAU OF BIOLOGICS [2]

Office of the Director.
Division of Compliance.
Division of Virology.
Division of Blood and Blood Products.
Division of Control Activities.
Division of Pathology.
Division of Bacterial Products.

BUREAU OF DRUGS [1]

Office of the Director.
Office of Planning and Evaluation.
Associate Director for Drug Monographs.
Division of OTC Drug Evaluation.
Division of Biopharmaceutics.
Division of Generic Drug Monographs.
Associate Director for Biometrics and Epidemiology.
Division of Biometrics.
Division of Poison Control.
Division of Drug Experience.
Associate Director for Compliance.
Division of Methadone Monitoring.
Division of Drug Product Quality.
Division of Drug Labeling Compliance.
Division of Drug Manufacturing.
Associate Director for Pharmaceutical Research and Testing.
Division of Drug Biology.
Division of Drug Chemistry.
National Center for Antibiotics Analysis.
National Center for Drug Analysis.
Associate Director for New Drug Evaluation.
Division of Anti-Infective Drug Products.
Division of Cardio-Renal Drug Products.
Division of Surgical-Dental Drug Products.
Division of Metabolism and Endocrine Drug Products.
Division of Neuropharmacological Drug Products.
Division of Oncology and Radiopharmaceutical Drug Products.
Division of Drug Advertising.
Associate Director for Information Systems.
Division of Drug Information Resources.
Division of Information Systems Design.
Medical Library.

BUREAU OF FOODS [3]

Office of the Director.
Associate Director for Compliance.
Division of Regulatory Guidance.
Division of Compliance Programs.
Division of Industry Programs.
Division of Food and Color Additives.
Associate Director for Sciences.
Division of Chemistry and Physics.
Division of Toxicology.
Division of Pathology.
Division of Microbiology.
Division of Mathematics.
Associate Director for Technology.
Division of Food Technology.
Division of Chemical Technology.
Division of Color Technology.
Division of Cosmetics Technology.
Associate Director for Nutrition and Consumer Sciences.
Division of Consumer Studies.
Division of Food Service.
Division of Nutrition.

BUREAU OF MEDICAL DEVICES AND DIAGNOSTIC PRODUCTS [1]

Office of the Director.
Division of Compliance.
Division of Diagnostic Product Standards and Research.
Division of Medical Device Standards and Research.
Division of Classification and Scientific Evaluation.

BUREAU OF RADIOLOGICAL HEALTH [1]

Office of the Director.
Division of Compliance.
Division of Biological Effects.
Division of Electronic Products.
Division of Radioactive Materials and Nuclear Medicine.
Division of Training and Medical Applications.

BUREAU OF VETERINARY MEDICINE [1]

Office of the Director.
Division of Compliance.
Division of New Animal Drugs.
Division of Nutritional Sciences.
Division of Veterinary Medical Review.
Division of Veterinary Research.

EXECUTIVE DIRECTOR OF REGIONAL OPERATIONS [1]

Office of the Executive Director.
Division of Field Operations.
Division of Planning and Analysis.
Division of Federal-State Relations.

NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH [4]

Office of the Director.
Office of Plans, Programs, and Systems.

[1] Mailing address: 5600 Fishers Lane, Rockville, MD 20852.
[2] Mailing address: 8800 Rockville Pike, Bethesda, MD 20014.
[3] Mailing address: 200 C St. SW., Washington, D.C. 20204.
[4] Mailing address: Jefferson, AR 72079.

Associate Director for Operations.
Division of Animal Husbandry.
Division of Diagnostics.
Division of Diet Preparation.
Division of Facilities Engineering and Maintenance.
Division of Chemistry.
Associate Director for Pathology.
Division of Histopathology.
Division of Clinical Pathology.
Division of Pathology Research.
Associate Director for Toxicology.
Division of Acute/Subacute Studies.
Division of Chronic Studies.
Division of Teratogenic Research.
Division of Mutagenic Research.
Division of Comparative Pharmacology.

§ 5.105 Chief Counsel for the Food and Drug Administration and Assistant General Counsel for Food and Drugs, Office of General Counsel, Department of Health, Education, and Welfare.

Chief Counsel for the Food and Drug Administration and Assistant General Counsel for Food and Drugs, Room 6–57, 5600 Fishers Lane, Rockville, MD 20852.

§ 5.110 FDA Public Records and Documents Center.

The FDA Public Records and Documents Center, HFC–18, is located in Rm. 4–62, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD 20852, Telephone: 301–443–6310.

§ 5.111 FDA Hearing Clerk.

The FDA Hearing Clerk, HFC–20, is located in Rm. 4–65, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20852. Telephone: 301–443–1753.

§ 5.115 Field structure.

REGION I

Regional Field Office: 585 Commercial Street, Boston, MA 02109.
District Office: 585 Commercial Street, Boston, MA 02109.
Winchester Engineering and Analytical Center: 109 Holton Street, Winchester, MA 01890.

REGION II

Regional Field Office: 850 Third Avenue, Brooklyn, NY 11232.
District Office: 850 Third Avenue, Brooklyn, NY 11232.
District Office: 599 Delaware Avenue, Buffalo, NY 14202.
District Office: Room 831, 970 Broad Street, Newark, NJ 07102.
District Office: Post Office Box S–4427, San Juan Station, San Juan, PR 00905.

REGION III

Regional Field Office: Room 1204, Second and Chestnut Streets, Philadelphia, PA 19106.
District Office: Room 1204, Second and Chestnut Streets, Philadelphia, PA 19106.
District Office: 900 Madison Avenue, Baltimore, MD 21201.

REGION IV

Regional Field Office: 880 West Peachtree Street, Atlanta, GA 30309.
District Office: 880 West Peachtree Street, Atlanta, GA 30309.
District Office: 297 Plus Park Boulevard, Nashville, TN 37217.
District Office: Post Office Box 118, Orlando, FL 32802.

REGION V

Regional Field Office: Room A–1945, 175 West Jackson Boulevard, Chicago, IL 60607.
District Office: Room 1222, 433 West Van Buren Street, Chicago, IL 60607.
District Office: 1141 Central Parkway, Cincinnati, OH 45202.
District Office: 1560 East Jefferson Avenue, Detroit, MI 48207.
District Office: 240 Hennepin Avenue, Minneapolis, MN 55401.
Minneapolis Center for Microbiological Investigations: 240 Hennepin Avenue, Minneapolis, MN 55401.

REGION VI

Regional Field Office: 3032 Bryan Street, Dallas, TX 75204.
District Office: 3032 Bryan Street, Dallas, TX 75204.
District Office: Room 222, 423 Canal Street, New Orleans, LA 70130.
Houston Section: Room 413, 201 Fannin Street, Houston, TX 77002.

REGION VII

Regional Field Office: 1009 Cherry Street, Kansas City, MO 64106.
District Office: 1009 Cherry Street, Kansas City, MO 64106.

REGION VIII

Regional Field Office: 721 19th Street, U.S. Customhouse, Denver, CO 80202.
District Office: 721 19th Street, U.S. Customhouse, Denver, CO 80202.

REGION IX

Regional Field Office: Room 518, 50 Fulton Street, San Francisco, CA 94102.
District Office: Room 518, 50 Fulton Street, San Francisco, CA 94102.
District Office: 1521 West Pico Boulevard, Los Angeles, CA 90015.

REGION X

Regional Field Office: Room 5003, 909 First Avenue, Seattle, WA 98174.
District Office: Room 5003, 909 First Avenue, Seattle, WA 98174.

PART 6—ENVIRONMENTAL IMPACT CONSIDERATIONS

§ 6.4 [Amended]

5. In Part 6, by amending § 6.4(a)(2) to change the reference to "§ 2.121" to read "Subpart B of Part 5".

PART 8—COLOR ADDITIVES

6. In Part 8, by revising § 8.12 to read as follows:

§ 8.12 Advisory committee on the applicability of the anticancer clause.

All requests for and procedures governing any advisory committee on the anticancer clause shall be subject to the provisions of Subpart D of Part 2, and particularly §§ 2.360 through 2.364, of this chapter.

§§ 8.13, 8.14 [Revoked].

7. By revoking §§ 8.13 and 8.14.

8. By revising §§ 8.18 and 8.19 to read as follows:

§ 8.18 Petition for exemption from certification.

A manufacturer, packer, or distributor of a color additive or color additive mixture may petition for an exemption from certification pursuant to Part 2 of this chapter. Any such petition shall show why such certification is not necessary for the protection of public health.

§ 8.19 Procedure for objections and hearings.

(a) Objections and hearings relating to color additive regulations under sections 706 (b) and (c) of the act shall be governed by Part 2 of this chapter.

(b) The fees specified in § 8.50 shall be applicable.

§§ 8.20, 8.21 [Revoked].

9. By revoking §§ 8.20 and 8.21.

10. By amending § 8.27 by adding a sentence at the end of paragraph (b) to read as follows:

§ 8.27 Certification.

* * * * *

(b) * * * Any person who contests such refusal shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Subpart F of Part 2 of this chapter.

11. By revising § 8.28(b) to read as follows:

§ 8.28 Authority to refuse certification service.

* * * * *

(b) Any person who contests suspension of service shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Subpart F of Part 2 of this chapter.

12. By amending § 8.33 by adding a sentence at the end of paragraph (a) to read as follows:

§ 8.33 Exemption of color additives for investigational use.

(a) * * * Any person who contests a refusal to grant such authorization shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Subpart F of Part 2 of this chapter.

* * * * *

PART 10—DEFINITIONS AND STANDARDS FOR FOOD

13. In Part 10, by revising § 10.2 to read as follows:

§ 10.2 Procedure for establishing a food standard.

(a) The procedure for establishing a food standard under section 401 of the act shall be governed by Part 2 of this chapter.

(b) Any petition for a food standard shall show that the proposal if adopted, would promote honesty and fair dealing in the interest of consumers.

(c) Any petition for a food standard shall assert that the petitioner commits himself to substantiate the information in the petition by evidence in a public hearing, if such a hearing becomes necessary.

(d) If a petitioner fails to appear, or to substantiate the information in his petition, at a public hearing on the matter, the Commissioner may either (1)

withdraw the regulation and terminate the proceeding or (2) if he concludes that it is in accordance with the requirements of section 401 of the act, continue the proceeding and introduce evidence to substantiate such information.

14. By adding a new paragraph (l) to § 10.5 to read as follows:

§ 10.5 Temporary permits for interstate shipment of experimental packs of food varying from the requirements of definitions and standards of identity.

* * * * *

(l) Any person who contests denial, modification, or revocation of a temporary permit shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Subpart F of Part 2 of this chapter.

PART 11—STANDARDS OF QUALITY FOR FOODS FOR WHICH THERE ARE NO STANDARDS OF IDENTITY

15. In Part 11, by revising § 11.1(e) to read as follows:

§ 11.1 General principles.

* * * * *

(e) The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may establish, amend, or repeal, under Subpart B of this Part, a regulation prescribing a standard of quality for a food pursuant to Part 2 of this chapter.

PART 80—DEFINITIONS AND STANDARDS OF IDENTITY FOR FOOD FOR SPECIAL DIETARY USES

16. In Part 80, by revising § 80.1(b)(4) to read as follows:

§ 80.1 Dietary supplements of vitamins and minerals; definition, identity, label statements.

* * * * *

(b) * * *

(4) Addition to or amendment of the list of permissible combinations of vitamins and/or minerals contained in paragraph (b)(1) of this section may be proposed by the Commissioner of Food and Drugs, on his own initiative, or upon petition by an interested person pursuant to Part 2 of this chapter. Any such petition shall include scientific data of a human nutritional and/or technological nature to support such addition or amendment as being consistent with the definition and purpose of dietary supplements as described by this section. The Commissioner, upon request, may extend the effective date of this section with respect to any particular product or class of products pending consideration and any administrative or court proceedings relating to any such petition, and may set a new effective date upon completion of the matter.

* * * * *

PART 90—EMERGENCY PERMIT CONTROL

17. In Part 90, by revising § 90.2(a) to read as follows:

§ 90.2 Establishment of requirements for exemption from section 404 of the act.

(a) Whenever the Commissioner finds after investigation that the distribution in interstate commerce of any class of food may, by reason of contamination with microorganisms during the manufacture, processing, or packing thereof in any locality, be injurious to health, and that such injurious nature cannot be adequately determined after such articles have entered interstate commerce, he shall promulgate regulations in Subpart B of this part establishing requirements and conditions governing the manufacture, processing, or packing of the food necessary to protect the public health. Such regulations may be proposed by the Commissioner on his own initiative or in response to a petition from any interested person pursuant to Part 2 of this chapter.

* * * * *

PART 100—NUTRITIONAL QUALITY GUIDELINES FOR FOODS

18. In Part 100, by revising § 100.2 to read as follows:

§ 100.2 Petitions.

The Commissioner of Food and Drugs, on his own initiative, on the advice of the National Academy of Sciences or other experts, or on behalf of any interested person who has submitted a petition, may issue a proposal to issue, amend, or revoke a regulation prescribing a nutritional quality guideline for a class of foods, pursuant to Part 2 of this chapter.

PART 102—COMMON OR USUAL NAMES FOR NONSTANDARDIZED FOODS

19. In Part 102, by revising § 102.2 to read as follows:

§ 102.2 Petitions.

(a) The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may publish a proposal to issue, amend, or revoke, under Subpart B of this Part, a regulation prescribing a common or usual name for a food, pursuant to Part 2 of this chapter.

(b) If the principal display panel of a food for which a common or usual name regulation is established is too small to accommodate all mandatory requirements, the Commissioner may establish by regulation an acceptable alternative, e.g., a smaller type size. A petition requesting such a regulation, which would amend the applicable regulation, shall be submitted pursuant to Part 2 of this chapter.

PART 121—FOOD ADDITIVES

20. In Part 121, by revising the introductory text of § 121.40(c)(1) to read as follows:

§ 121.40 Affirmation of generally recognized as safe (GRAS) status.

* * * * *

(c) (1) Persons seeking the affirmation of GRAS status of substances as provided for in § 121.3(e), except those subject to the NAS–NRC GRAS list survey (36 FR 20546), shall submit a petition for GRAS affirmation pursuant to Part 2 of this chapter. Such petition shall contain information to establish that the GRAS criteria as set forth in § 121.3(b) have been met, in the following form:

* * * * *

21. By revising § 121.4(b)(1) to read as follows:

§ 121.41 Determination of food additive status.

* * * * *

(b) (1) The Commissioner, on his own initiative or on the petition of any interested person, pursuant to Part 2 of this chapter, may issue a notice in the FEDERAL REGISTER proposing to determine that a substance is not GRAS and is a food additive subject to section 409 of the act. Any petition shall include all relevant data and information of the type described in § 121.74(b). The Commissioner will place all of the data and information on which he relies on public file in the office of the Hearing Clerk and will include in the FEDERAL REGISTER notice the name of the substance, its known uses, and a summary of the basis for the determination.

* * * * *

22. By revising § 121.55 to read as follows:

§ 121.55 Procedure for objections and hearings.

Objections and hearings relating to food additive regulations under section 409 (c), (d), or (h) of the act shall be governed by Part 2 of this chapter.

§§ 121.56, 121.57, 121.58, 121.59, 121.60, 121.61, 121.62, 121.63, 121.64, 121.65, 121.66, 121.67, 121.68, 121.69, 121.70, 121.71, 121.73 [Revoked]

23. By revoking §§ 121.56, 121.57, 121.58, 121.59, 121.60, 121.61, 121.62, 121.63, 121.64, 121.65, 121.66, 121.67, 121.68, 121.69, 121.70, 121.71, and 121.73.

24. By revising § 121.72(b) to read as follows:

§ 121.72 Adoption of regulation on initiative of Commissioner.

* * * * *

(b) Action upon a proposal made by the Commissioner shall proceed as provided in Part 2 of this chapter.

25. By revising § 121.74 to read as follows:

§ 121.74 Procedure for amending and repealing tolerances or exemptions from tolerances.

(a) The Commissioner, on his own initiative or on the petition of any interested person, pursuant to Part 2 of this chapter, may propose the issuance of a regulation amending or repealing a regu-

lation pertaining to a food additive or granting or repealing an exception for such additive.

(b) Any such petition shall include an assertion of facts, supported by data, showing that new information exists with respect to the food additive or that new uses have been developed or old uses abandoned, that new data are available as to toxicity of the chemical, or that experience with the existing regulation or exemption may justify its amendment or repeal. New data shall be furnished in the form specified in § 121.51 for submitting petitions.

26. By revising the introductory text of § 121.4000(c) to read as follows:

§ 121.4000 General.

* * * * *

(c) The Commissioner, on his own initiative or on the petition of any interested person, pursuant to Part 2 of this chapter, may propose an interim food additive regulation. A final order promulgating an interim food additive regulation shall provide that continued use of the substance in food is subject to each of the following conditions:

* * * * *

PART 202—PRESCRIPTION DRUG ADVERTISING

27. In Part 202, by adding a new paragraph (j)(5) to § 202.1 to read as follows:

§ 202.1 Prescription-drug advertisements.

* * * * *

(j) * * *

(5) The sponsor shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Subpart F of Part 2 of this chapter with respect to any determination that prior approval is required for advertisements concerning a particular prescription drug, or that a particular advertisement is not approvable.

* * * * *

PART 310—NEW DRUGS

28. In Part 310, by revising § 310.200 (b) to read as follows:

§ 310.200 Prescription-exemption procedure.

* * * * *

(b) *Prescription-exemption procedure for drugs limited by a new drug application.* Any drug limited to prescription use under section 503(b)(1)(C) of the act shall be exempted from prescription-dispensing requirements when the Commissioner finds such requirements are not necessary for the protection of the public health by reason of the drug's toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, and he finds that the drug is safe and effective for use in self-medication as directed in proposed labeling. A proposal to exempt a drug from the prescription-dispensing requirements of section 503(b)(1)(C) of the act may be initiated by the Commissioner or by any interested person. Any interested person may file a petition seeking such exemption, which petition may be pursuant to Part 2 of this chapter, or in the form of a supplement to an approved new drug application.

* * * * *

29. By revising § 310.303(b) to read as follows:

§ 310.303 Continuation of long term studies, records, and reports on certain drugs for which new drug applications have been approved.

* * * * *

(b) A proposal to require additional or continued studies with a drug for which a new drug application has been approved may be made by the Commissioner on his own initiative or on the petition of any interested person, pursuant to Part 2 of this chapter. Prior to issuance of such a proposal, the applicant will be provided an opportunity for a conference with representatives of the Food and Drug Administration. When appropriate, investigators or other individuals may be invited to participate in the conference. All requirements for special studies, records, and reports will be published in § 310.304.

PART 312—NEW DRUGS FOR INVESTIGATIONAL USE

30. In Part 312, by revising § 312.1 (c)(1) and (4), (d), and (g) to read as follows:

§ 312.1 Conditions for exemption of new drugs for investigational use.

* * * * *

(c) (1) Whenever the Food and Drug Administration has information indicating that an investigator has repeatedly or deliberately failed to comply with the conditions of these exempting regulations outlined in Form FD-1572 or FD-1573, set forth in paragraph (a)(12) and (13) of this section, or has submitted to the sponsor of the investigation false information in his Form FD-1572 or FD-1573 or in any required report, the Director, Bureau of Drugs, will furnish the investigator written notice of the matter complained of in general terms and offer him an opportunity to explain the matter in an informal conference and/or in writing. If an explanation is offered but not accepted by the Bureau of Drugs, the investigator shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Subpart F of Part 2 of this chapter, on the question of whether the investigator is entitled to receive investigational new drugs.

* * * * *

(4) If the Commissioner determines, after the unreliable data submitted by the investigator are eliminated from consideration, that the data remaining are inadequate to support a conclusion that it is reasonably safe to continue the investigation, he will notify the sponsor who shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Subpart F of Part 2 of this chapter. If a danger to the public health exists, however, he shall terminate the exemption forthwith and notify the sponsor of the termination. In such event the sponsor shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Subpart F of Part 2 of this chapter on the question of whether the exemption should be reinstated.

* * * * *

(d) If the Director, Bureau of Drugs, finds that:

(1) The submitted "Notice of claimed investigational exemption for a new drug" contains an untrue statement of a material fact or omits material information required by said notice; or

(2) The results of prior investigations made with the drug are inadequate to support a conclusion that it is reasonably safe to initiate or continue the intended clinical investigations with the drug; or

(3) There is substantial evidence to show that the drug is unsafe for the purposes and in the manner for which it is offered for investigational use; or

(4) There is convincing evidence that the drug is ineffective for the purposes for which it is offered for investigational use; or

(5) The methods, facilities, and controls used for the manufacturing, processing, and packing of the investigational drug are inadequate to establish and maintain appropriate standards of identity, strength, quality, and purity as needed for safety and to give significance to clinical investigations made with the drug; or

(6) The plan for clinical investigations of the drugs described under section 10 of the "Notice of claimed investigational exemption for a new drug" is not a reasonable plan in whole or in part, solely for a bona fide scientific investigation to determine whether or not the drug is safe and effective for use; or

(7) The clinical investigations are not being conducted in accordance with the plan submitted in the "Notice of claimed investigational exemption for a new drug"; or

(8) The drug is not intended solely for investigational use, since it is being or is to be sold or otherwise distributed for commercial purposes not justified by the requirements of the investigation; or

(9) The labeling or other informational material submitted for the drug as required by section 7 of the "Notice of claimed investigational exemption for a new drug" or any other labeling of the drug disseminated within the United States by or on behalf of the sponsor fails to contain an accurate description of prior investigations or experience and their results pertinent to the safety and possible usefulness of the drug, including all relevant hazards, contraindications, side-effects, and precautions; or any promotional materials disseminated within the United States by or on behalf of the sponsor contains any representation or suggestion that the drug is safe or that

its usefulness has been established for the purposes for which it is offered for investigations; or

(10) The sponsor fails to submit accurate reports of the progress of the investigations with significant findings at intervals not exceeding 1 year; or

(11) The sponsor fails promptly to investigate and inform the Food and Drug Administration and all investigators of newly found serious or potentially serious hazards, contraindications, side-effects, and precautions pertinent to the safety of the new drug; he shall notify the sponsor and invite his immediate correction or explanation. A conference will be arranged with the Bureau of Drugs if requested. If the Bureau of Drugs does not accept the explanation or the correction submitted by the sponsor, the sponsor shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Subpart F of Part 2 of this chapter on the question of whether his exemption should be terminated. Such hearing shall be requested within 10 days after receipt of notification that the explanation or correction is not acceptable. After evaluating all the available information including any explanation and or correction submitted by the sponsor, if the Commissioner determines that the exemption should be terminated he shall notify the sponsor of the termination of the exemption and the sponsor shall recall unused supplies of the drug. If at any time the Commissioner concludes that continuation of the investigation presents a danger to the public health, he shall terminate the exemption forthwith and notify the sponsor of the termination. The Commissioner will inform the sponsor that the exemption is subject to reinstatement on the basis of additional submissions that eliminate such danger and will afford the sponsor an opportunity for a regulatory hearing before the Commissioner pursuant to Subpart F of Part 2 of this chapter on the question of whether the exemption should be reinstated. The sponsor shall recall the unused supplies of the drug upon notification of the termination.

* * * * *

(g) A "Notice of Claimed Investigational Exemption for a New Drug" which pertains to a product subject to the licensing provisions of the Public Health Service Act of July 1, 1944 (58 Stat. 682, as amended; 42 U.S.C. 201 et seq.), shall be submitted initially to the Director, Bureau of Biologics, 8800 Rockville Pike, Bethesda, MD 20014. Amendments of or supplements to such notice, and progress reports, consultations, or other communications with regard to the investigation, shall be directed to the Bureau of Biologics, which monitors the development of biological products subject to license under section 351 of the Public Health Service Act. A sponsor for a "Notice of Claimed Investigational Exemption for a New Drug" pertaining to such biologic shall substitute in reading this § 312.1 "Bureau of Biologics" for "Bureau of Drugs," wherever it appears.

* * * * *

31. By revising § 312.9(c)(2) to read as follows:

§ 312.9 New drugs for investigational use in laboratory research animals or in vitro tests.

* * * * *

(c) * * *

(2) The continuance of the investigation is unsafe or otherwise contrary to the public interest or the drug is used for purposes other than bona fide scientific investigation. He shall notify the sponsor and invite his immediate correction. If the conditions of the exemption are not immediately met, the sponsor shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Subpart F of Part 2 of this chapter. If the exemption is terminated, the sponsor shall recall or have destroyed the unused supplies of the drug.

PART 314—NEW DRUG APPLICATIONS

32. In Part 314, by revising the introductory paragraph of § 314.115 to read as follows:

§ 314.115 Withdrawal of approval of an application.

The Commissioner shall notify the person holding an approved new drug application, and all other persons who manufacture or distribute identical, related, or similar drug products as defined in § 310.6 of this chapter, and afford an opportunity for a hearing on a proposal to withdraw approval of the application as provided in section 505(e) of the act and in accordance with the procedure in §§ 314.200 and 314.201, if:

* * * * *

32a. By revising § 314.200 to read as follows:

§ 314.200 Notice of opportunity for hearing; notice of appearance and request for hearing; grant or denial of hearing.

(a) The notice to the applicant, and to all other persons who manufacture or distribute identical, related, or similar drug products as defined in § 310.6 of this chapter, of an opportunity for a hearing on a proposal by the Director of the Bureau of Drugs to refuse to approve an application or to withdraw the approval of an application will state the reasons for his action and the grounds upon which he proposes to issue his order.

(1) Such notice may be general (i.e., simply summarizing in a general way the information resulting in the notice) or specific (i.e., either referring to specific requirements in the statute and regulations with which there is a lack of compliance, or providing a detailed description and analysis of the specific facts resulting in the notice).

(2) The notice will be published in the FEDERAL REGISTER and will state that the applicant, and other persons subject to the notice pursuant to § 310.6 of this chapter, has 30 days after the date of publication of the notice within which he is required to file a written notice of appearance and request for hearing if he elects to avail himself of the opportunity for a hearing. The failure to file such a written notice of appearance and request for hearing within that 30 days constitutes an election by the applicant, and other persons subject to the notice pursuant to § 310.6 of this chapter, not to avail himself of the opportunity for a hearing.

(3) It is the responsibility of every manufacturer or distributor of a drug product to review every notice of opportunity for hearing published in the FEDERAL REGISTER to determine whether it covers any drug product he manufactures or distributes. Any person may request an opinion of the applicability of such a notice to a specific product he manufactures or distributes that may be identical, related, or similar by writing to the Food and Drug Administration, Bureau of Drugs, Division of Drug Labeling Compliance, HFD–310, 5600 Fishers Lane, Rockville, MD 20852. If such an opinion is requested, the time for filing an appearance and request for hearing and supporting studies and analyses shall begin as of the date or receipt of the opinion from the Food and Drug Administration.

(b) The notice of opportunity for hearing shall be provided to applicants and to other persons subject to the notice pursuant to § 310.6 of this chapter:

(1) To any person who has submitted a new drug application, by delivering the notice in person or by sending it by registered or certified mail to the last address shown in the new drug application.

(2) To any person who has not submitted a new drug application but who is subject to the notice pursuant to § 310.6 of this chapter, by publication of the notice in the FEDERAL REGISTER.

(c)(1) If the applicant, or any other person subject to the notice pursuant to § 310.6 of this chapter, elects to avail himself of the opportunity for a hearing, he shall file with the Hearing Clerk (i) within 30 days after the date of the publication of the notice (or of the date of receipt of an opinion requested pursuant to paragraph (a)(3) of this section) a written notice of appearance and request for hearing, and (ii) within 60 days after the date of publication of the notice, unless a different period of time is specified in the notice of opportunity for hearing, the studies on which he relies to justify a hearing as specified in paragraph (d) of this section. The raw data underlying a study submitted may be incorporated by reference from a prior submission as part of a new drug application or other report.

(2) No data or analysis submitted after such 60 days will be considered in determining whether a hearing is warranted unless they are derived from well-controlled studies begun prior to the date of the notice of opportunity for hearing, the results of which were not in existence during that 60 days. Exceptions may be made on the basis of a showing of inadvertent omission and hardship. All studies in progress, the results of which the person requesting the hearing intends later to submit in support of the request

for hearing, shall be listed. A copy of the complete protocol, a list of the participating investigators, and a brief status report of the studies shall be included in the submission made pursuant to paragraph (c)(1)(ii) of this section.

(3) Any other interested person who is not subject to the notice of opportunity for hearing may also submit comments on the proposal to withdraw approval of the new drug application. Such comments shall be submitted within the time and pursuant to the requirements specified in this section.

(d) A request for hearing shall be supported by a submission as specified in paragraph (c)(1)(ii) of this section containing the studies (including all protocols and underlying raw data) on which the person relies to justify a hearing with respect to his drug product.

(1) If effectiveness is at issue, a request for hearing shall be supported only by adequate and well-controlled clinical studies meeting all of the precise requirements of § 314.111(a)(5) and, for combination drug products, § 300.50 of this chapter, or by other studies not meeting those requirements for which a waiver has been previously granted by the Food and Drug Administration pursuant to the provisions of § 314.111(a)(5). All adequate and well-controlled clinical studies on the drug product known to the person requesting the hearing shall be submitted. Any unfavorable analyses, views, or judgments with respect to such studies known to such person shall also be submitted. No other data, information, or studies shall be submitted.

(2) Such submission shall include a factual analysis of all studies submitted. If effectiveness is at issue, such analysis shall specify how each such study accords, on a point-by-point basis, with each criterion required for an adequate well-controlled clinical investigation established in § 314.111(a)(5) and, if the product is a combination drug product, with each of the requirements for a combination drug established in § 300.50 of this chapter, or shall be accompanied by an appropriate waiver previously granted by the Food and Drug Administration. If a study deals with a drug entity or dosage form, or condition of use, or mode of administration other than the one(s) in question, such fact(s) shall be clearly stated. Any study conducted on the final marketed form of the drug product shall be so designated.

(3) Such analysis shall be submitted in the following format, except that the required information relating either to safety or to effectiveness shall be omitted if the notice of opportunity for hearing does not raise any issue with respect to that aspect of the drug; and information on compliance with § 300.50 shall be omitted if the drug product is not a combination drug product. Submissions not made in this format or not containing the required analyses will not be considered and will result in denial of a hearing, except that minor technical deficiencies may be excused if it is apparent that a good faith attempt has been made to comply with the requirements of this section and any deficiencies noted are immediately corrected upon request.

I. Safety data.
A. Animal safety data.
1. Individual active component(s).
a. Controlled studies.
b. Partially controlled or uncontrolled studies.
2. Combinations of the individual active components.
a. Controlled studies.
b. Partially controlled or uncontrolled studies.
B. Human safety data.
1. Individual active component(s).
a. Controlled studies.
b. Partially controlled or uncontrolled studies.
c. Documented case reports.
d. Pertinent marketing experiences that may influence a determination as to the safety of each individual active component.
2. Combinations of the individual active components.
a. Controlled studies.
b. Partially controlled or uncontrolled studies.
c. Documented case reports.
d. Pertinent marketing experiences that may influence a determination as to the safety of combinations of the individual active components.

II. Effectiveness data.
A. Individual active components: Controlled studies, with an analysis showing clearly how each such study satisfies, on a point-by-point basis, each of the criteria required by § 314.111(a)(5).
B. Combinations of individual active components.
1. Controlled studies, with an analysis showing clearly how such study satisfies, on a point-by-point basis, each of the criteria required by § 314.111(a)(5).
2. An analysis showing clearly how each requirement of § 300.50 of this chapter has been satisfied.

III. A summary of the data and views setting forth the medical rationale and purpose for the drug and its ingredients and the scientific basis for the conclusion that the drug and its ingredients have been proven safe and/or effective for the intended use. If there is an absence of controlled studies in the material submitted, or the requirements of any element of § 300.50 of this chapter or § 314.111(a)(5) have not been fully met, such fact(s) shall be clearly stated, and a waiver obtained pursuant to § 314.111(a)(1) shall be enclosed.

IV. A statement signed by the person responsible for such submission, that it includes in full (or incorporates by reference as permitted in § 314.200(c)(2)) all studies and information specified in § 314.200(d). (Warning: A willfully false statement is a criminal offense, 18 U.S.C. 1001).

(e) A notice of opportunity for hearing encompasses all issues relating to the legal status of the drug product(s) subject to it, including identical, related, and similar drug products as defined in § 310.6 of this chapter. Any contention that any such product is not a new drug because it is generally recognized as safe and effective within the meaning of section 201(p) of the act, or because it is exempt from part or all of the new drug provisions of the act pursuant to the exemption for products marketed prior to June 25, 1938, contained in section 201(p) of the act, or pursuant to section 107(c) of the Drug Amendments of 1962, or for any other reason shall be stated in a notice of appearance and request for hearing pursuant to paragraph (c)(1)(i) of this section and supported by a submission pursuant to paragraph (c)(1)(ii) of this section and shall be the subject of an administrative determination by the Commissioner. The failure of any person subject to a notice of opportunity for a hearing, including any person who manufactures or distributes an identical, related, or simular drug product as defined in § 310.6 of this chapter, to submit a notice of appearance and request for hearing or to raise all such contentions on which he relies shall constitute a waiver of any such contentions not so raised.

(1) A contention that a drug product is generally recognized as safe and effective within the meaning of section 201(p) of the act must be supported by submission of the same quantity and quality of scientific evidence as is required to obtain approval of a new drug application for the product, unless a waiver has been obtained from such requirement for effectiveness (as provided in § 314.111(a)(5)) and/or safety for good cause shown. Such submission shall be in the format and with the analyses required by paragraph (d) of this section. The failure to submit such scientific evidence or a submission that is not in the format or does not contain the analyses required by paragraph (d) of this section shall constitute a waiver of any such contention. General recognition of safety and effectiveness shall ordinarily be based upon published studies which may be corroborated by unpublished studies and other data and information.

(2) A contention that a drug product is exempt from part or all of the new drug provisions of the act pursuant to the exemption for products marketed prior to June 25, 1938 contained in section 201(p) of the act, or pursuant to section 107(c) of the Drug Amendments of 1962, shall be supported by submission of evidence of past and present quantitative formulas, labeling, and evidence of marketing, on which reliance is made for such contention. The failure to submit such formulas, labeling, and evidence of marketing in the following format shall constitute a waiver of any such contention.

I. Formulation.
A. A copy of each pertinent document or record to establish the exact quantitative formulation of the drug (both active and inactive ingredients) on the date of initial marketing of the drug.
B. A statement whether such formulation has at any subsequent time been changed in any manner. If any such change has been made, the exact date, nature, and rationale for each change in formulation, including any deletion or change in the concentration of any active ingredient and/or inactive ingredient, shall be submitted, together with a copy of each pertinent document or record to establish the date and nature of each such change including but not limited to the formula which resulted from each such change. If no such change has been made, a copy of representative documents or records showing the formula at representative points in time shall be submitted to support the statement.

II. Labeling.

A. A copy of each pertinent document or record to establish the identity of each item of written, printed, or graphic matter used as labeling on the date the drug was initially marketed.

B. A statement whether such labeling has at any subsequent time been discontinued or changed in any manner. If such discontinuance or change has been made, the exact date, nature, and rationale for each discontinuance or change and a copy of each pertinent document or record to establish each such discontinuance or change shall be submitted, including but not limited to the labeling which resulted from each such discontinuance or change. If no such discontinuance or change has been made, a copy of representative documents or records showing labeling at representative points in time shall be submitted to support the statement.

III. Marketing.

A. A copy of each pertinent document or record to establish the exact date the drug was initially marketed.

B. A statement whether such marketing has at any subsequent time been discontinued. If such marketing has been discontinued, the exact date of each such discontinuance shall be submitted, together with a copy of each pertinent document or record to establish each such date.

IV. Verification.

A statement signed by the person responsible for such submission, that all appropriate records have been searched and to the best of his knowledge and belief it includes a true and accurate presentation of the facts (Warning: A willfully false statement is a criminal offense, 18 U.S.C. 1001).

(3) No drug product, including any active ingredient, which is identical, related, or similar, as defined in § 310.6, to a drug product, including any active ingredient for which a new drug application is or at any time has been effective or deemed approved, or approved under section 505 of the act, will be determined to be exempt from part or all of the new drug provisions of the act.

(4) A contention that a drug product is not a new drug for any other reason must be supported by submission of such factual records, data, and information as is necessary and appropriate to support such contention.

(5) It is the responsibility of every person who manufactures or distributes a drug product in reliance upon a "grandfather" provision(s) of the act to maintain in his files, organized as required by this paragraph, the data and information necessary fully to document and support such status.

(f) Upon receipt of any request for hearing, the Director of the Bureau of Drugs shall prepare an analysis of the request and a proposed order ruling upon the matter. The analysis and proposed order, the request for hearing, and any proposed order denying a hearing and response pursuant to paragraph (g) (2) or (3) of this section, shall be submitted to the office of the Commissioner for independent review and decision. No representative of the Bureau of Drugs shall participate or advise in the review and decision by the Commissioner. The office of the General Counsel shall observe the same separation of functions.

(g) A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing with respect to the particular drug product(s) specified in the request for hearing.

(1) Where a specific notice of opportunity for hearing (as defined in paragraph (a)(1) of this section) is used, it shall state that, if it conclusively appears from the face of the data, information, and factual analyses in the request for the hearing that there is no genuine and substantial issue of fact which precludes the refusal to approve the application or the withdrawal of approval of the application, e.g., no adequate and well-controlled clinical investigations meeting each of the precise elements of § 314.111(a)(5) and, for a combination drug product, § 300.50 of this chapter, showing effectiveness have been identified, or when a request for hearing is not made in the required format or with the required analyses, the Commissioner will enter summary judgment against the person(s) who requests the hearing, making findings and conclusions, denying a hearing. Any such order entering summary judgment shall set forth the Commissioner's findings and conclusions in detail and shall specify why each study submitted fails to meet the requirements of the statute and regulations or why the request for hearing does not raise a genuine and substantial issue of fact or shall specify the requirements of this section with respect to format or analyses with which there is a lack of compliance.

(2) Where a general notice of opportunity for hearing (as defined in paragraph (a)(1) of this section) is used and the Director of the Bureau of Drugs concludes that summary judgment against the person(s) requesting a hearing should be considered, he shall serve upon such person(s) by registered mail a proposed order denying a hearing. Such person(s) shall have 60 days after receipt of such proposed order to respond with sufficient data, information, and analyses to demonstrate that there is a genuine and substantial issue of fact which justifies a hearing.

(3) Where a general or specific notice of opportunity for hearing is used and the person(s) requesting a hearing submits data or information of a type required by the statute and regulations, and the Director of the Bureau of Drugs concludes that summary judgment against such person(s) should be considered, he shall serve upon such person(s) by registered mail a proposed order denying a hearing. Such person(s) shall have 60 days after receipt of such proposed order to respond with sufficient data, information, and analyses to demonstrate that there is a genuine and substantial issue of fact which justifies a hearing.

(4) If review of the data, information, and analyses submitted warrants the conclusion that the ground(s) cited in the notice are not valid, e.g., that substantial evidence of effectiveness exists, the Commissioner shall deny the hearing, enter summary judgment for the person(s) requesting the hearing, and rescind the notice of opportunity for hearing.

(5) If a hearing is requested and is justified the hearing will commence no more than 90 days after the expiration of such 30 days unless the parties otherwise agree in the case of denial of approval, and as soon as practicable in the case of withdrawal of approval.

(6) A hearing shall be granted if there exists a genuine and substantial issue of fact or if the Commissioner concludes, in his discretion, that a hearing would otherwise be in the public interest.

(7) If the manufacturer or distributor of a drug product that may be an identical, related, or similar drug product requests and is granted a hearing, the issue whether the product is in fact identical, related, or similar to the drug subject to new drug application is properly encompassed within the hearing.

(8) A request for hearing, and any subsequent grant or denial of a hearing, shall be applicable only to the particular drug product(s) named in such documents.

(h) Any drug product subject to a notice of opportunity for hearing, including any identical, related, or similar drug product as defined in § 310.6 of this chapter, for which an opportunity for a hearing is waived or for which a hearing is denied shall promptly be the subject of a notice withdrawing the new drug application approval and declaring all such products unlawful. The Commissioner may, in his discretion, defer or stay such action pending a ruling on any related request for a hearing or pending any related hearing or other administrative or judicial proceeding.

33. By adding a new § 314.201 to read as follows:

§ 314.201 Procedure for hearings.

Hearings relating to new drugs under section 505 (d) and (e) of the act shall be governed by Part 2 of this chapter.

§§ 314.202, 314.203, 314.204, 314.205, 314.206, 314.220, 314.221, 314.222, 314.230, 314.231, 314.232 [Revoked].

34. By revoking §§ 314.202, 314.203, 314.204, 314.205, 314.206, 314.220, 314.221, 314.222, 314.230, 314.231 and 314.232.

35. By revising § 314.235 to read as follows:

§ 314.235 Judicial review.

(a) The transcript and record shall be certified by the Commissioner. In any case in which the Commissioner enters an order without a hearing pursuant to § 314.200(g), the requests for hearing together with the data and information submitted and the Commissioner's findings and conclusions shall be included in the record certified by the Commissioner.

(b) Judicial review of an order withdrawing approval of a new drug application, whether or not a hearing has been held, may be sought by a manufacturer or distributor of an identical, related, or similar drug product, as defined in § 310.6 of this chapter, in a United States court of appeals pursuant to section 505 (h) of the act.

PART 328—IN VITRO DIAGNOSTIC PRODUCTS FOR HUMAN USE

36. In Part 328, by revising § 328.30(a) to read as follows:

§ 328.30 Procedure for establishing, amending or repealing standards.

(a) *Basis for standards and available approaches to developing standards.* Whenever in the judgment of the Commissioner the establishment of a product class standard is necessary to reduce or eliminate unreasonable risk of illness or injury associated with exposure to or use of an in vitro diagnostic product and there are no other more practicable means to protect the public from such risk, he may propose such a standard. In proposing a product class standard he shall consider, and publish in the FEDERAL REGISTER findings on, the degree of risk or injury associated with the use of the product, the availability of information relating to the sciences upon which the products or their uses are based, the approximate number of products subject to the standard, the medical need for the products, and the probable effect of the standard upon the utility, cost, or availability of the product, and available means of achieving the objective of the standard with a minimal disruption of supply and of reasonable manufacturing and other commercial practices. Three procedures are available for developing product class standards and may be proposed on the initiative of the Commissioner or by petition of interested persons, pursuant to Part 2 of this chapter: (1) An existing standard may be utilized, (2) interested persons outside of the Food and Drug Administration may develop a proposed standard or (3) the Food and Drug Administration may develop the standard.

* * * * *

PART 330—OVER-THE-COUNTER (OTC) HUMAN DRUGS WHICH ARE GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE AND NOT MISBRANDED

37. In Part 330, by revising § 330.10 (a)(12) to read as follows:

§ 330.10 Procedures for classifying OTC drugs as generally recognized as safe and effective and not misbranded, and for establishing monographs.

* * * * *

(a) * * *

(12) *Amendment of monographs.* The Commissioner may propose on his own initiative to amend or repeal any monograph established pursuant to this section. Any interested person may petition the Commissioner for such proposal, pursuant to Part 2 of this chapter. The Commissioner may deny the petition if he finds a lack of safety or effectiveness employing the standards in paragraph (a)(4) of this section (in which case the appeal provisions of paragraph (a)(11) of this section shall apply) or he may issue a proposed amendment or repeal in the FEDERAL REGISTER if he finds general recognition of safety and effectiveness employing the standards in paragraph (a)(4) of this section (in which case the provisions of paragraph (a)(6), (7), (8), and (9) of this section shall apply). A new drug application may be submitted in lieu of or in addition to a petition under this paragraph.

* * * * *

PART 429—DRUGS COMPOSED WHOLLY OR PARTLY OF INSULIN

38. In Part 429, by revising § 429.50 to read as follows:

§ 429.50 Hearing procedure.

Hearings pursuant to § 429.47 shall be governed by Subpart F of Part 2 of this chapter.

PART 430—ANTIBIOTIC DRUGS: GENERAL

39. In Part 430, by revising § 430.20 to read as follows:

§ 430.20 Procedure for the issuance, amendment, or repeal of regulations.

(a) The procedures for the issuance, amendment, or repeal of regulations under section 507 of the act shall be governed by Part 2 of this chapter.

(b)(1) The Commissioner, on his own initiative or on the application or request of any interested person, may publish in the FEDERAL REGISTER a notice of proposed rule making and order to issue, amend, or repeal any regulation contemplated by section 507 of the act. Such notice and order may be general (i.e., simply summarizing in a general way the information resulting in the notice and order) or specific (i.e., either referring to specific requirements in the statute and regulations with which there is a lack of compliance, or providing a detailed description and analysis of the specific facts resulting in the notice and order).

(2) An opportunity shall be given for interested persons to submit written comments and to request an informal conference on the proposal, unless such notice and opportunity for comment and informal conference have already been provided in connection with the announcement of the reports of the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, to persons who will be adversely affected, or as provided in §§ 2.10(e) or 2.110(b)(2) of this chapter. The time for requesting an informal conference shall be 30 days unless otherwise specified in the notice of proposed rule making. If an informal conference is requested and granted, those persons participating in the conference shall be provided an additional 30 days for comment, beginning the date of the conference, unless otherwise specified in the proposal.

(3) It is the responsibility of every manufacturer or distributor of an antibiotic drug product to review every proposal published in the FEDERAL REGISTER to determine whether it covers any product he manufactures or distributes.

(4) After considering the written comments, the results of any conference, and the data available, the Commissioner will publish an order in the FEDERAL REGISTER acting on the proposal, with opportunity for any person who will be adversely affected to file objections, to request a hearing, and to show reasonable grounds for the hearing. Any such person who elects to avail himself of the opportunity for a hearing shall file with the Hearing Clerk (i) within 30 days after the date of publication of the order a written notice of appearance and request for hearing, and (ii) within 60 days after the date of publication of the order, unless a different period of time is specified in the order, the studies on which he relies to justify a hearing as specified in paragraph (b)(6) of this section. The raw data underlying a study submitted may be incorporated by reference from a prior submission as part of an antibiotic application, or other applications or reports.

(5) No data or analysis submitted after such 60 days will be considered in determining whether a hearing is warranted unless they are derived from well-controlled studies begun prior to the date of the order, the results of which were not in existence during that 60 days. Exceptions may be made on the basis of a showing of inadvertent omission and hardship. All studies in progress, the results of which the person requesting the hearing intends later to submit in support of the request for hearing, shall be listed. A copy of the complete protocol, a list of the participating investigators, and a brief status report of the studies shall be included in the submission made pursuant to paragraph (b)(4)(ii) of this section.

(6) A request for hearing shall be supported by a submission as specified in § 314.200(c)(1)(ii) of this chapter containing the studies (including all underlying raw data) on which the person relies to justify a hearing with respect to his drug product.

(i) If effectiveness is at issue, a request for hearing shall be supported only by adequate and well-controlled clinical studies meeting all of the precise requirements of § 314.111(a)(5) of this chapter and, for combination drug products, § 300.50 of this chapter, or by other studies not meeting those requirements for which a waiver has been previously granted by the Food and Drug Administration pursuant to the provisions of § 314.111(a)(5) of this chapter. All adequate and well-controlled clinical studies on the drug product known to the person requesting the hearing shall be submitted. Any unfavorable analyses, views, or judgments with respect to such studies known to such person shall also be submitted. No other data, information, or studies shall be submitted.

(ii) Such submission shall include a factual analysis of all studies submitted. If effectiveness is at issue, such analysis shall specify how each such study accords, on a point-by-point basis, with each criterion required for an adequate and well-controlled clinical investigation established in § 314.111(a)(5) of this chapter and, if the product is a combination drug product, with each of the requirements for a combination drug es-

tablished in § 300.50 of this chapter, or shall be accompanied by an appropriate waiver previously granted by the Food and Drug Administration. If a study deals with a drug entity or dosage form, or condition of use, or mode of administration other than the one(s) in question, such fact(s) shall be clearly stated. Any study conducted on the final marketed form of the drug product shall be so designated.

(iii) Such analysis shall be submitted in the following format, except that information relating to safety or effectiveness shall be omitted if the order does not raise any issue with respect to that aspect of the drug; and information on compliance with § 300.50 of this chapter shall be omitted if the drug product is not a combination drug product. Submissions not made in this format or not containing the required analyses will not be considered and will result in denial of hearing, except that minor technical deficiencies may be excused if it is apparent that a good faith attempt has been made to comply with the requirements of this section and any deficiencies noted are immediately corrected upon request.

I. Safety data.
A. Animal safety data.
1. Individual active component(s).
a. Controlled studies.
b. Partially controlled or uncontrolled studies.
2. Combinations of the individual active components.
a. Controlled studies.
b. Partially controlled or uncontrolled studies.
B. Human safety data.
1. Individual active component(s).
a. Controlled studies.
b. Partially controlled or uncontrolled studies.
c. Documented case reports.
d. Pertinent marketing experiences that may influence a determination as to the safety of each individual active component.
2. Combinations of the individual active components.
a. Controlled studies.
b. Partially controlled or uncontrolled studies.
c. Documented case reports.
d. Pertinent marketing experiences that may influence a determination as to the safety of combinations of the individual active components.
II. Effectiveness data.
A. Individual active components: Controlled studies, with an analysis showing clearly how each such study satisfies, on a point-by-point basis, each of the criteria required by § 314.111(a)(5) of this chapter.
B. Combinations of individual active components.
1. Controlled studies with an analysis showing clearly how each such study satisfies, on a point-by-point basis, each of the criteria required by § 314.111(a)(5) of this chapter.
2. An analysis showing clearly how each requirement of § 300.50 of this chapter has been satisfied.
III. A summary of the data and views setting forth the medical rationale and purpose for the drug and its ingredients and the scientific basis for the conclusion that the drug and its ingredients have been proven safe and/or effective for the intended use. If there is an absence of controlled studies in the material submitted, or the requirements of any element of § 300.50 of this chapter or § 314.111(a)(5) of this chapter have not been fully met, such fact(s) shall be clearly stated, and a waiver obtained pursuant to § 314.111(a)(5) of this chapter shall be enclosed.
IV. A statement signed by the person responsible for such submission, that it includes in full (or incorporates by reference as permitted in § 430.20(b)(4)) all studies and information specified in § 430.20(b). (Warning: A willfully false statement is a criminal offense, 18 U.S.C. 1001.)

(7) Upon receipt of any request for hearing, the Director of the Bureau of Drugs shall prepare an analysis of the request and a proposed order ruling upon the matter. The analysis and proposed order, the request for hearing, and any proposed order denying a hearing and response pursuant to paragraph (b)(8)(ii) or (iii) of this section, shall be submitted to the office of the Commissioner for independent review and decision. No representative of the Bureau of Drugs shall participate or advise in the review and decision by the Commissioner. The office of the General Counsel shall observe the same separation of functions.

(8) A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact with respect to the particular drug product(s) which is specified in the request for hearing that requires a hearing.

(i) Where a specific proposal or order (as defined in paragraph (b)(1) of this section) is used, the order published in the FEDERAL REGISTER shall state that, if it conclusively appears from the face of the data, information, and factual analyses in the request for hearing that there is no genuine and substantial issue of fact which precludes the action taken on the proposal, e.g., no adequate and well-controlled clinical investigations meeting each of the precise elements of § 314.111(a)(5) of this chapter and, for a combination drug product, §300.50 of this chapter, showing effectiveness have been identified, or when a request for hearing is not made in the required format or with the required analyses, the Commissioner will enter summary judgment against the person(s) who requests a hearing, making findings and conclusions, denying a hearing. Any such order entering summary judgment shall set forth the Commissioner's findings and conclusions in detail and shall specify why each study submitted fails to meet the requirements of the statute and regulations or why the request for hearing otherwise does not raise a genuine and substantial issue of fact or shall specify the requirements of this paragraph with respect to format or analyses with which there is a lack of compliance.

(ii) Where a general notice or order (as defined in paragraph (b)(1) of this section) is used and the Director of the Bureau of Drugs concludes that summary judgment against the person(s) requesting a hearing should be considered, he shall serve upon such person(s) by registered mail a proposed order denying a hearing. Such person(s) shall have 60 days after receipt of such proposed order to respond with sufficient data, information and analyses to demonstrate that there is a genuine and substantial issue of fact which justifies a hearing.

(iii) Where a general or specific notice or order is used and the person(s) requesting a hearing submits data or information of a type required by the statute and regulations, and the Director of the Bureau of Drugs concludes that summary judgment against such person(s) should be considered, he shall serve upon such person(s) by registered mail a proposed order denying a hearing. Such person(s) shall have 60 days after receipt of such proposed order to respond with sufficient data, information, and analyses to demonstrate that there is a genuine and substantial issue of fact which justifies a hearing.

(iv) If review of the data, information, and analyses submitted warrants the conclusion that the basis for the order is not valid, e.g., that substantial evidence of effectiveness exists, the Commissioner shall deny the hearing, enter summary judgment for the person(s) requesting the hearing, and revoke the order. If a hearing is not requested, the order will become effective as published.

(v) If a hearing is requested and justified, the provisions of Part 2 of this chapter shall apply to such hearing.

(vi) A hearing shall be granted if there exists a genuine and substantial issue of fact or if the Commissioner concludes, in his discretion, that a hearing would otherwise be in the public interest.

(9) The repeal of any regulation constitutes a revocation of all outstanding certificates based upon such regulation. However, the Commissioner may, in his discretion, defer or stay such action pending a ruling on any related request for a hearing or pending any related hearing or other administrative or judicial proceeding.

(c) Whenever any interested person submits an application or request pursuant to provisions of section 507 of the act, or regulations promulgated thereunder, which application or request contemplates the issuance, amendment, or repeal of any regulation, and such person has been informed in writing that such application or request is not approvable, or whenever such person has received no written communication advising whether or not such application is approvable by the 180th day after its submission, such interested person may file a petition proposing the issuance, amendment, or repeal of such regulation under the provisions of section 507(f) of the act and Part 2 of this chapter. The Commissioner shall cause the regulation proposed in such petition to be published in the FEDERAL REGISTER within 60 days of the receipt of an acceptable petition and further proceedings shall be in accord with the provisions of sections 507(f) and 701(f) and (g) of the act and Part 2 of this chapter.

(d)(1) No regulation providing for the certification of any batch of any drug composed wholly or in part of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any

other antibiotic drug, or any derivative thereof, intended for use by man shall be promulgated and no existing regulation will be continued in effect unless it is established by substantial evidence that the drug will have such characteristics of identity, strength, quality, and purity necessary to adequately insure safety and efficacy of use. "Substantial evidence" has been defined by Congress to mean "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effectiveness it purports and is represented to have under the conditions prescribed, recommended or suggested in the labeling thereof." This definition is made applicable to a number of antibiotic drugs by section 507(h) of the act and it is the test of efficacy that will be applied in promulgating, amending, or repealing regulations for the certification of all antibiotics under section 507(a) of the act as well.

(2) The scientific essentials of an adequate and well-controlled clinical investigation are described in § 314.111(a)(5) of this chapter.

PART 431—CERTIFICATION OF ANTIBIOTIC DRUGS

40. In Part 431, by revising § 431.52 to read as follows:

§ 431.52 Hearings.

Any person who contests the suspension of certification service under § 431.51 shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Subpart F of Part 2 of this chapter.

PART 433—EXEMPTIONS FROM ANTIBIOTIC CERTIFICATION AND LABELING REQUIREMENTS

41. In Part 433, by revising § 433.2 (c) and (d) to read as follows:

§ 433.2 Conditions on the effectiveness of exemptions from certification.

* * * * *

(c) If the Commissioner repeals or suspends an exemption for an antibiotic drug, the approved new drug application, or an exemption from batch certification requirements, a notice to that effect and the reasons therefor will be published in the FEDERAL REGISTER.

(d) Any person who contests the revocation or suspension or denial of reinstatement of an exemption shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Subpart F of Part 2 of this chapter.

42. By revising § 433.12(b)(4) and adding a paragraph (b)(5) to read as follows:

§ 433.12 Exemption for labeling.

* * * * *

(b) * * *

(4) When the Commissioner finds that such application contains any untrue statement of a material fact or that any provision of any such agreement has been violated he may revoke such permit.

(5) Any person who contests the denial or revocation of a permit shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Subpart F of Part 2 of this chapter.

* * * * *

43. By revising § 433.13(b) to read as follows:

§ 433.13 Exemption for manufacturing use.

* * * * *

(b) An application for such a permit shall be in a form specified by the Commissioner, shall give the name and location of the establishment in which such drug is to be used and shall be accompanied by;

(1) A written agreement signed by the applicant that he will keep complete records showing the date, quantity, and batch mark of each shipment and other delivery of any such drug to such establishment, and that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within 3 years after the date of such shipment or delivery;

(2) A written statement signed by the operator of such establishment showing that he has adequate facilities for the manufacture of such other drug; such statement shall contain an agreement that he will keep complete records showing the date of receipt by him and the quantity and batch mark of each such shipment and delivery and the disposition thereof and showing the quantity and batch mark of each batch of such other drug manufactured by him and the disposition thereof; that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within 3 years after the date of such disposition, and that he will accord full opportunity to such officer or employee to make inventories of stocks on hand and otherwise check the correctness of such records; and

(3) A written agreement signed by the person who will own the drug after its manufacture is completed that he will request certification of each batch thereof unless it is exempt under section 801 (d) of the act or §§ 433.12, 433.14, 433.16, or 433.17, and that he will not remove any of such drug from such establishment unless it complies with section 502(l) of the act or the certification requirements of section 512(n) of the act or is so exempt or is returned to him for labeling.

When the Commissioner finds that such application contains any untrue statement of a material fact or that any provision of any such agreement has been violated, he may revoke such permit. Any person who contests the denial or revocation of a permit shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Subpart F of Part 2 of this chapter.

* * * * *

44. By revising § 433.14(b) to read as follows:

§ 433.14 Exemption for storage.

* * * * *

(b) An application for such a permit shall be in a form specified by the Commissioner, and shall give the name and location of the warehouse in which such drug is to be stored. Such application shall be accompanied by:

(1) A written agreement signed by the applicant that he will request certification of each batch thereof unless it is exempt under section 801(d) of the act or §§ 433.12, 433.13, or 433.16, that he will not remove any of such drug from such warehouse unless it complies with section 502(l) of the act or the certification requirements of section 512(n) of the act or is so exempt or, if certification is refused unless it is returned within a reasonable time to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured; that he will keep complete records showing the date, quantity, and batch mark of each shipment and other delivery of any such drug to such warehouse, and that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within 3 years after the date of such shipment or delivery; and

(2) A written statement signed by the operator of such warehouse showing that he has adequate facilities for such storage; such statement shall contain an agreement that he will hold each shipment or other delivery of such drug intact, under such conditions as will not cause failure of the drug to comply with the requirements for certification, that he will keep complete records showing the date of receipt by him and the quantity and batch mark of each such shipment and delivery and the disposition thereof, that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within 3 years after the date of such disposition, and that he will accord full opportunity to such officer or employee to make inventories of stocks on hand and otherwise check the correctness of such records.

If the applicant keeps complete records showing the date, quantity, and batch mark of each shipment and other delivery of any such drug from such warehouse and the name and post-office address of the person to whom such shipment or delivery was made, the agreement to keep records of such disposals, to make such records available, and to

afford opportunity for checking their correctness may be included in the applicant's agreement and omitted from that of the operator. When the Commissioner finds that such application contains any untrue statement of a material fact or that any provision of any such agreement has been violated he may revoke such permit. Any person who contests the denial or revocation of a permit shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Subpart F of Part 2 of this chapter.

* * * * *

45. By revising § 433.15(b) to read as follows:

§ 433.15 Exemption for processing.

* * * * *

(b) An application for such a permit shall be in a form specified by the Commissioner and shall give the name and location of the establishment in which such processing is to be done. Such application shall be accompanied by:

(1) A written agreement signed by the applicant that he will keep complete records showing the date, quantity, potency, and batch mark of each shipment and other delivery of any such solution to such establishment, and that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within 3 years after the date of such shipment or delivery;

(2) A written agreement signed by the operator of such establishment showing that he has adequate facilities for such processing; such statement shall contain an agreement that he will keep complete records showing the date of receipt by him and the quantity and batch mark of each such shipment and delivery and the disposition thereof, that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within 3 years after the date of such disposition, and that he will accord full opportunity to such officer or employee to make inventories of stocks on hand and otherwise check the correctness of such records; and

(3) A written agreement signed by the person who will own the drug after the processing is completed that he will request certification of each batch thereof unless it is exempt under section 801(d) of the act or §§ 433.12, 433.13, 433.14, 433.16, or 433.17, and that he will not remove any of such drug from such establishment unless it complies with section 502(l) of the act or the certification requirements of section 512(n) of the act or is so exempt.

When the Commissioner finds that such application contains any untrue statement of a material fact or that any provision of any such agreement has been violated he may revoke such permit. Any person who contests the denial or revocation of a permit shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Subpart F of Part 2 of this chapter.

* * * * *

46. By revising § 433.16(b) to read as follows:

§ 433.16 Exemption for repacking.

* * * * *

(b) An application for such a permit shall be in a form specified by the Commissioner, and shall give the name and location of the establishment in which such repacking is to be done. Such application shall be accompanied by:

(1) A written agreement signed by the applicant that he will keep complete records showing the date, quantity, and batch mark of each shipment and other delivery of any such drug to such establishment, and that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within 3 years after the date of each shipment or delivery;

(2) A written statement signed by the operator of such establishment showing that he has adequate facilities for such repacking; such statement shall contain an agreement that he will keep complete records showing the date of receipt by him and the quantity and batch mark of each such shipment and delivery and the disposition thereof, that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within 3 years after the date of such disposition, and that he will accord full opportunity to such officer or employee to make inventories of stocks on hand and otherwise check the correctness of such records; and

(3) A written agreement signed by the person who will own the drug after the repacking is completed that he will request certification of each batch thereof unless it is exempt under section 801(d) of the act or §§ 433.12, 433.13, 433.14, or 433.17, and that he will not remove any of such drug from such establishment unless it complies with section 502(l) of the act or the certification requirements of section 512(n) of the act or is so exempt or is returned to him for labeling or, if certification is refused, unless it is returned within a reasonable time to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured.

When the Commissioner finds that such application contains any untrue statement of a material fact or that any provision of any such agreement has been violated he may revoke such permit. Any person who contests the denial or revocation of a permit shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Subpart F of Part 2 of this chapter.

* * * * *

PART 511—NEW ANIMAL DRUGS FOR INVESTIGATIONAL USE

47. In Part 511, by amending § 511.1 by revising the undesignated paragraph at the end of paragraph (b)(5) and paragraphs (c) (1) and (4) and (d)(2) to read as follows:

§ 511.1 New animal drugs for investigational use exempt from section 512 (a) of the act.

* * * * *

(b) * * *

(5) * * *

Authorizations granted under this subparagraph do not exempt investigational animals and their products from compliance with other applicable inspection requirements. Any person who contests a refusal to grant such authorization shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Subpart F of Part 2 of this chapter.

* * * * *

(c) *Withdrawal of eligibility to receive investigational-use new animal drugs.* (1) Whenever the Food and Drug Administration has information indicating that an investigator has repeatedly or deliberately failed to comply with the conditions of these exempting regulations or has submitted false information either to the sponsor of the investigation or in any required report, the Director, Bureau of Veterinary Medicine, will furnish the investigator written notice of the matter complained of in general terms and offer him an opportunity to explain the matter in an informal conference and/or in writing. If an explanation is offered but not accepted by the Bureau of Veterinary Medicine, the investigator shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Subpart F of Part 2 of this chapter on the question of whether the investigator is entitled to receive investigational new animal drugs.

* * * * *

(c)(4) If the Commissioner determines, after the unreliable data submitted by the investigator are eliminated from consideration, that the data remaining are inadequate to support a conclusion that it is reasonably safe to continue the investigation, he shall first notify the sponsor, who shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Subpart F of Part 2 of this chapter on whether the exemption should be terminated. If a danger to the public health exists, however, he shall terminate the exemption forthwith and notify the sponsor of the termination. In such event the sponsor shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Subpart F of Part 2 of this chapter on the question of whether the exemption should be reinstated.

* * * * *

(d) * * *

(2) The continuance of the investigation is unsafe or otherwise contrary to the public interest or the drug is being or has been used for purposes other than bona fide scientific investigation, he shall first notify the sponsor and invite his immediate correction. If the conditions of the exemption are not immediately met, the sponsor shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Subpart F of Part 2 of this chapter on whether the exemption should be terminated. If the exemption is terminated the sponsor shall recall or have destroyed the unused supplies of the new animal drug.

* * * * *

PART 514—NEW ANIMAL DRUG APPLICATIONS

48. In Part 514, by revising § 514.201 to read as follows:

§ 514.201 Procedure for hearings.

Hearings relating to new animal drugs under section 505 (d), (e), (m)(3), and (m)(4) of the act shall be governed by Part 2 of this chapter.

§§ 514.202, 514.203, 514.204, 514.205, 514.206 [Revoked].

49. By revoking §§ 514.202, 514.203, 514.204, 514.205, and 514.206.

50. By revising § 514.210 to read as follows:

§ 514.210 Hearing procedure.

Hearings pursuant to § 514.155 shall be governed by Subpart F of Part 2 of this chapter.

§§ 514.220, 514.221, 514.222, 514.230, 514.231, 514.232 [Revoked].

51. By revoking §§ 514.220, 514.221, 514.222, 514.230, 514.231, and 514.232.

52. By revising § 514.235 as follows:

§ 514.235 Judicial review.

(a) The transcript and record shall be certified by the Commissioner. In any case in which the Commissioner enters an order without a hearing pursuant to § 314.200(g) of this chapter, the request(s) for hearing together with the data and information submitted and the Commissioner's findings and conclusions shall be included in the record certified by the Commissioner.

(b) Judicial review of an order withdrawing approval of a new drug application, whether or not a hearing has been held, may be sought by a manfacturer or distributor of an identical, related, or similar drug product, as defined in § 310.6 of this chapter, in a United States court of appeals pursuant to section 505(h) of the act.

PART 601—LICENSING

53. In Part 601, by revoking §§ 601.4, 601.5, and 601.6(c), by redesignating the remainder of § 601.6 as § 601.12, by adding new §§ 601.4 through 601.9, and by revising § 601.22 to read as follows:

§ 601.4 Issuance and denial of license.

(a) An establishment or product license shall be issued upon a determination by the Commisioner that the establishment or the product, as the case may be, meets the applicable standards established in this chapter. Licenses shall be valid until suspended or revoked.

(b) If the Commissioner determines that the establishment or product does not meet the standards established in this chapter, he shall deny the application and inform the applicant of the grounds for, and of an opportunity for a hearing on, his decision. If the applicant so requests, the Commissioner shall issue a notice of opportunity for hearing on the matter pursuant to § 2.111(b) of this chapter.

§ 601.5 Revocation of license.

(a) An establishment or product license shall be revoked upon application of the manufacturer giving notice of intention to discontinue the manufacture of all products or to discontinue the manufacture of a particular product for which a license is held, and waiving an opportunity for a hearing on the matter.

(b) If the Commissioner finds that (1) authorized Food and Drug Administration employees after reasonable efforts have been unable to gain access to an establishment or a location for the purpose of carrying out the inspection required under § 600.21 of this chapter, (2) manufacturing of products or of a product has been discontinued to an extent that a meaningful inspection or evaluation cannot be made, (3) the manufacturer has failed to report a change as required by § 601.12, (4) the establishment or any location thereof, or the product for which the license has been issued, fails to conform to the applicable standards established in the license and in this chapter designed to ensure the continued safety, purity, and potency of the manufactured product, (5) the establishment or the manufacturing methods have been so changed as to require a new showing that the establishment or product meets the standards established in this chapter in order to protect the public health, or (6) the licensed product is not safe and effective for all of its intended uses or is misbranded with respect to any such use, he shall notify the licensee of his intention to revoke the license, setting forth the grounds for, and offering an opportunity for a hearing on, the proposed revocation. Except as provided in § 601.6 and in cases involving willfulness, the notification required in this paragraph shall provide a reasonable period for the licensee to demonstrate or achieve compliance with the requirements of this chapter, before proceedings will be instituted for the revocation of the license. If compliance is not demonstrated or achieved and the licensee does not waive the opportunity for a hearing, the Commissioner shall issue a notice of opportunity for hearing on the matter pursuant to § 2.111(b) of this chapter.

§ 601.6 Suspension of license.

(a) Whenever the Commissioner has reasonable grounds to believe that any of the grounds for revocation of a license exist and that by reason thereof there is a danger to health, he may notify the licensee that his license for the establishment or the product is suspended and require that the licensee (1) notify the selling agents and distributors to whom such product or products have been delivered of such suspension, and (2) furnish to the Director, Bureau of Biologics, complete records of such deliveries and notice of suspension.

(b) Upon suspension of a license, the Commissioner shall either (1) proceed pursuant to the provisions of § 601.5(b) to revoke the license, or (2) if the licensee agrees, hold revocation in abeyance pending resolution of the matters involved.

§ 601.7 Procedure for hearings.

(a) A notice of opportunity for hearing, notice of appearance and request for hearing, and grant or denial of hearing for a biological drug pursuant to this Part, for which the exemption from the Federal Food, Drug, and Cosmetic Act in § 310.4 of this chapter has been revoked, shall be subject to the provisions of § 314.200 of this chapter except to the extent that the notice of opportunity for hearing on the matter issued pursuant to § 2.111(b) of this chapter specifically provides otherwise.

(b) Hearings pursuant to §§ 601.4 through 601.6 shall be governed by Part 2 of this chapter.

(c) When a license has been suspended pursuant to § 601.6 and a hearing request has been granted, the hearing shall proceed on an expedited basis.

§ 601.8 Publication of revocation.

Notice of revocation of a license, with statement of the cause therefor, shall be issued by the Commissioner and published in the FEDERAL REGISTER.

§ 601.9 Licenses; reissuance.

(a) *Compliance with standards.* An establishment or product license, previously suspended or revoked, may be reissued or reinstated upon a showing of compliance with required standards and upon such inspection and examination as may be considered necessary by the Commissioner.

(b) *Exclusion of noncomplying location.* An establishment or product license, excluding a location or locations that fail to comply with required standards, may be issued without further application and concurrently with the suspension or revocation of the license for noncompliance at the excluded location or locations.

§ 601.22 Products in short supply; initial manufacturing at other than licensed establishment.

Licenses issued to a manufacturer for an establishment shall authorize persons other than such manufacturer to conduct at places other than such establishment the initial, and partial manufac-

turing of a product for shipment solely to such manufacturer only to the extent that the names of such persons and places are registered with the Commissioner of Food and Drugs and he finds upon application of such manufacturer, that (a) the product is in short supply due either to the peculiar growth requirements of the organism involved or to the scarcity of the animal required for manufacturing purposes, and (b) such manufacturer has established with respect to such persons and places such procedures, inspections, tests or other arrangements as will assure full compliance with the applicable regulations of this subchapter related to continued safety, purity, and potency. Such persons and places shall be subject to all regulations of this subchapter except §§ 601.1 to 601.6, 601.9, 601.10, 601.20, 601.21, 601.30 to 601.33, and 610.60 to 610.65 of this chapter. Failure of such manufacturer to maintain such procedures, inspections, tests, or other arrangements, or failure of any person conducting such partial manufacturing to comply with applicable regulations shall constitute a ground for suspension or revocation of the authority conferred pursuant to this section on the same basis as provided in §§ 601.6 to 601.8 with respect to the suspension and the revocation of licenses.

§§ 601.40, 601.41, 601.42, 601.43, 601.44 [Revoked].

54. By revoking §§ 601.40 through 601.44.

PART 701—COSMETIC LABELING

55. In Part 701, by revising § 701.3 (b) and (c) to read as follows:

§ 701.3 Designation of ingredients.

* * * * *

(b) The declaration of ingredients shall appear with such prominence and conspicuousness as to render it likely to be read and understood by ordinary individuals under normal conditions of purchase. The declaration shall appear on any appropriate information panel in letters not less than 1/16 of an inch in height and without obscuring design, vignettes, or crowding. In the absence of sufficient space for such declaration on the package, or where the manufacturer or distributor wishes to use a decorative container, the declaration may appear on a firmly affixed tag, tape, or card. In those cases where there is insufficient space for such declaration on the package, and it is not practical to firmly affix a tag, tape, or card, the Commissioner may establish by regulation an acceptable alternate, e.g., a smaller type size. A petition requesting such a regulation as an amendment to this paragraph shall be submitted pursuant to Part 2 of this chapter.

* * * * *

(e) Interested persons may submit a petition requesting the establishment of a specific name for a cosmetic ingredient pursuant to Part 2 of this chapter. The Commissioner may also propose such a name on his own initiative.

PART 1003—NOTIFICATION OF DEFECTS OF FAILURE TO COMPLY

56. In Part 1003, by amending § 1003.11 by adding an undesignated paragraph at the end of paragraph (a) as follows:

§ 1003.11 Determination by Secretary that product fails to comply or has a defect.

(a) * * *

The manufacturer shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Subpart F of Part 2 of this chapter.

* * * * *

57. By adding § 1003.31(d) to read as follows:

§ 1003.31 Granting the exemption.

* * * * *

(d) Any person who contests denial of an exemption shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Subpart F of Part 2 of this chapter.

PART 1004—REPURCHASE, REPAIRS, OR REPLACEMENT OF ELECTRONIC PRODUCTS

58. In Part 1004, by amending § 1004.6 by adding the following new sentence at the end, as follows:

§ 1004.6 Approval of plans.

* * * Any person who contests denial of a plan shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Subpart F of Part 2 of this chapter.

PART 1210—REGULATIONS UNDER THE FEDERAL IMPORT MILK ACT

59. In Part 1210, by revising the heading of Subpart D and § 1210.30 to read as follows:

Subpart D—Hearings

§ 1210.30 Hearing procedure for permit denial, suspension, and revocation.

Any person who contests denial, suspension, or revocation of a permit shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Subpart F of Part 2 of this chapter.

60. By revoking § 1210.31 and by redesignating § 1210.63 as new § 1210.31 to read as follows:

§ 1210.31 Hearing before prosecution.

Before violation of the act is referred to the Department of Justice for prosecution under section 5 of the Federal Import Milk Act, an opportunity to be heard will be given to the party against whom prosecution is under consideration. The hearing will be private and confined to questions of fact. The party notified may present evidence, either oral or written, in person or by attorney, to show cause why he should not be prosecuted. After a hearing is held, if it appears that the law has been violated, the facts will be reported to the Department of Justice.

§§ 1210.32, 1210.33, 1210.40, 1210.41, 1210.42, 1210.43, 1210.44, 1210.50, 1210.51, 1210.52, 1210.53, 1210.54, 1210.55, 1210.56, 1210.57, 1210.58, 1210.59, 1210.60, 1210.61, 1210.62, [Revoked].

61. By revoking §§ 1210.32, 1210.33, and Subparts E, F and G of Part 1210, including 1210.40, 1210.41, 1210.42, 1210.43, 1210.44, 1210.50, 1210.51, 1210.52, 1210.53, 1210.54, 1210.55, 1210.56, 1210.57, 1210.58, 1210.59, 1210.60, 1210.61, 1210.62.

Interested persons may, on or before (insert date 30 days after date of publication in the FEDERAL REGISTER), submit to the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852, written comments regarding this proposal. Comments should be filed in quintuplicate (except that individuals may submit single copies), and should be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office Monday through Friday, from 9 a.m. to 4 p.m., except on Federal legal holidays.

Dated: August 29, 1975.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.75-23409 Filed 9-2-75;8:45 am]

federal register

WEDNESDAY, SEPTEMBER 3, 1975

PART IV:

PRIVACY ACT OF 1974

■

VARIOUS AGENCIES

Proposed Rules and Notices of Systems of Records

Title 16—Commercial Practices

CHAPTER I—FEDERAL TRADE COMMISSION

SUBCHAPTER A—PROCEDURES AND RULES OF PRACTICE

PART 4—MISCELLANEOUS RULES

Implementation of Privacy Act Regulations

The Commission announces the following rules, which are effective on October 3, 1975, to implement the Privacy Act of 1974 (Pub. L. 93-579, 5 U.S.C. 552a). The Commission's proposed rules, which were promulgated on August 14, 1975 (40 FR 34162), are amended by these rules. The only changes made have been renumbering the rules and clarifying that all requests under § 4.13 (c) (formerly § 4.13.3) must name the system of records which is the subject of the request and must include any additional information specified in the pertinent system notice as necessary to locate the records requested. Other than correction of typographical errors, no other changes have been made.

Section 4.13 is added to read as follows:

§ 4.13 Privacy Act rules.

(a) *Purpose and Scope*—(1) This section is promulgated to implement the Privacy Act of 1974 (Pub. L. 93-579, 5 U.S.C. 552a) by establishing procedures whereby an individual can, as to all systems of records maintained by the Commission except those set forth in § 4.13(m) as exempt from disclosure, (i) request notification of whether the Commission maintains a record pertaining to him in any system of records, (ii) request access to such a record or to an accounting of its disclosure, (iii) request that the record be amended or corrected, and (iv) appeal an initial adverse determination of any such request. This section also establishes those systems of records that are specifically exempt from disclosure and from other requirements.

(2) The procedures of this section apply only to requests by an individual as defined in § 4.13(b). Except as otherwise provided, they govern only records containing personal information in systems of records for which notice has been published by the Commission in the FEDERAL REGISTER pursuant to section 552a(e)(4) of the Privacy Act of 1974 and which are neither exempt from the provisions of this section nor contained in government-wide systems of personnel records for which notice has been published in the FEDERAL REGISTER by the Civil Service Commission. Requests for notification, access, and amendment of personnel records which are contained in a system of records for which notice has been given by the Civil Service Commission are governed by the Civil Service Commission's notices, 5 CFR Part 297. Access to records which are not subject to the requirements of the Privacy Act are governed by §§ 4.8-4.11.

(b) *Definitions.*—The following definitions apply to this section only:

(1) "Individual" means a natural person who is a citizen of the United States or an alien lawfully admitted for permanent residence.

(2) "Record" means any item, collection, or grouping of personal information about an individual that is maintained by the Commission, including, but not limited to, his education, financial transactions, medical history, and criminal or employment history and that contains his name, or the identifying number, symbol, or other identifying particular assigned to the individual, such as a finger or voice print or a photograph, but does not include information concerning proprietorships, businesses, or corporations.

(3) "System of records" means a group of any records under the control of the Commission from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual, for which notice has been published by the Commission in the FEDERAL REGISTER pursuant to 5 U.S.C. 552a(e)(4).

(c) *Procedures for requests pertaining to individual records in a record system.*—An individual may request access to his records or any information pertaining to him in a system of records, and notification of whether and to whom the Commission has disclosed a record for which an accounting of disclosures is required to be kept and made available to him, using the procedures of this subsection. Requests for the disclosure of records under this subsection or to determine whether a system of records contains records pertaining to an individual or to obtain an accounting of disclosures, shall be in writing and if mailed, addressed as follows:

Privacy Act Request, Office of the Secretary, Federal Trade Commission, 6th Street and Pennsylvania Avenue NW., Washington, D.C. 20580.

If requests are presented in person at the Office of the Secretary, the individual shall be required to execute a written request. All requests must name the system of records which is the subject of the request, and must include any additional information specified in the pertinent system notice as necessary to locate the records requested. If the requester desires to permit a person to accompany him to review his record, the request shall so state. Nothing in this section shall allow an individual access to any information compiled in reasonable anticipation of a civil action or proceeding.

(d) *Times, places, and requirements for identification of individuals making requests.*—Verification of identity of persons making written requests to the Secretary ordinarily will not be required. The signature upon such requests shall be deemed to be a certification by the person signing that he is the individual to whom the record pertains or the parent of a minor or the duly appointed legal guardian of the individual to whom the record pertains. The Secretary may require additional verification of identity as specified by him when necessary reasonably to assure that records are not improperly disclosed; provided, however, that no verification of identity will be required where the records sought are publicly available under the Freedom of Information Act.

(e) *Disclosure of requested information to individuals.*—Within ten (10) working days of receipt of a request under § 4.13 (c), the Secretary shall acknowledge receipt of the request. Within thirty (30) working days of the receipt of a request under § 4.13(c), the Secretary shall inform the requester whether a system of records containing retrievable information pertaining to the requester exists, and if so, either that his request has been granted or that the requested records or information is exempt from disclosure pursuant to § 4.13(m). When, for good cause shown, the Secretary is unable to respond within thirty (30) working days of the receipt of the request, he shall notify the requester of that fact and approximately when it is anticipated that a response will be made.

(f) *Special procedures: Medical records.*—When the Secretary determines that disclosure of a medical or psychological record directly to a requesting individual could have an adverse effect on the individual, he shall require the individual to designate a medical doctor to whom the record will be transmitted.

(g) *Request for correction or amendment of record.*—An individual to whom access to his records or any information pertaining to him in a system of records has been granted may request that any portion thereof be amended or corrected because he believes it is not accurate, relevant, timely, or complete. An initial request for correction or amendment of a record shall be in writing whether presented in person or by mail, and if by mail, addressed as in § 4.13(c). In making a request under this subsection, the requesting party shall state the nature of the information in the record the individual believes to be inaccurate, irrelevant, untimely, or incomplete, the correction or amendment desired, and the reasons therefore.

(h) *Agency review of request for correction or amendment of record.*—Whether presented in person or by mail, requests under § 4.13(g) shall be acknowledged by the Secretary within ten (10) working days of the receipt of the request if action on the request cannot be completed and the individual notified of the results within that time. Thereafter, the Secretary shall promptly either make the requested amendment or correction or inform the requester of his refusal to make the amendment or correction, the reasons for the refusal, and the requester's right to appeal that determination in accordance with § 4.13 (i).

(i) *Appeal of initial adverse agency determination.*—(1) If the Secretary denies an initial request under § 4.13(c) or § 4.13(g), the requester may appeal that determination to the Commission. The appeal shall be in writing and addressed as follows:

Privacy Act Appeal, Office of the General Counsel, Federal Trade Commission, 6th Street and Pennsylvania Avenue NW., Washington, D.C. 20580.

The Commission shall notify the requester within thirty (30) working days of the receipt of his appeal of the disposition of that appeal, except that the thirty (30) day period may be extended for good cause, in which case the requester will be advised of the approximate date on which review will be completed.

(2) (i) If the Commission refuses to amend or correct the record in accordance with a request under § 4.13(g), it shall notify the requester of that determination and inform him of his right to file with the Secretary of the Commission a concise statement setting forth the reasons for his disagreement with that determination and the fact that such a statement will be treated as set forth in subparagraph (ii). The Commission shall also inform the requester that judicial review of the determination is available by a civil suit in the district in which the requester resides, or has his principal place of business, or in which the agency records are situated, or in the District of Columbia.

(ii) If the individual files a statement disagreeing with the Commission's determination not to amend or correct a record, it shall be clearly noted in the record involved and made available to anyone to whom the record has been disclosed after September 27, 1975, or is subsequently disclosed together with, if the Commission deems it appropriate, a brief statement of the reasons for refusing to amend the record.

(j) *Disclosure of record to person other than the individual to whom it pertains.*—Except as provided by 5 U.S.C. 552a(b), the written request or prior written consent of the individual to whom a record pertains, or of his parent if a minor, or legal guardian if incompetent, shall be required before such record is disclosed. If the individual elects to inspect a record in person and desires to be accompanied by another person, the Secretary may require the individual to furnish a signed statement authorizing his record to be disclosed in the presence of the accompanying named person.

(k) *Fees.*—No fees shall be charged for searching for a record, reviewing it, or for copies of records made by the Commission for its own purposes incident to granting access to a requester. Copies of records to which access has been granted under this section may be obtained by the requester from the Secretary upon payment of the reproduction fees provided in § 4.8(c)(2).

(l) *Penalties.* Section 552a(i)(3) of the Privacy Act, 5 U.S.C. 552a(i)(3), makes it a misdemeanor, subject to a maximum fine of $5,000, to knowingly and willfully request or obtain any record concerning an individual under false pretenses. Sections 552a(i) (1) and (2) of the Privacy Act, 5 U.S.C. 552a(i) (1) and (2), provide penalties for violations by agency employees of the Privacy Act or regulations established thereunder. Title 18 U.S.C. 1001, Crimes and Criminal Procedures, makes it a criminal offense, subject to a maximum fine of $10,000 or imprisonment for not more than 5 years or both, to knowingly and willfully make or cause to be made any false or fraudulent statements or representations in any matter within the jurisdiction of any agency of the United States.

(m) *Specific exemptions.*—Pursuant to 5 U.S.C. § 552a(k)(2), investigatory material compiled for law enforcement purposes in the following systems of records is exempt from subsections (c)(3), (d), (e)(1), (e)(4) (G), (H), and (I), and (f) of 5 U.S.C. 552a, and from the provisions of this section, except as otherwise provided in § 552a(k)(2):

Disciplinary Action Investigatory Files—FTC.
Investigational, Legal, and Public Records—FTC.
Litigation Information Management Systems for Investigations, Rulemaking, and Adjudicatory Proceedings—FTC.
Preliminary Investigation Files—FTC.

Issued by direction of the Commission dated August 27, 1975.

CHARLES A. TOBIN,
Secretary.

[FR Doc.75-23270 Filed 9-2-75;8:45 am]

CIVIL AERONAUTICS BOARD

PRIVACY ACT OF 1974

Notices of Systems of Records

By PDR-39, 40 F.R. 30283, the Civil Aeronautics Board issued notice of its proposed rules to implement the Privacy Act of 1974, and proposed notices of various "systems of records," under that Act, were published at 40 F.R. 33181. The Board hereby gives notice of the existence and character of two additional systems of records which it maintains. Public comment is invited with respect to the "routine use" which the Board proposes to make of the within-described information, as set forth in these notices. Comments may be filed on or before September 27, 1975, addressed to the Docket Section, Civil Aeronautics Board, Washington, D.C. 20428.

Dated: August 27, 1975.

Edwin Z. Holland,
Secretary.

CAB—11

System name: Members of Congress biographical information and correspondence—CAB

System location: Office of Community and Congressional Relations, Civil Aeronautics Board, 1825 Connecticut Avenue, N. W., Washington, D. C. 20428.

Categories of individuals covered by the system: Individuals who are current Members of Congress.

Categories of records in the system: Biographical information, including committee assignments and voting records, from public sources such as the Congressional Quarterly, Congressional Directory, and extracts from the Congressional Record and various aviation publications; and copies of correspondence between Members of Congress and the CAB which are duplicates of those maintained in the "Correspondence between Civil Aeronautics Board and persons outside the Board—CAB" system of records and subject to that Notice of System of Records.

Authority for maintenance of the system: Section 204 of the Federal Aviation Act, 49 U.S.C. 1324.

Routine uses of records maintained in the system, including categories of users and the purposes of such uses: Used by CAB staff to answer staff and Congressional inquiries, and may be used for any regulatory purpose including evidence in proceedings before the Board and the courts. Relevant records in this system of records may be disclosed to any person if required under "freedom of information" or other laws governing access to materials in the Board's possession.

Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system:

Storage: Maintained in individual file folders. Indexed by name of Member of Congress.

Safeguards: Folders are located in lockable metal file cabinets in an area to which access is controlled by CAB personnel and which is locked after business hours.

Retention and disposal: Biographical material is retained during the time an individual is a Member of Congress and then destroyed; duplicate correspondence is retained through the current session of Congress and is then destroyed.

System manager(s) and address: Director, Office of Community and Congressional Relations, Civil Aeronautics Board, 1825 Connecticut Avenue, N. W., Washington, D. C. 20428.

Notification procedure: By mailing or delivering to the Office of the Secretary, Civil Aeronautics Board, 1825 Connecticut Avenue, N. W., Washington, D. C. 20428 a written request bearing the individual's return address, printed or typewritten name, and signature.

Record access procedures: Same as above.

Contesting record procedures: Same as above.

Record source categories: Published Congressional reference materials, aviation publications, Members of Congress writing to the CAB, and the CAB.

CAB—12

System name: Mailing lists of persons requesting CAB informational, technical, or statistical material - CAB.

System location: Publications Services Section, Office of Facilities and Operations, Civil Aeronautics Board, 1825 Connecticut Avenue, N. W., Washington, D. C. 20428.

Categories of individuals covered by the system: Individuals who have requested that they be placed on a CAB mailing list, including regular publication customers.

Categories of records in the system: CAB Form 103—"Subscription and Publications Order" containing name, address, item(s) requested, and amount of order; and requests for materials for which no charge is made containing name, address, and item(s) requested.

Authority for maintenance of the system: Section 204 of the Federal Aviation Act, 49 U.S.C. 1324.

Routine uses of records maintained in the system, including categories of users and the purposes of such uses: Used by CAB staff to send items requested, and may be used for any regulatory purpose including use in evidence in proceedings before the Board and the courts.

Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system:

Storage: Maintained in individual file folders, address card files, and metal addressograph plates.

Retrievability: Folders indexed by name, cards and addressograph plates filed alphabetically by name.

Safeguards: Stored in metal cabinets in an area to which access is controlled by and restricted to CAB personnel and which is locked after business hours.

Retention and disposal: CAB Form 103 is retained until the end of each calendar year and then destroyed; address card files and metal addressograph plates retained until the individual requests removal from the mailing list and then destroyed; requests for materials for which no charge is made are kept for up to one year after the material is sent and then destroyed.

System manager(s) and address: Chief, Publications Services Section, Office of Facilities and Operations, Civil Aeronautics Board, 1825 Connecticut Avenue, N. W., Washington, D. C. 20428.

Notification procedure: By mailing or delivering to the Office of the Secretary, Civil Aeronautics Board, 1825 Connecticut Avenue, N. W., Washington, D. C. 20428 a written request bearing the individual's return address, printed or typewritten name, and signature.

Record access procedures: Same as above.

Contesting record procedures: Same as above.

Record source categories: Individual or person requesting the material.

[FR Doc.75-23126 Filed 8-28-75;10:21 am]

COMMISSION ON CIVIL RIGHTS

[45 CFR Part 706]

THE REQUIREMENTS OF THE PRIVACY ACT OF 1974

Proposed Rulemaking

The Commission on Civil Rights proposes to adopt rules regarding records maintained by the Commission concerning individuals pursuant to and in accordance with Section F of the Privacy Act of 1974. After consideration by the Commission of any comments regarding the proposed rules, final rules will be adopted by the Commission. When adopted, the rules will reflect the Commission's implementation of the requirement of the Privacy Act of 1974, 5 U.S.C. 552a (Pub. L. 93-579), and will comprise a new Part 706 of Title 45 of the Code of Federal Regulations.

Interested persons are invited to submit comments, suggestions, or objections regarding the proposed rules to the Office of General Counsel, Commission on Civil Rights, 1121 Vermont Avenue, NW., Washington, D.C. 20425. Comments received prior to September 26, 1975, will be considered before final action is taken on this proposal.

It is proposed to make these rules effective September 27, 1975, the effective date of the Privacy Act of 1974.

LOUIS NUNEZ,
Acting Staff Director.

AUGUST 25, 1975.

PART 706—MATERIALS AVAILABLE PURSUANT TO 5 U.S.C. 552a

Sec.

AUTHORITY: Pub. L. 93-579; 5 U.S.C. 552a.

§ 706.1 Purpose and scope.

(a) The purpose of this part is to set forth rules to inform the public regarding information maintained by the Commission on Civil Rights about identifiable individuals and to inform those individuals how they may gain access to and correct or amend information about themselves.

(b) The rules in this part carry out the requirements of the Privacy Act of 1974 (Pub. L. 93-579) and in particular 5 U.S.C. 552a as added by that Act.

(c) The rules in this part apply only to records disclosed or requested under the Privacy Act of 1974, and not to requests for information made pursuant to the Freedom of Information Act, 5 U.S.C. § 552.

§ 706.2 Definitions.

For the purpose of this regulation:

(a) The terms "Commission" and "agency" mean the U.S. Commission on Civil Rights;

(b) The term "individual" means a citizen of the United States or an alien lawfully admitted for permanent residence;

(c) The term "maintain" includes maintain, collect, use, or disseminate;

(d) The term "record" means any item, collection, or grouping of information about an individual that is maintained by the Commission, including, but not limited to, his or her education, financial transactions, medical history, and criminal or employment history and that contains his or her name, or the identifying number, symbol, or other identifying particular assigned to the individual;

(e) The term "system record" means a group of any records under the control of the Commission from which information may be retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to that individual;

(f) The term "statistical record" means a record in a system of records maintained for statistical research or reporting purposes only and not used in whole or in part in making any determination about an identifiable individual, except as provided in section 8 of title 13; and

(g) The term "routine use" means, with respect to the disclosure of a record, the use of such record for a purpose which is compatible with the purpose for which it was collected.

§ 706.3 Procedures for requests pertaining to individual records in a system of records.

(a) An individual seeking notification of whether a system of records contains a record pertaining to him or her or an individual seeking access to information or records pertaining to him or her which is available under the Privacy Act of 1974, shall present his or her request in person or in writing to the General Counsel of the Commission.

(b) In addition to meeting the requirements set forth in § 706.4(d), the individual seeking notification or access, either in person or by mail, shall describe the nature of the records sought, the approximate dates covered by the record, and the system in which it is thought to be included, as described in the "Notices of Record Systems" published in the FEDERAL REGISTER. (Citation to be supplied upon final adoption of the rules.)

§ 706.4 Times, places, and requirements for identification of individuals making requests and identification of records requested.

(a) The General Counsel is the designated Privacy Act Officer for the Commission.

(b) An individual making a request to the General Counsel in person may do so at the Commission's headquarters office, 1121 Vermont Avenue, NW., Washington, D.C. 20425, on any business day during business hours. Persons may also appear for purposes of identification only at any of the regional offices of the Commission on any business day during business hours. Regional offices are located as follows:

Central States Regional Office, U.S. Commission on Civil Rights, 911 Walnut Street, Kansas City, Missouri 64106, (816) 374-5253 or 374-2454 (8:00-5:00).

Mid-Atlantic Regional Office, U.S. Commission on Civil Rights, 2120 L Street, N.W., (Room 510), Washington, D.C. 20037, (202) 254-6717 or 254-6670 (8:45-5:30).

Midwestern Regional Office, U.S. Commission on Civil Rights, 230 South Dearborn Street, 32nd Floor, Chicago, Illinois 60604, (312) 353-7371 or 353-7479 (8:45-5:30).

Mountain States Regional Office, U.S. Commission on Civil Rights, Ross Building (Room 216), 1726 Champa Street, Denver, Colorado 80202, (303) 837-2211 or 837-2485 (8:00-4:30).

Northeastern Regional Office, U.S. Commission on Civil Rights, 26 Federal Plaza (Room 1639), New York, New York 10007, (212) 264-0400 or 264-0543 (9:00-5:30).

Southern Regional Office, U.S. Commission on Civil Rights, Citizens Trust Bank Bldg. (Room 362), 75 Piedmont Avenue, N.E., Atlanta, Georgia 30303, (404) 526-4391 or 526-4344 (9:00-5:30).

Southwestern Regional Office, U.S. Commission on Civil Rights, New Moore Building (Room 249), 106 Broadway, San Antonio, Texas 78205, (512) 225-4764 or 225-4810 (8:45-5:30).

Western Regional Office, U.S. Commission on Civil Rights, 312 North Spring Street (Room 1015), Los Angeles, California 90012, (213) 688-3437 or 688-5705 (8:30-5:00).

(c) An individual seeking access to records in person may establish his or her identity by the presentation of one document bearing a photograph (such as a driver's license, passport, or identification card or badge) or by the presentation of two items of identification which do not bear a photograph, but do bear both a name and address (such as a credit card). When identification is made without photographic identification the Commission will request a signature comparison to the signature appearing on the items offered for identification, whenever possible and practical.

(d) An individual seeking access to records by mail shall establish his or her identity by a signature, address, date of birth, and one other identifier, such as a driver's license or other document. The words "PRIVACY ACT REQUEST" should be placed in capital letters on the face of the envelope in order to facilitate requests by mail.

(e) An individual seeking access in person or by mail who cannot provide the required documentation of identification may provide a notarized statement, swearing or affirming to his or her identity and to the fact that he or she understands that there are criminal penalties for the making of false statements.

(f) The parent or guardian of a minor or a person judicially determined to be incompetent, in addition to establishing the identity of the minor or incompetent person he or she represents as required by paragraphs (a) through (c) of this section, shall establish his or her own parentage or guardianship by furnishing a copy of a birth certificate showing parentage or court order establishing guardianship.

(g) An individual seeking to review information about himself or herself may be accompanied by another person of his or her own choosing. In all such cases, the individual seeking access shall be required to furnish a written statement authorizing the discussion of his or her record in the presence of the accompanying person.

§ 706.5 Disclosure of requested information to individuals.

The General Counsel, or one or more assistants designated by him or her, upon receiving a request for notification of the existence of a record, or for access to a record shall (a) determine whether such record exists; (b) determine whether access is available under the Privacy Act; (c) notify the requesting person of those determinations within 10 (ten) working days (excluding Saturdays, Sundays, and legal public holidays); and (d) provide access to information pertaining to that person which has been determined to be available.

§ 706.6 Request for correction or amendment to record.

(a) Any individual who has reviewed a record pertaining to him or her that was furnished to him or her under this part may request the agency to correct or amend all or part of that record.

(b) Each individual requesting a correction or amendment shall send the request to the General Counsel.

(c) Each request for a correction or amendment of a record shall contain the following information:

(1) The name of the individual requesting the correction or amendment.

(2) The name of the system of records in which the record sought to be amended is maintained.

(3) The location of the record system from which the record was obtained.

(4) A copy of the record sought to be amended or a description of that record.

(5) A statement of the material in the record that should be corrected or amended.

(6) A statement of the specific wording of the correction or amendment sought.

(7) A statement of the basis for the requested correction or amendment including any material that the individual can furnish to substantiate the reasons for the amendment sought.

§ 706.7 Agency review of request for correction or amendment of the record.

Within ten (10) working days (excluding Saturdays, Sundays and legal public holidays) of the receipt of the request for the correction or amendment of a record, the General Counsel shall acknowledge receipt of the request and inform the individual that his or her request has been received and inform the individual whether further information is required before the correction or amendment can be considered. Further, the General Counsel shall promptly, and, under normal circumstances, not later than thirty (30) working days after receipt of the request, make the requested correction or amendment or notify the individual of his or her refusal to do so, including in the notification the reasons for the refusal, and the procedures established by the Commission by which the individual may initiate a review of that refusal.

§ 706.8 Appeal of an initial adverse agency determination.

(a) Any individual whose request for access or for a correction or amendment which has been denied, in whole or in part, by the General Counsel may appeal that decision to the Staff Director of the Commission, 1121 Vermont Avenue, NW., Room 800, Washington, D.C. 20425, or to a designee of the Staff Director.

(b) The appeal shall be in writing and shall:

(1) Name the individual making the appeal;

(2) Identify the record sought to be amended or corrected;

(3) Name the record system in which that record is contained;

(4) Contain a short statement describing the amendment or correction sought; and

(5) State the name of the person who initially denied the correction or amendment.

(c) Not later than thirty (30) working days (excluding Saturdays, Sundays, and legal public holidays) after the date on which the agency received the appeal, the Staff Director shall complete his or her review of the appeal and make a final decision thereon, unless, for good cause shown, the Staff Director extends the appeal period beyond the initial thirty (30) day appeal period. In the event of such an extension the Staff Director shall promptly notify the individual making the appeal that the period for a final decision has been extended.

(d) After review of an appeal request, the Staff Director will send a written notice to the requester containing the following information:

(1) The decision, and if the denial is upheld, the reasons for the decision;

(2) The right of the requester to institute a civil action in a Federal District Court for judicial review of the decision, if the appeal is denied; and

(3) The right of the requester to file with the Commission a concise statement setting forth the reasons for his or her disagreement with the Commission's decision denying the request. The Commission shall make this statement available to any person to whom the record is later disclosed, together with a brief statement, if the Commission considers it appropriate, of the agency's reasons for denying the requested correction or amendment.

§ 706.9 Disclosure of records to a person other than the individual to whom the record pertains.

(a) Any individual who desires to have his or her record disclosed to or mailed to a third person may authorize that person to act as his or her agent for that specific purpose. The authorization shall be in writing, signed by the individual, and notarized. The agent shall also submit proof of his or her own identity as provided in § 706.4.

(b) The parent of any minor individual or the legal guardian of any individual who has been declared by a court to be incompetent, due to physical or mental incapacity, may act on behalf of that individual in any matter covered by this part. A parent or guardian who desires to act on behalf of such an individual shall present suitable evidence of parentage or guardianship, by birth certificate, copy of a court order or similar documents, and proof of the individual's identity as provided in § 706.4.

(c) An individual to whom a record is to be disclosed, in person, pursuant to this part may have a person of his or her own choosing accompany the individual when the record is disclosed.

§ 706.10 Fees.

If an individual requests copies of his or her records the charge shall be three (3) cents per page, provided, however, that the Commission shall not charge for copies furnished to an individual as a necessary part of the process of disclosing the record to an individual. Fees may be waived or reduced in accordance with § 704.1(e) of the Commission's regulations (45 CFR 704) because of indigency, where the cost is nominal, when it is in the public interest not to charge, or when waiver would not constitute an unreasonable expense to the Commission.

§ 706.11 Penalties.

Any person who makes a false statement in connection with any request for a record, or in any request for an amendment to a record under this part, is subject to the penalties prescribed in 18 U.S.C. 494 and 495.

§ 706.12 Special procedures: information furnished by other agencies.

When records or information sought from the Commission include information furnished by other Federal agencies, the General Counsel shall consult with the appropriate agency prior to making a decision to disclose or to refuse to disclose the record, but the decision whether or not to disclose the record shall be made by the General Counsel.

§ 706.13 Exemptions.

(a) Systems of records or portions of such records are exempt under the Privacy Act of 1974, 5 U.S.C. 552a(k), including the following:

(1) Investigatory material compiled for law enforcement purposes, other than material within the scope of subsection (j)(2) of the Privacy Act: Provided, however, That if any individual is denied any right, privilege, or benefit that he

or she would otherwise be eligible for, as a result of the maintenance of such material, such material shall be provided to such individual, except to the extent that the disclosure of such material would reveal the identify of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence, or, prior to the effective date of this section, under an implied promise that the identity of the source would be held in confidence.

(2) Statistical personnel records that are used only to generate aggregate data or for other evaluative or analytical purposes and which are not used to make decisions on the rights, benefits, or entitlements of individuals.

(3) Investigatory material maintained solely for the purposes of determining an individual's qualifications, eligibility, or suitability for employment in the Federal civilian service, Federal contracts, or access to classified information, but only to the extent that disclosure of such material would reveal the identity of the source who furnished information to the Government under an express promise that the identity of the source would be held in confidence, or prior to September 27, 1975, under an implied promise that the identity of the source would be held in confidence.

(4) Testing or examination material used solely to determine individual qualifications for promotion or appointment in the Federal service the disclosure of which would compromise the objectivity or fairness of the testing or examination process.

(b) For purposes of this section, a "confidential source" means a source who furnished information to the Government under an express promise that the identity of the source would remain confidential, or, prior to September 27, 1975, under an implied promise that the identity of the source would be held in confidence.

U.S. COMMISSION ON CIVIL RIGHTS

PRIVACY ACT OF 1974

Notice of Systems of Records

The Privacy Act of 1974, Pub. L. 93-579, amended Title 5 of the United States Code by adding a new section, 5 U.S.C. sec. 552a, to afford safeguards against the invasion of personal privacy. The Privacy Act becomes effective on September 27, 1975. Agencies of the Federal Government are required by the Act to publish each year a notice of systems of records they maintain.

Pursuant to the Privacy Act of 1974, the Civil Rights Commission submits the following notices of the existence and character of systems of records maintained by the Civil Rights Commission. Interested persons are invited to submit written data, views, or arguments concerning the routine use portions of the notices to the Office of General Counsel, U.S. Commission on Civil Rights, 1121 Vermont Avenue, N.W., Washington, D.C. 20425. Comments, data, views or arguments received on or before September 26, 1975, will be considered prior to final publication of the notices.

August 26, 1075.

Louis Nunez,
Acting Staff Director.

Alphabetical Listing and Table of Contents to Notices of Systems of Records Pursuant to the Privacy Act

CRC—001

System name: Appeals, Grievances and Complaints (staff)

System location:

Office of Management
Personnel Office
U.S. Commission on Civil Rights
1121 Vermont Avenue, N.W., Room 507
Washington, D.C. 20425

Categories of individuals covered by the system: Applicants for Federal employment, current and former employees, agencies and annuitants who appeal a determination made by the Commission.

Categories of records in the system: This system of records contains information or documents relating to a decision and determination made by the Commission affecting an individual. The records consist of the initial grievance, complaint, or appeal, letters of notices to the individual, records of hearings when conducted, materials placed into the record to support the decision or determination, affidavits or statements, testimony of witnesses, investigative reports, notice of decision and related correspondence, opinions and recommendations.

Authority for maintenance of the system:

42 U.S.C. sec. 1975d(a)
Federal Personnel Regulation (FPM) 293
Federal Personnel Regulation (FPM) 771
Federal Personnel Regulation (FMP) 752

Routine uses of records maintained in the system, including categories of users and the purposes of such uses: The records and information in the records may be used to respond to a request from a member of Congress regarding the status of an appeal, complaint or grievance; to provide information to the public on the decision of an appeal, complaint or grievance required by the Freedom of Information Act; to respond to a court subpena and/or refer to a district court in connection with a civil suit; to adjudicate an appeal, complaint, or grievance; as a data source for management information for production of summary descriptive statistics and analytical studies in support of the function for which the records are collected and maintained, or for related personnel management functions or personnel resources studies; may also be utilized to respond to general requests for statistical information (without personal identification of individuals) under the Freedom of Information Act or to locate a specific individual for personnel research or other personnel management functions; and to provide information or disclose to a Federal agency, in response to another agency's request, in connection with the hiring or retention of an employee.

Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system: Storage—These records are maintained in secured file folders, and index card. Retrievability—These records are indexed by the names of the individuals on whom they are maintained. Safeguards—Access to and use of these records are limited to those persons whose official duties require such access. Personnel screening is employed to prevent unauthorized disclosure. Retention and Disposal—The records are maintained up to two years and are transferred to the National Personnel Records Center, St. Louis, Missouri. They are destroyed by the Federal Records Center when the records are seven (7) years old.

System manager(s) and address:

Office of Management
Personnel Officer
U.S. Commission on Civil Rights
1121 Vermont Avenue, N.W.
Washington, D.C. 20425

Notification procedure: Individuals who have filed appeals or grievances are aware of that fact and have been provided a copy of the record. They may, however, contact the:

Office of General Counsel
U.S. Commission on Civil Rights
1121 Vermont Avenue, N.W., Room 600
Washington, D.C. 20425

Record access procedures: Same as above with appeal to the Staff Director.

Record source categories: Individual to whom the record pertains; agency and/or Commission officials; affidavits or statements from employees; testimony of witnesses; official documents relating to the appeal, grievance, or complaints; and correspondence from specific organizations or persons.

CRC—002

System name: Applications for Employment

System location:

U.S. Commission on Civil Rights
Office of Management
Personnel Division
1121 Vermont Avenue, N.W., Room 507
Washington, D.C. 20425 Occasionally located on a temporary basis in divisional or regional offices.

Categories of individuals covered by the system: Applicants seeking employment with the U.S. Commission on Civil Rights.

Categories of records in the system: The system comprises S.F. 171's, personal resumes, and in many instances Civil Service Commission examination scores of individuals seeking employment with the Commission on Civil Rights.

Authority for maintenance of the system: 5 U.S.C. secs. 1302, 3109, 3301, 3302, 3304, 3306, 3307, 3309, 3313, 3317, 3318, 3319, 3326, 3349, 4103, 5532, 5533, 5723, and Executive Orders 1057 and 11103. 42 U.S.C. 1975d.

Routine uses of records maintained in the system, including categories of users and the purposes of such uses: Information in these records may be used to refer applicants to the various offices of the Commission for purposes of consideration for placement in positions for which the applicants have applied and are qualified. The records are available to personnel specialists who review the applicants' qualifications and consider them for appropriate agency vacancies.

Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system: Storage—The records are maintained in file folders. Retrievability—In some regional and divisional offices, the records are retrieved by name. In the Personnel Office, the records are recorded by name and grade in a log book. They can also be retrieved, however, by grade classification. Safeguards—Access to these records are restricted to those with appropriate function within the agency. Retention and Disposal—In

divisional or regional offices, the records are retained for an indefinite period of time. They are then forwarded to the Personnel Office or discarded. In the Personnel Office, every year the applications are returned to the applicants for update and resubmission if applicants are still interested in employment with the Commission.

System manager(s) and address:

Personnel Officer
Office of Management, Room 507
U.S. Commission on Civil Rights
1121 Vermont Avenue, N.W.
Washington, D.C. 20425

Notification procedure:

General Counsel
Office of General Counsel, Room 600
U.S. Commission on Civil Rights
1121 Vermont Avenue, N.W.
Washington, D.C. 20425

Record access procedures: Address inquiries same as Notification, with appeals to the Staff Director.

Record source categories: Information submitted by applicants seeking employment with the Commission.

CRC—003

System name: Complaints

System location:

U.S. Commission on Civil Rights
1121 Vermont Avenue, N.W.
Washington, D.C. 20425
Office of Federal Civil Rights Enforcement, Complaints Division
Office of General Counsel
Office of Field Operations Regional Offices:
Central States Regional Office, U.S.C.C.R.
911 Walnut Street
Kansas City, Missouri 64106
Mid-Atlantic Regional Office, U.S.C.C.R.
2120 L Street, N.W. (Room 510)
Washington, D.C. 20037
Midwestern Regional Office, U.S.C.C.R.
230 South Dearborn Street, 32nd Floor
Chicago, Illinois 60604
Mountain States Regional Office, U.S.C.C.R.
Ross Building (Room 216)
1726 Champa Street
Denver, Colorado 80282
Northeastern Regional Office, U.S.C.C.R.
26 Federal Plaza (Room 1639)
New York, New York 10007
Southern Regional Office, U.S.C.C.R.
Citizens Trust Bank Building (Room 362)
75 Piedmont Avenue, N.E.
Atlanta, Georgia 30303
Southwestern Regional Office, U.S.C.C.R.
New Moore Building (Room 249)
106 Broadway
San Antonio, Texas 78205
Western Regional Office, U.S.C.C.R.
312 North Spring Street (Room 1015)
Los Angeles, California 90012

Categories of individuals covered by the system: Records are maintained by the name of the person filing the complaint and by the name of the person or organization the complaint is filed against.

Categories of records in the system: The record contains the complaint alleging a denial of equal protection based on race, color, religion, national origin, or sex or in the Administration of Justice and the action taken by the Commission on that complaint.

Authority for maintenance of the system: 42 U.S.C. sec. 1975c(a)(1) and (5)

Routine uses of records maintained in the system, including categories of users and the purposes of such uses: The record is used to assist in resolving complaints alleging denials of rights based on race, color, religion, national origin, or sex or in the Administration of Justice. Users of the record are the person or persons, groups, corporations or governmental agencies against whom the complaint is made and the Commissioners and Commission staff dealing with the complaint, as well as Federal or State agencies to which complaints may be referred. (Subject to the requirements of 42 U.S.C. sec. 1975a(e).)

Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system: Storage—Records are maintained on paper. Retrievability—Records are indexed by subject matter, name of the complaining person or persons and the name of the persons, groups, corporations or governmental agencies against whom the complaint is brought. Retention and Disposal—Records are maintained in file cabinets during the course of the complaint investigation and for a reasonable period of time afterwards until they are retired to the National Archives.

System manager(s) and address:

Director
Office of Management
U.S. Commission on Civil Rights
1121 Vermont Avenue, N.W.
Washington, D.C. 20425

Notification procedure:

General Counsel
U.S. Commission on Civil Rights
1121 Vermont Avenue, N.W.
Washington, D.C. 20425

Record access procedures: General Counsel

Contesting record procedures:

Staff Director
U.S. Commission on Civil Rights
1121 Vermont Avenue, N.W.
Washington, D.C. 20425

Record source categories: Complaints are received from the public; responses are received from those the complaint is filed against; further information is developed by Commission staff during the course of dealing with complaints.

CRC—004

System name: Commission projects

System location:

U.S. Commission on Civil Rights
1121 Vermont Avenue, N.W.
Washington, D.C. 20425

Categories of individuals covered by the system: Members of the public from whom the Commission has sought information; individuals active or interested in civil rights issues who have information on project subject areas; public and private individuals with civil rights responsibilities.

Categories of records in the system: Reports from staff field investigations; interview reports; hearing files; transcripts; letters to and from individuals regarding civil rights; reports and publications prepared by governmental agencies and private groups and individuals concerning civil rights; reports from Commissioners regarding civil rights; communications between the Commission and other governmental agencies and between the Commission and private groups and individuals generated in the course of project investigations; Commission reports and publications.

Project files have been compiled by the following offices: Office of General Counsel; Office of Research, Office of National Civil Rights Issues; Office of Staff Director, Women's Rights Program Unit; Office of Program and Policy Review; Office of Federal Civil Rights Evaluation; Office of Field Operations.

Authority for maintenance of the system: 42 U.S.C. sec. 1975c

Routine uses of records maintained in the system, including categories of users and the purposes of such uses: Records are used to determine what projects the Commission should initiate; records are used as background and supporting material for the conduct of Commission projects; records are used during Commission hearings; records are used as background and supporting material in the preparation of Commission reports and publications. Primary users of these records are Commissioners and staff of the U.S. Commission on Civil Rights in the conduct of projects. The 51 State Advisory Committees to the Commission make use of project records in carrying out their advisory functions. Records are also available, in part, to use by the public upon request under the Freedom of Information Act. (Subject to 42 U.S.C. sec. 1975a(e).)

Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system: Storage—Material is maintained in the form of typed paper copy. Retrieveability—System is indexed by project title, subject matter, and by name of person or

organization. Retaining—Records are kept in file cabinets during the project and for a reasonable time thereafter, and are retired to the National Archives when the records no longer serve a continuing use.

System manager(s) and address:

Director
Office of Management
U.S. Commission on Civil Rights
1121 Vermont Avenue, N.W.
Washington, D.C. 20425

Notification procedure:

General Counsel
U.S. Commission on Civil Rights
1121 Vermont Avenue, N.W.
Washington, D.C. 20425

Record access procedures: Same as above with appeal to the Staff Director.

Record source categories: Members of the public, Commissioners, State Advisory Committee members, and Commission staff.

CRC—005

System name: Information on Commissioners, staff and State Advisory Committee members, past and present.

System location:

U.S. Commission on Civil Rights
1121 Vermont Avenue, N.W.
Washington, D.C. 20425
Office of the Staff Director
Office of Information and Publication
Office of Field Operations
All Regional Offices

Categories of individuals covered by the system: Commissioners who are appointed by the President and confirmed by members of the Senate; State Advisory Committee members appointed by the Commissioners, and information on past Commissioners and advisory committee members. Limited information is kept on former employees in this system; also limited information is included on potential State Advisory Committee members.

Categories of records in the system: Contains rosters of Commissioners, State Advisory Committee members and staff; biographical information, and correspondence between the individual Commissioners, Advisory Committee members and staff. Staff lists reflect position and grade level.

Authority for maintenance of the system: 42 U.S.C. sec. 1975; and sec. 1975d(a) and (c)

Routine uses of records maintained in the system, including categories of users and the purposes of such uses: Information (names, rosters) is maintained for distribution to the public, and for mailing Commission materials and publications. Rosters containing names of employees, position and grade level are used to review staffing patterns, personnel practices, hirings and separations. Biographical data on advisory committee members is reviewed by the Commissioners and staff in selecting, reappointing or rechartering State Advisory Committees. Biographical data on the Commissioners is also made available to the public.

Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system: Storage—Information is stored in file folders. Retrievability—Information is retrieved by subject matter, i.e., Commissioners, a named State Advisory Committee, or staff; and then by individual name. Safeguards—Information is contained in unlocked file drawers with access limited to staff who manage or assist in activities relating to the categories of individuals covered. Retention and Disposal—Information is kept in files during current tenure of Commissioners, Advisory Committee members, and staff. Upon resignation or change of membership files are retained for 2-3 years and then retired to the National Archives.

System manager(s) and address:

Director
Office of Management
U.S. Commission on Civil Rights
1121 Vermont Avenue, N.W., Room 502A
Washington, D.C. 20425 For State Advisory Committee files:
Assistant Staff Director, Office of Field Operations
U.S. Commission on Civil Rights
Office of Field Operations
1121 Vermont Avenue, N.W., Room 500
Washington, D.C. 20425

Notification procedure:

General Counsel
U.S. Commission on Civil Rights
1121 Vermont Avenue, N.W.
Washington, D.C. 20425

Record access procedures: Same as above for notification with appeals to the Staff Director.

Record source categories: Individual to whom the record pertains; personnel office and some members of the general public.

CRC—006

System name: Other Employee Programs: Equal Employment Opportunity, Troubled Employee and Upward Mobility

System location:

Office of Staff Director
Director of Equal Employment Opportunity
U.S. Commission on Civil Rights
1121 Vermont Avenue, N.W.
Washington, D.C. 20425

Categories of individuals covered by the system: Equal Employment Opportunity: all employees of the Commission. Troubled Employee Program: employees with personal problems which detract from job effectiveness (alcoholism, drug abuse, mental stress, etc.). Upward Mobility: clerical employees who are eligible for entry into the program or who are participating in the program.

Categories of record: in the system: Equal Employment Opportunity: open and restricted investigative files pertaining to equal employment opportunity complaints and problems. Troubled Employee Program: records are confidential and contain data regarding employees enrolled in the program, what assistance or counselling is received, and related information. Upward Mobility: records of enrollment in training or educational programs, class progress and grades, as well as promotions or advancements within the Commission.

Authority for maintenance of the system: Executive Order 11478; 42 U.S.C. sec. 1975d(a) and Federal Personnel Regulations, Chapter 293, 42 U.S.C. sec. 2000e

Routine uses of records maintained in the system, including categories of users and the purposes of such uses: Equal Employment Opportunity: Used by Equal Employment Opportunity director, counsellors, investigators and other agency officials where appropriate to resolve discrimination complaints. After disposition is made of the case, files are reviewed by the Office of General Counsel and where appeals are taken, files are reviewed by hearing officers and Civil Service Board of Appeals and Review. Where court actions are filed, records are reviewed by the courts and attorneys for the parties.

Equal Employment Opportunity records are used to meet Civil Service Commission and Federal employment reporting requirements.

Troubled Employee Program files are used by the Equal Employment Opportunity director and supervisory or management personnel in determining the prognosis, need for counselling, or other action in individual cases.

Upward Mobility files are used to counsel employees and supervisors; to monitor the effectiveness of the program, the training received, on-the-job experience and overall progress of the participants. Records in the Equal Employment Opportunity and Upward Mobility Programs are used to assist the agency in developing its Affirmative Action program.

Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system: Records are maintained in the Office of the Director, Equal Employment Opportunity with access limited to the staff of that office. Investigative files (Equal Employment Opportunity) are retained in secured file cabinets. Troubled Employee files are maintained in locked file cabinets and are unavailable to agency staff (except the Equal Employment Opportunity Director) in their entirety, however extractions are made as necessary for management decisions.

Upward Mobility files are maintained in the same office. The Equal Employment Opportunity director and the Federal Women's Program Coordinator are the primary users of these records with extracts made available to Personnel, supervisors or others within management. Upon completion of the program some of this data may be placed in the Official Personnel Folder.

System manager(s) and address:

Director of Equal Employment Opportunity
Office of Staff Director
U.S. Commission on Civil Rights
1121 Vermont Avenue, N.W.
Washington, D.C. 20425

Notification procedure:

General Counsel
U.S. Commission on Civil Rights
1121 Vermont Avenue, N.W.
Washington, D.C. 20425

Record access procedures: Same as above with appeals to the Staff Director.

Record source categories: The employee in the program, supervisors, management and co-workers. Educational institutions, trainers, medical officials and other third parties dealing with covered employees.

CRC—007

System name: Personnel Records

System location:

U.S. Commission on Civil Rights
Office of Management
Personnel Division
1121 Vermont Avenue, N.W., Room 507
Washington, D.C. 20425
Office of the Staff Director
Office of Management
Office of Information and Publications
Office of General Counsel
Office of Program and Policy Review
Office of Field Operations
Office of Research
Office of Federal Civil Rights Evaluation
Office of National Civil Rights Issues
All Regional Offices

Categories of individuals covered by the system: Current Commission employees and those formerly employed by the Commission.

Categories of records in the system: This system consists of a variety of records relating to personnel actions and determinations made about an individual while employed at the Commission. These records contain information about an individual relating to his birth date; Social Security Number; veterans preference; tenure; handicap; past and present salaries, grades, and position titles; letters of communication, reprimand, charges, and decisions on charges; notice of reduction-in-force; locator files; personnel actions, including but not limited to, appointment, reassignment, demotion, detail, promotion, transfer, and separation; training; minority group designator; records relating to life insurance, health benefits, and designation of beneficiary; training; performance ratings, data documenting the reasons for personnel actions or decisions made about an individual; awards; and other information relating to the status of the individual.

Authority for maintenance of the system: 42 U.S.C. sec. 1975d(a); and Federal Personnel Regulations, Chapter 293

Routine uses of records maintained in the system, including categories of users and the purposes of such uses: Information in these records is used or a record may be used by agency officials for purposes of review in connection with appointments, transfers, promotions, reassignments, adverse actions, disciplinary actions, and determination of qualifications of an individual. Records are used to provide information to a prospective employer of a Commission employee or former employee.

These records are used in accordance with Civil Service Commission notices of Systems of Personnel Records including as a data source for management information for production of summary descriptive statistics and analytical studies in support of the function for which the records are collected and maintained, or for related personnel management functions or manpower studies; may also be utilized to respond to general requests for statistical information (without personal identification of individuals) under the Freedom of Information Act or to locate specific individuals for personnel research or other personnel management functions.

Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system: Storage—Records are maintained in file folders, in file cabinets with access limited to those persons whose official duties require access. Personnel screening is employed to prevent unauthorized disclosure. Retention and Disposal—The Official Personnel Folder (OPF) is retained indefinitely. The OPF is sent to the National Personnel Records Center within 30 days of the date of the employee's separation from the Federal service. Some records such as letters of reprimand, indebtedness, and vouchers are maintained for two years or destroyed when an individual resigns, transfers, or is separated from the Federal service.

System manager(s) and address:

Office of Management
Personnel Officer
1121 Vermont Avenue, N.W., Room 507
Washington, D.C. 20425

Notification procedure:

General Counsel
U.S. Commission on Civil Rights
1121 Vermont Avenue, N.W.
Washington, D.C. 20425

Record access procedures: Same as above with appeals to the Staff Director. Former Federal employees who wish to contest their records should direct such a request in writing to:

Director
Bureau of Manpower Information Systems
U.S. Civil Service Commission
1900 E Street, N.W.
Washington, D.C. 20415

Record source categories: Information in this system of records either comes from the individual to whom it applies or is derived from information he/she supplied, except information provided by agency officials.

CRC—008

System name: Resource and Consultant

System location:

U.S. Commission on Civil Rights
1121 Vermont Avenue, N.W.
Washington, D.C. 20425
Office of Staff Director, Room 800
Women's Rights Program Unit, Room 503
Office of General Counsel, Room 600
Office of Information and Publications, Room 700 All Regional Offices:
Central States Regional Office, U.S.C.C.R.
911 Walnut Street
Kansas City, Missouri 64106
Mid-Atlantic Regional Office, U.S.C.C.R.
2120 L Street, N.W., Room 510
Washington, D.C. 20037
Midwestern Regional Office, U.S.C.C.R.
230 South Dearborn Street, 32nd Floor
Chicago, Illinois 60604
Mountain States Regional Office, U.S.C.C.R.
Ross Building, Room 216
1726 Champa Street
Denver, Colorado 80282
Northeastern Regional Office, U.S.C.C.R.
26 Federal Plaza, Room 1639
New York, New York 10007
Southern Regional Office, U.S.C.C.R.
Citizens Trust Bank Building, Room 362
75 Piedmont Avenue, N.E.
Atlanta, Georgia 30303
Southwestern Regional Office, U.S.C.C.R.
New Moore Building, Room 249
106 Broadway
San Antonio, Texas 78205
Western Regional Office, U.S.C.C.R.
312 North Spring Street, Room 1015
Los Angeles, California 90012

Categories of individuals covered by the system: Individuals with expertise and experience in civil rights matters; consultants, conference participants, appointees to Federal employment, boards of directors, state advisory committees, and other organizations.

Categories of records in the system: This system contains resumes, biographical sketches, mailing lists, rosters, some some employment data and interview reports, newspaper clippings, magazine articles, and miscellaneous information about individuals.

Authority for maintenance of the system: 42 U.S.C. sec. 1975d(a) and (c), and sec. 1975c(a)(4)

Routine uses of records maintained in the system, including categories of users and the purposes of such uses: Information is referred to other Commission offices upon request for use in recruitment of employees, for use in obtaining information on persons interested in serving on advisory committees, or providing potential resource or consultant assistance to the agency. Data is shared with non-agency requesters where individuals have consented or data is of a public nature. Mailing lists and rosters are used for correspondence between the Commissioners, staff, advisory committees and members of the public; also for dissemination of information where appropriate.

Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system: Records are on paper in file folders. Most data are stored strictly by project and subject title. Project directors and division heads are primary personnel using the system. Women's Rights Program Unit: Resumes are filed by name in the Unit's locked file cabinets; access is available to Unit staff and, on occasion, to other Commission supervisory staff and hiring officials. Office of General Counsel and Office of Information and Publication: Data is stored in file cabinets with limited access. These records are kept for an indefinite period of time within the agency and subsequently retired to the National Archives when the project file is inactive.

System manager(s) and address:

Director
Office of Management
U.S. Commission on Civil Rights, Room 502A
1121 Vermont Avenue, N.W.
Washington, D.C. 20425

Notification procedure:

Office of General Counsel, Room 600
U.S. Commission on Civil Rights
1121 Vermont Avenue, N.W.
Washington, D.C. 20425

Record access procedures: Same as above with appeal to the Staff Director.

Record source categories: Biographical information and background information is obtained from the individual; resumes and S.F. 171's are also obtained from the individual. Other information is obtained from newspapers, magazines, and public sources.

CRC—009

System name: State Advisory Committee Project Files

System location:

Office of Field Operations
U.S. Commission on Civil Rights
1121 Vermont Avenue, N.W.
Washington, D.C. 20425 Regional Offices:
Central States Regional Office, U.S.C.C.R.
911 Walnut Street
Kansas City, Missouri 64106
Mid-Atlantic Regional Office, U.S.C.C.R.
2120 L Street,N.W., Room 510
Washington, D.C. 20037
Midwestern Regional Office, U.S.C.C.R.
230 South Dearborn Street, 32nd Floor
Chicago, Illinois 60604
Mountain States Regional Office, U.S.C.C.R.
Ross Building, Room 216
1726 Champa Street
Denver, Colorado 80282
Northeastern Regional Office, U.S.C.C.R.
26 Federal Plaza, Room 1639
New York, New York 10007
Southern Regional Office, U.S.C.C.R.
Citizens Trust Bank Building, Room 362
75 Piedmont Avenue, N.E.
Atlanta, Georgia 30303
Southwestern Regional Office, U.S.C.C.R.
New Moore Building, Room 249
106 Broadway
San Antonio, Texas 78205
Western Regional Office, U.S.C.C.R.
312 North Spring Street, Room 1015
Los Angeles, California 90012

Categories of individuals covered by the system: Members of the public from whom staff or advisory committee members seek information in connection with a project or their advisory function; individuals active or interested in civil rights issues in their States and local communities; public and private individuals with civil rights responsibilities.

Categories of records in the system: Reports from staff field investigations; interview reports; informal hearings or open meetings files; transcripts; letters to and from individuals regarding civil rights, reports and publications prepared by governmental agencies and private groups and individuals concerning civil rights; reports from State Advisory Committee members concerning civil rights; communications between the State Advisory Committees and State, local and Federal governmental agencies and between the State Advisory Committees and private individuals and groups generated during the course of State Advisory Committee project investigations; Commission reports and investigations. (Subject to the requirements of 42 U.S.C. sec. 1975a(e).)

Project files by the 51 State Advisory Committees have been compiled by the Office of Field Operations in Washington, D.C. and in the following regional offices:

Central States Regional Office: Iowa; Kansas; Missouri; Nebraska.

Mid-Atlantic Regional Office: Delaware; District of Columbia; Maryland; Pennsylvania; Virginia; West Virginia.

Midwestern Regional Office: Illinois; Indiana; Michigan; Minnesota; Ohio; Wisconsin.

Mountain States Regional Office: Arizona; Colorado; Montana; North Dakota; South Dakota; Utah; Wyoming.

Northeastern Regional Office: Connecticut; Maine; Massachusetts; New Hampshire; New Jersey; New York; Rhode Island; Vermont.

Southern Regional Office: Alabama; Florida; Georgia; Kentucky; Mississippi; North Carolina; South Carolina; Tennessee.

Southwestern Regional Office: Arkansas; Louisiana; Oklahoma; Texas; New Mexico.

Western Regional Office: Alaska; California; Hawaii; Idaho; Nevada; Oregon; Washington.

Authority for maintenance of the system: 42 U.S.C. sec. 1975d(c)

Routine uses of records maintained in the system, including categories of users and the purposes of such uses: Records are used to determine what projects State Advisory Committees should initiate and as background and supporting material for the conduct of State Advisory Committee projects; records are used by State Advisory Committees as background and supporting material for the preparation of State Advisory Committee reports and recommendations to the U.S. Commission on Civil Rights. Primary users of these records are State Advisory Committee members and Commission staff assisting State Advisory Committees in the conduct of projects. State Advisory Committee records are available, in part, to the public upon request under the Freedom of Information Act. (Subject to 42 U.S.C. sec. 1975a(e).)

Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system: Storage—records are stored on paper. Retrievability—records are indexed by project title, subject matter and within these categories by name of individuals and organization. Retention—records are maintained by the Office of Field Operations in the headquarters office in Washington, D.C. and in the regional offices.

System manager(s) and address:

Assistant Staff Director
Office of Field Operations
U.S. Commission on Civil Rights
1121 Vermont Avenue, N.W.
Washington, D.C. 20425

Notification procedure:

General Counsel
U.S. Commission on Civil Rights
1121 Vermont Avenue, N.W.
Washington, D.C. 20425

Record access procedures: Same as above with appeal to the Staff Director.

Record source categories: Members of the public, State Advisory Committee members, Commissioners and Commission staff.

CRC—010

System name: Travel, payroll, time and attendance of Commissioners, staff, consultants, and State Advisory Committee members.

System location:

Office of Management

U.S. Commission on Civil Rights
1121 Vermont Avenue, N.W., Room 502
Washington, D.C. 20425 All divisional offices All regional offices

Categories of individuals covered by the system: Commissioners, staff, consultants, and State Advisory Committee members.

Categories of records in the system: Records consist of manual files containing payroll related information for staff and consultants. Payroll and time and attendance records and information includes many records or information also maintained in the Official Personnel Folder and related files maintained in accordance with Civil Service Commission regulations and of which notice has been given by the Civil Service Commission in its notice of government-wide systems of personnel records. Payroll and related information consists of various forms which discloses on a biweekly, year-to-date, and in some cases, an annual basis, payroll and leave data for staff and consultants relating to rate and amount of pay, leave, and hours worked, and leave balances; tax and retirement deductions; life insurance and health insurance deductions; savings allotments, savings bond and charity deductions.

For all categories of individuals covered, records include mailing addresses and home addresses, travel requests and travel vouchers where appropriate, statements of per diem and expense allowances.

Official travel records for the Commission are maintained by the General Services Administration.

Authority for maintenance of the system: 42 U.S.C. 1975d(a), Federal Personnel Manual and Treasury Fiscal Requirements Manual.

Routine uses of records maintained in the system, including categories of users and the purposes of such uses: Relevant records in this system are referred to the General Services Administration for preparation of payroll; to meet government payroll recordkeeping and reporting requirements; and for retrieving and supplying payroll and leave information as required for agency needs. Travel records or vouchers may be used for purposes of providing reimbursements to covered individuals for travel expenses and/or record ofof official travel. Relevant records in this system may be referred as a routine use, to the Department of Justice or other appropriate Federal agency for investigating or prosecuting any violation of any Federal law or requirement thereunder.

Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system: Storage—Maintained in individual folders for each category of individuals covered. Retrievability—Files are maintained in alphabetical order by category and by name. Safeguards—Maintained in areas to which access is controlled by or restricted to Commission management personnel. Retention and Disposal—In accordance with General Services Administration requirements for financial/ payroll/travel related records.

System manager(s) and address:

Director
Office of Management
U.S. Commission on Civil Rights
1121 Vermont Avenue, N.W.
Washington, D.C. 20425

Notification procedure:

Office of General Counsel
U.S. Commission on Civil Rights
1121 Vermont Avenue, N.W.
Washington, D.C. 20425

Record access procedures: Same as above with appeal to the Staff Director.

Record source categories: Provided by Civil Rights Commission employees and all categories of individuals covered.

[FR Doc.75-23064 Filed 9-2-75;8:45 am]

ENVIRONMENTAL PROTECTION AGENCY

[40 CFR Part 16]

[FRL 424-1]

IMPLEMENTATION OF PRIVACY ACT OF 1974

Proposed Rulemaking

Notice is hereby given that the Environmental Protection Agency (EPA) proposes to amend Chapter I of Title 40 of the Code of Federal Regulations by adding a new Part 16 to implement provisions of the Privacy Act of 1974, 5 U.S.C. 552a (Pub. L. 93-579, 88 Stat. 1896). Interested persons may participate in the proposed rulemaking by submitting written data, views, or arguments pertaining to these proposed rules. Comments on the proposed rules received by the Agency on or before September 17, 1975, will be considered before taking final action on the proposed rules. Necessity for considering comments and finalizing the rules by September 27, 1975, furnishes good cause for an abbreviated comment period. Such comments should be addressed to Director, Management and Organization Division, PM-213, Environmental Protection Agency, Washington, D.C. 20460. Copies of all written comments will be available for examination by interested persons between 8 a.m. and 4:30 p.m. Mondays through Fridays (except holidays) at Public Information Reference Unit, Room 2922 (EPA Library), 401 M Street, SW., Washington, D.C. 20460.

These proposed regulations establish procedures to be followed by individuals who request information about records pertaining to themselves and access to or amendments of records which are contained in systems of records maintained by EPA.

In consideration of the foregoing, it is proposed to amend Chapter I of Title 40, Code of Federal Regulations, by adding a new Part 16 as follows:

PART 16—IMPLEMENTATION OF PRIVACY ACT OF 1974

Sec.

AUTHORITY: 5 U.S.C. 552a.

§ 16.1 Purpose and scope.

(a) This part sets forth the Environmental Protection Agency procedures under the Privacy Act of 1974 as required by 5 U.S.C. 552a(f).

(b) These procedures describe how an individual may request notification of whether EPA maintains a record pertaining to him or her in any of its systems of records, request access to the record or to an accounting of its disclosure, request that the record be amended or corrected, and appeal an initial adverse determination concerning any such request.

(c) These procedures apply only to requests by individuals and only to records maintained by EPA, excluding those systems specifically exempt under §§ 16.13 and 16.14 and those determined as government-wide and published by the Civil Service Commission in 5 CFR Parts 293 and 297.

§ 16.2 Definitions.

As used in this Part:

(a) The terms "individual," "maintain," "record," "system of records," and "routine use" shall have the meaning given them by 5 U.S.C. 552a (a)(2), (a)(3), (a)(4), (a)(5) and (a)(7), respectively.

(b) "EPA" means the Environmental Protection Agency.

(c) "Working days" means calendar days excluding Saturdays, Sundays, and legal public holidays.

§ 16.3 Procedures for requests pertaining to individual records in a record system.

Any individual who wishes to have EPA inform him or her whether a system of records maintained by EPA contains any record pertaining to him or her which is retrieved by name or personal identifier, or who wishes to request access to any such record, shall submit a written request in accordance with the instructions set forth in EPA's annual notice of systems for that system of records. This request shall include:

(a) The name of the individual making the request;

(b) The name of the system of records (as set forth in the EPA notice of systems) to which the request relates;

(c) Any other information which the system notice indicates should be included; and

(d) If the request is for access, a statement as to whether a personal inspection or a copy by mail is desired.

§ 16.4 Times, places, and requirements for identification of individuals making requests.

(a) If an individual submitting a request for access under § 16.3 has asked that EPA authorize a personal inspection of records, and EPA has granted the request, he or she may present himself or herself at the time and place specified in EPA's response or arrange another time with the appropriate agency official.

(b) Prior to inspection of records, an individual shall present sufficient identification (e.g., driver's license, employee identification card, social security card, credit card) to establish that he or she is the individual to whom the records pertain. An individual who is unable to provide such identification shall complete and sign, in the presence of an agency official, a statement declaring his or her identity and stipulating that he or she understands it is a misdemeanor punishable by fine up to $5,000 to knowingly and willfully seek or obtain access to records about another individual under false pretenses.

(c) If an individual, having requested personal inspection of his or her records, wishes to have another person accompany him or her during inspection, he or she shall submit a written statement authorizing disclosure in the presence of the other person(s).

(d) An individual who has made a personal inspection of records may then request copies of those records. Such requests may be granted, but fees may be charged in accordance with § 16.11.

(e) If an individual submitting a request under § 16.3 wishes to have copies furnished by mail, he or she must include with the request sufficient data to allow EPA to verify his or her identity. Should sensitivity of the records warrant it, EPA may require a requester to submit a signed and notarized statement indicating that he or she is the individual to whom the records pertain and that he or she understands it is a misdemeanor punishable by fine up to $5,000 to knowingly and willfully seek or obtain access to records about another individual under false pretenses. Such mail requests may be granted, but fees may be charged in accordance with § 16.11.

(f) No verification of identity will be required where the records sought are publicly available under the Freedom of Information Act, as EPA procedures under 40 CFR Part 2 will then apply.

§ 16.5 Disclosure of requested information to individuals.

(a) Each request received will be acted upon promptly.

(b) Within 10 working days of receipt of a request, the system manager shall acknowledge the request. Whenever practicable, the acknowledgment will indicate whether or not access will be granted and, if so, when and where. When access is to be granted, it shall be provided within 30 working days of first receipt. If the agency is unable to meet this deadline, the records system manager shall so inform the requester stating reasons for the delay and an estimate of when access will be granted.

(c) If a request pursuant to § 16.3 for access to a record is in a system of records which is exempted, the records system manager will determine whether the information will nonetheless be made available. If the determination is to deny access, the reason for denial and the appeal procedure will be given to the requester.

(d) Any person whose request is initially denied may appeal that denial to the Privacy Act Officer, who shall make

an appeal determination within 10 working days.

(e) If the appeal under paragraph (d) of this section is denied, the requester may bring a civil action under 5 U.S.C. 552a(g) to seek review of the denial.

§ 16.6 Special procedures: medical records.

Should EPA receive a request for access to medical records (including psychological records) disclosure of which the system manager determines would be harmful to the individual to whom they relate, EPA may refuse to disclose the records directly to the individual and instead offer to transmit them to a physician designated by the individual.

§ 16.7 Request for correction or amendment of record.

(a) An individual may request correction or amendment of any record pertaining to him or her in a system of records maintained by EPA by submitting to the system manager, in writing, the following:

(1) The name of the individual making the request;

(2) The name of the system, as described in the notice of systems;

(3) A description of the nature and substance of the correction or amendment request; and

(4) Any additional information specified in the system notice.

(b) Any person submitting a request under this section shall include sufficient information in support of that request to allow EPA to apply the standards set forth in 5 U.S.C. 552a (e)(1) and (e)(5).

(c) Any person whose request is denied may appeal that denial to the Privacy Act Officer.

(d) In the event that appeal is denied, the requester may bring a civil action to seek review of the denial, under 5 U.S.C. 552a(g).

§ 16.8 Initial determination on request for correction or amendment of record.

(a) Within 10 working days of receipt of a request for amendment or correction, the system manager shall acknowledge the request, and promptly either:

(1) Make any correction, deletion, or addition which the requester believes should be made; or

(2) Inform the requester of his or her refusal to correct or amend the record, the reason for refusal, and the procedures for appeal.

(b) If the system manager is unable to comply with the preceding paragraphs within 30 working days of his or her receipt of a request, he or she will inform the requester of that fact, the reasons, and an estimate of when a determination will be reached.

(c) In conducting the review of the request, the system manager will be guided by the requirements of 5 U.S.C. 552a (e)(1) and (e)(5).

(d) If the system manager determines to grant all or any portion of the request, he or she will:

(1) Advise the individual of that determination;

(2) Make the correction or amendment; and

(3) So inform any person or agency outside EPA to whom the record has been disclosed, and, where an accounting of that disclosure is maintained in accordance with 5 U.S.C. 552a(c), note the occurrence and substance of the correction or amendment in the accounting.

(e) If the system manager determines not to grant all or any portion of a request for correction or amendment, he or she will:

(1) Comply with paragraph (d)(3) of this section (if necessary);

(2) Advise the individual of the determination and its basis;

(3) Inform the individual that an appeal may be made; and

(4) Describe the procedures for making the appeal.

(f) If EPA receives from another Federal agency a notice of correction or amendment of information furnished by that agency and contained in one of EPA's systems of records, the system manager shall advise the individual and make the correction as if EPA had originally made the correction or amendment.

§ 16.9 Appeal of initial adverse agency determination on request for correction or amendment.

(a) Any individual whose request for correction or amendment is initially denied by EPA and who wishes to appeal may do so by letter to the Privacy Act Officer. The appeal shall contain a description of the initial request sufficient to identify it.

(b) The Privacy Act Officer shall make a final determination not later than 30 working days from the date on which the individual requests the review, unless, for good cause shown, the Privacy Act Officer extends the 30-day period and notifies the requester. Such extension will be utilized only in exceptional circumstances.

(c) In conducting the review of an appeal, the Privacy Act Officer will be guided by the requirements of 5 U.S.C. 552a (e)(1) and (e)(5).

(d) If the Privacy Act Officer determines to grant all or any portion of an appeal he or she shall so inform the requester and EPA shall make the correction or amendment and comply with § 16.8(d)(3).

(e) If the Privacy Act Officer determines not to grant all or any portion of an appeal he or she shall inform the requester:

(1) Of the determination and its basis;

(2) Of the requester's right to file a concise statement of reasons for disagreeing with EPA's decision;

(3) Of the procedures for filing such statement of disagreement;

(4) That such statements of disagreements will be made available in subsequent disclosures of the record, together with an agency statement (if deemed appropriate) summarizing its refusal;

(5) That prior recipients of the disputed record will be provided with statements as in paragraph (e)(4) of this section, to the extent that an accounting of disclosures is maintained under 5 U.S.C. 552a(c); and

(6) Of the requester's right to seek judicial review under 5 U.S.C. 552a(g).

§ 16.10 Disclosure of record to person other than the individual to whom it pertains.

EPA shall not disclose any record which is contained in a system of records it maintains except pursuant to a written request by, or with the written consent of, the individual to whom the record pertains, unless the disclosure is authorized by one or more of the provisions of 5 U.S.C. 552a(b).

§ 16.11 Fees.

No fees shall be charged for providing the first copy of a record or any portion to an individual to whom the record pertains. The fee schedule for reproducing other records is the same as that set forth in 40 CFR § 2.120.

§ 16.12 Penalties.

The Act provides, in pertinent part:

"Any person who knowingly and willfully requests or obtains any record concerning an individual from an agency under false pretenses shall be guilty of a misdemeanor and fined not more than $5,000." (5 U.S.C. 552a(i)(3).)

§ 16.13 [Reserved]

§ 16.14 Specific exemptions.

Pursuant to 5 U.S.C. 552a(k)(2), investigatory material compiled for law enforcement purposes in the following systems of records is exempt from subsections (c)(3), (d), (e)(1), (e)(4) (G), (H) and (I), and (f) of 5 U.S.C. 552a and from the provisions of this Part, except as otherwise provided in 552a (k)(2).

(Reserved for list of exempt systems to be later identified.)

Dated: August 27, 1975.

RUSSELL E. TRAIN,
Administrator,
Environmental Protection Agency.

[FR Doc.75-23199 Filed 8-28-75;10:00 am]

NATIONAL SECURITY COUNCIL

[32 CFR Part 2102]

PRIVACY ACT OF 1974

Proposed Rulemaking

AUGUST 27, 1975.

Notice is hereby given that the National Security Council proposes to amend Title 32, Chapter XXI Code of Federal Regulations by adding a new Part 2102 to implement the provisions of the Privacy Act of 1974, 5 U.S.C. 552a (f), Pub. L. 93-579.

Interested persons are invited to submit written comments, suggestions or objections regarding these proposed rules to the Staff Secretary, National Security Council, Washington, D.C. 20506. All relevant material received before September 15, 1975 will be considered by the NSC in formulating its final regulations.

JEANNE W. DAVIS,
Staff Secretary.

Notice is hereby given that it is proposed to make the final regulations effective September 27, 1975, the effective date of section 3, Pub. L. 93-579.

These regulations are the exclusive means by which individuals may request personally identifiable records and information from the National Security Council.

Title 32, Chapter XII, Code of Federal Regulations is proposed to be amended by establishing a new Part 2102, as follows:

PART 2102—PRIVACY ACT REGULATIONS

Sec.

§ 2102.1 Introduction.

Insofar as the Privacy Act of 1974 (5 U.S.C. 552a) applies to the National Security Council (hereafter NSC), it provides the American public with expanded opportunities to gain access to records maintained by the NSC Staff which may pertain to them as individuals.

The NSC Staff, in addition to performing the functions prescribed in the National Security Act of 1947, as amended (50 U.S.C. 401), also serves as the supporting staff to the President in the conduct of foreign affairs. In doing so the NSC Staff is acting not as an agency but as an extension of the White House Office. In that the White House Office is not considered an agency for the purposes of this Act, the materials which are used by NSC Staff personnel in their role as supporting staff to the President are not subject to the provisions of the Privacy Act of 1974. A description of these White House Office files is, nevertheless, appended to the NSC notices of systems of files and will be published annually in the FEDERAL REGISTER.

In general, Records in NSC files pertain to individual members of the public only if these individuals have been (1) employed by the NSC, (2) have corresponded on a foreign policy matter with a member of the NSC or its staff, or (3) have, as a U.S. Government official, participated in an NSC meeting or in the preparation of foreign policy-related documents for the NSC.

§ 2102.2 Purpose and scope.

The following regulations set forth procedures whereby individuals may seek and gain access to records concerning themselves and will guide the NSC Staff response to requests under the Privacy Act. In addition, they outline the requirements applicable to the personnel maintaining NSC systems of records.

(a) These regulations, published pursuant to the Privacy Act of 1974, Pub. L. 93-579, section 552a (f) and (k), 5 U.S.C. (hereinafter the Act), advise of procedures whereby an individual can:

(1) Request notification of whether the NSC Staff maintains or has disclosed a record pertaining to him or her in any non-exempt system of records;

(2) Request a copy of such record or an accounting of that disclosure,

(3) Request an amendment to a record; and

(4) Appeal any initial adverse determination of any request under the Act.

(b) These regulations also specify those systems of records which the NSC has determined to be exempt from certain provisions of the Act and thus not subject to procedures established by this regulation.

§ 2102.3 Definitions.

As used in these regulations:

(a) *Individual:* A citizen of the United States or an alien lawfully admitted for permanent residence.

(b) *Maintain:* includes maintain, collect, use or disseminate. Under the Act it is also used to connote control over, and, therefore, responsibility for, systems of records in support of the NSC statutory function (50 U.S.C. 401, et seq.).

(c) *Systems of Records:* a grouping of any records maintained by the NSC from which information is retrieved by the name of the individual or by some other identifying particular assigned to the individual.

(d) *Determination:* any decision made by the NSC or designated official thereof which affects the individual's rights, opportunities, benefits, etc. and which is based in whole or in part on information contained in that individual's record.

(e) *Routine Use:* with respect to the disclosure of a record, the use of such a record in a manner which is compatible with the purpose for which it was collected.

(f) *Disclosure:* the granting of access or transfer of a record by any means.

§ 2102.4 Procedures for determining if an individual is the subject of a record.

(a) Individuals desiring to determine if they are the subject of a record or system of records maintained by the NSC Staff should address their inquiries, marking them plainly as a Privacy Act Request, to:

Staff Secretary, National Security Council, Room 374, Old Executive Office Building, Washington, D.C. 20506.

(b) All requests must be made in writing and should contain:

(1) A specific reference to the system of records maintained by the NSC as listed in the NSC Notices of Systems and Records (copies available upon request); or

(2) A description of the record or systems of records in sufficient detail to allow the NSC to determine whether the record does, in fact, exist in an NSC system of records.

(c) All requests must contain the printed or typewritten name of the individual to whom the record pertains, the signature of the individual making the request, and the address to which the reply should be sent. In instances when the identification is insufficient to insure disclosure to the individual to whom the information pertains in view of the sensitivity of the information, NSC reserves the right to solicit from the requestor additional identifying information.

(d) Responses to all requests under the Act will be made by the Staff Secretary, or by another designated member of the NSC Staff authorized to act in the name of the Staff Secretary in responding to a request under this Act. Every effort will be made to inform the requestor if he or she is the subject of a specific record or system of records within ten working days (excluding Saturdays, Sundays and legal Federal Holidays) of receipt of the request. Such a response will also contain the procedures to be followed in order to gain access to any record which may exist and a copy of the most recent NSC notice, as published in the FEDERAL REGISTER, on the system of records in which the record is contained.

(e) Whenever it is not possible to respond in the time period specified above, the NSC Staff Secretary or a designated alternate will, within ten working days (excluding Saturdays, Sundays and legal Federal Holidays), inform the requestor of the reasons for the delay (e.g., insufficient requestor information, difficulties in record location, etc.), steps that need to be taken in order to expedite the request, and the date by which a response is anticipated.

§ 2102.13 Requirements for access to a record.

(a) Individuals requesting access to a record or system or records in which

there is information concerning them must address a request in writing to the Staff Secretary of the NSC (see Section 1, above). Due to restricted access to NSC offices in the Old Executive Office Building where the files are located, requests cannot be made in person.

(b) All written requests should contain a concise description of the records to which access is requested. In addition, the requestor should include any other information which he or she feels would assist in the timely identification of the record. Verification of the requestor's identity will be determined under the same procedures used in requests for learning of the existence of a record.

(c) To the extent possible, any request for access will be answered by the Staff Secretary or a designated alternate within ten working days (excluding Saturdays, Sundays, and legal Federal holidays) of the receipt of the request. In the event that a response cannot be made within this time, the requestor will be notified by mail of the reasons for the delay and the date upon which a reply can be expected.

(d) The NSC response will forward a copy of the requested materials unless further identification or clarification of the request is required. In the event access is denied, the requestor shall be informed of the reasons therefor and the name and address of the individual to whom an appeal should be directed.

§ 2102.15 Requirements for requests to amend records.

(a) Individuals wishing to amend a record contained in the NSC systems of records pertaining to them must submit a request in writing to the Staff Secretary of the NSC in accordance with the procedures set forth herein.

(b) All requests for amendment or correction of a record must state concisely the reason for requesting the amendment. Such requests should include a brief statement which describes the information the requestor believes to be inaccurate, incomplete, or unnecessary and the amendment or correction desired.

(c) To the extent possible, every request for amendment of a record will be answered within ten working days (excluding Saturdays, Sundays, and legal Federal holidays) of the receipt of the request. In the event that a response cannot be made within this time, the requestor will be notified by mail of the reasons for the delay and the date upon which a reply can be expected. A final response to a request for amendment will include the NSC Staff determination on whether to grant or deny the request. If the request is denied, the response will include:

(1) The reasons for the decision;

(2) The name and address of the individual to whom an appeal should be directed;

(3) A description of the process for review of the appeal within the NSC; and

(4) A description of any other procedures which may be required of the individual in order to process the appeal.

§ 2101.21 Procedures for appeal of determination to deny access to or amendment of requested records.

(a) Individuals wishing to appeal an NSC Staff denial of a request for access or to amend a record concerning them must address a letter of appeal to the Staff Secretary of the NSC. The letter must be received within thirty days from the date of the Staff Secretary's notice of denial and, at a minimum, should identify the following:

(1) The records involved;

(2) The dates of the initial request and subsequent NSC determination; and

(3) A brief statement of the reasons supporting the request for reversal of the adverse determination.

(b) Within thirty working days (excluding Saturdays, Sundays and legal Federal Holidays) of the date of receipt of the letter of appeal, the Assistant to the President for National Security Affairs (hereinafter the "Assistant"), or the Deputy Assistant to the President for National Security Affairs (hereinafter the "Deputy Assistant", acting in his name, shall issue a determination on the appeal. In the event that a final determination cannot be made within this time period, the requestor will be informed of the delay, the reasons therefor and the date on which a final response is expected.

(c) If the original request was for access and the initial determination is reversed, a copy of the records sought will be sent to the individual. If the initial determination is upheld, the requestor will be so advised and informed of the right to judicial review pursuant to 5 U.S.C. 552a(g).

(d) If the initial denial of a request to amend a record is reversed, the records will be corrected and a copy of the amended record will be sent to the individual. In the event the original decision is upheld by the Assistant to the President, the requestor will be so advised and informed in writing of his or her right to seek judicial review of the final agency determination, pursuant to Section 552a (g) of Title 5, U.S.C. In addition, the requestor will be advised of his right to have a concise statement of the reasons for disagreeing with the final determination appended to the disputed records. This statement should be mailed to the Staff Secretary within ten working days (excluding Saturdays, Sundays, and legal Federal Holidays) of the date of the requestor's receipt of the final determination.

§ 2102.31 Disclosure of a record to persons other than the individual to whom it pertains.

Except as provided by the Privacy Act, 5 U.S.C. 552a(b), the NSC will not disclose a record concerning an individual to another person or agency without the prior written consent of the individual to whom the record pertains.

§ 2102.41 Fees.

(a) Individuals will not be charged for:

(1) The first copy of any record provided in response to a request for access or amendment;

(2) The search for, or review of, records in NSC files;

(3) Any copies reproduced as a necessary part of making a record or portion thereof available to the individual.

(b) After the first copy has been provided, records will be reproduced at the rate of twenty-five cents per page for all copying of four pages or more.

(c) The Staff Secretary may provide copies of a record at no charge if it is determined to be in the interest of the Government.

(d) The Staff Secretary may require that all fees be paid in full prior to the issuance of the requested copies.

(e) Remittances shall be in the form of a personal check or bank draft drawn on a bank in the United States, or a postal money order. Remittances shall be made payable to the "United States Treasury" and mailed to the Staff Secretary, National Security Council, Washington, D.C. 20506.

(f) A receipt for fees paid will be given only upon request. Refund of fees paid for services actually rendered will not be made.

§ 2102.51 Penalties.

Title 18, U.S.C. section 1001, Crimes and Criminal Procedures, makes it a criminal offense, subject to a maximum fine of $10,000 or imprisonment for not more than five years or both, to knowingly and willfully make or cause to be made any false or fraudulent statements or representations in any matter within the jurisdiction of any agency of the United States. Section (i)(3) of the Privacy Act (5 U.S.C. 552a) makes it a misdemeanor, subject to a maximum fine of $5,000, to knowingly and willfully request or obtain any record concerning an individual under false pretenses. Sections (i) (1) and (2) of 5 U.S.C. 552a provide penalties for violations by agency employees, of the Privacy Act or regulations established thereunder.

§ 2102.61 Exemptions.

Pursuant to subsection (k) of the Privacy Act, (5 U.S.C. 552a), the Staff Secretary has determined that certain NSC systems of records may be exempt in part from sections 553 (c)(3), (d), (e)(1), (e)(4) (G), (H), (I), and (f) of Title 5, and from the provisions of these regulations. These systems of records may contain information which is classified pursuant to Executive Order 11652. To the extent that this occurs, records in the following systems would be exempt under the provision of 5 U.S.C. 552a(k)(1):

NSC 1.1—Central Research Index.
NSC 1.2—NSC Correspondence Files.
NSC 1.3—NSC Meetings Registry.

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NOTICE TO FEDERAL REGISTER READERS

As part of its continuing program to improve the quality of the daily FEDERAL REGISTER and CODE OF FEDERAL REGULATIONS, the Office of the Federal Register is soliciting the views of interested persons on the effectiveness of individual Federal Register documents and on regulations contained in the CODE OF FEDERAL REGULATIONS.

Our goal is twofold:

First—to make each document published in the FEDERAL REGISTER easily understandable, thus making compliance easier, more efficient, and less costly; and

Second—to identify and correct any existing Federal regulations which are obsolete, unnecessarily wordy, or unclearly stated.

We believe this effort is consistent with the objectives stated by President Ford in his October 8th speech on the economy in which he announced "a joint effort by the Congress, the executive branch and the private sector to identify and eliminate existing Federal rules and regulations that increase costs to the consumer without any good reason in today's economic climate."

The Office of the Federal Register welcomes your comments and suggestions. The survey blank below is provided for that purpose. All comments received will be maintained in a public docket and will be available for inspection in the Office of the Federal Register to any interested persons or agencies. Comments which point out the need for substantive changes in existing regulations also will be forwarded to the responsible agency.

- -

I. For the following reasons I found it difficult to understand the document from ____________ (agency) in column ______, page ______ of the ______ (date) issue of the FEDERAL REGISTER:

☐ only technical language was used; ☐ document contained long and difficult sentences; ☐ preamble did not contain a clear and concise explanation of the document's purpose; ☐ other (explain) ____________________

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II. I believe that the requirement(s) contained in:

A. The document from ____________ (agency) in column ______, page ______ of the ______ (date) issue of the FEDERAL REGISTER, or

B. Section(s) ______ of Title ______ of the CODE OF FEDERAL REGULATIONS

impose(s) an: ☐ unnecessary; ☐ unreasonable; ☐ impractical; or ☐ obsolete requirement on those persons subject to that regulation.

My reasons are: ____________________

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III. (Optional) I suggest that the provision(s) mentioned above be rewritten as follows:

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Please mail to:

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