harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the ICH for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission, European Medicines Evaluation Agency, European Federation of Animal Health; Committee on Veterinary Medicinal Products, FDA, the U.S. Department of Agriculture, the Animal Health Institute, the Japanese Veterinary Pharmaceutical Association, the Japanese Association of Veterinary Biologics, and the Japanese Ministry of Agriculture, Forestry and Fisheries.

Two observers are eligible to participate in the VICH Steering Committee: One representative from the Government of Australia/New Zealand and one representative from the industry in Australia/New Zealand. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the Confédération Mondiale de L’Industrie de la Santé Animale (COMISA). A COMISA representative also participates in the VICH Steering Committee meetings.

II. Draft Guidance on Carcinogenicity Testing

The VICH Steering Committee held a meeting on June 28, 2001, and agreed that the draft guidance document entitled “Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Carcinogenicity Testing” (VICH GL28) should be made available for public comment. This guidance is one of a series of VICH guidelines developed to facilitate the mutual acceptance of safety data necessary for the establishment of acceptable daily intakes for veterinary drug residues in human food by the relevant regulatory authorities. The guidance on the overall strategy for the evaluation of veterinary drug residues in human food (“VICH Guidance on General Testing Approach”) will be made available at a later time.

VICH developed this draft guidance after consideration of the existing ICH guidelines for pharmaceuticals for human use entitled “Final Guideline on the Need for Long-Term Rodent Carcinogenicity Studies of Pharmaceuticals” and “Testing for Carcinogenicity of Pharmaceuticals,” which published in the Federal Register of March 1, 1996 (61 FR 8153), and February 23, 1998 (63 FR 8983), respectively. The draft guidance has been adapted for veterinary use by the VICH from the aforementioned guidelines regarding pharmaceuticals for human use. VICH also took into account the Organisation for Economic Cooperation and Development methodological guidelines and the current practices for evaluating the safety of veterinary drug residues in human food in the European Union, Japan, the United States, Australia, and New Zealand.

FDA and the VICH Safety Working Group will consider comments about the draft guidance document. Ultimately, FDA intends to adopt the VICH Steering Committee’s final guidance and publish it as future guidance. (Information collection is covered under OMB No. 0910–0117. Information collection also could be covered by OMB No. 0910–0032.)

III. Significance of Guidance

This draft document, developed under the VICH process, has been revised to conform to FDA’s good guidance practices regulation (21 CFR 10.115). For example, the document has been designated “guidance” rather than “guideline.” Because guidance documents are not binding, unless specifically supported by statute or regulation, mandatory words such as “must,” “shall,” and “will” in the original VICH documents have been substituted with “should.” Similarly, words such as “require” or “requirement” have been replaced by “recommendation” or “recommended,” as appropriate to the context. The draft guidance represents the agency’s current thinking on carcinogenicity testing for veterinary drug residues in human food. This guidance does not create or confer any requirement, related forms, and explanatory material may be obtained by contacting the Service Information

DEPARTMENT OF THE INTERIOR
Fish and Wildlife Service

Information Collection Submitted to the Office of Management and Budget (OMB) for Approval Under the Paperwork Reduction Act

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of information collection; request for comments.

SUMMARY: The collection of information listed below has been submitted to the Office of Management and Budget (OMB) for renewal under the provisions of the Paperwork Reduction Act. Copies of the specific information collection requirements, related forms, and explanatory material may be obtained by contacting the Service Information
management of migratory bird populations frequenting the United States and for the setting of hunting regulations that allow appropriate harvests that are within the guidelines that will allow for those populations’ well being. These responsibilities dictate the gathering of accurate data on various characteristics of migratory bird harvest of a geographic and temporal nature. Knowledge attained by determining harvests and harvest rates of migratory game birds is used to regulate populations (by promulgating hunting regulations) and to encourage hunting opportunity, especially where crop deprivations are chronic and/or lightly harvested populations occur. Based on information from harvest surveys, hunting regulations can be adjusted as needed to optimize harvests at levels that provide a maximum of hunting recreation while keeping populations at desired levels.

This information collection approval request combines three sets of surveys (the Waterfowl Hunter Survey, the Migratory Bird Hunter Survey, and the Parts Collection Survey. OMB Approval Number 1018–0015) and associated forms because they are interrelated and/or dependent upon each other.

The Waterfowl Hunter Survey, which estimates the harvest of ducks and geese, is based on Federal Duck Stamp sales. This survey asks people who purchase Federal Duck Stamps from randomly sampled Post Offices and other stamp vendors to complete and return a postcard (form 3–1823A) with their name and address. Hunters who complete and return the postcard are sent a postcard questionnaire (form 3–2056G) at the end of the hunting season, asking them to report their harvest of ducks and geese. Their responses provide estimates of the average harvest per hunter, which, combined with total Federal Duck Stamp sales, enables the Service to estimate the total harvest of ducks and geese.

The Migratory Bird Hunter Survey is based on the Migratory Bird Harvest Information Program, under which each State annually provides a list of all licensed migratory bird hunters in the State. Randomly selected migratory bird hunters are sent either a waterfowl questionnaire (form 3–2056F), a dove and band-tailed pigeon questionnaire (form 3–2056K), a woodcock questionnaire (form 3–2056L), or a snipe, rail, gallinule, and coot questionnaire (form 3–2056M) and are asked to report their harvest of those species. The resulting estimates of harvest are compared with the complete list of migratory bird hunters to provide estimates of the total harvest of those species. This survey will replace the Waterfowl Hunter Survey after it has been fully implemented in all States and comparisons of results with Waterfowl Hunter Survey results have been completed.

The Parts Collection Survey estimates the species, sex, and age composition of the harvest, and the geographic and temporal distribution of the harvest. Randomly selected successful hunters who responded to the Waterfowl Hunter Survey or the Migratory Bird Hunter Survey the previous year are asked to complete and return a postcard (forms 3–165A and C) if they are willing to participate in the Parts Collection Survey. Respondents are provided postage-paid envelopes before the hunting season and asked to send in a wing or the tail feathers from each duck, goose, or coot (form 3–165) they harvest, or a wing from each woodcock, band-tailed pigeon, snipe, rail, or gallinule (form 3–165B) they harvest. The wings and tail feathers are used to identify the species, age, and sex of the harvested sample. Respondents are also asked to report on the envelope the date and location (state and county) of harvest for each bird. Results of this survey are combined with harvest estimates from the Waterfowl Hunter Survey and the Migratory Bird Hunter Survey to provide species-specific national harvest estimates.

The combined results of these surveys enable the Service to evaluate the effects of season length, season dates, and bag limits on the harvest of each species, and thus help determine appropriate hunting regulations.


Description of Respondents: Individuals and households.

Total Annual Burden Hours: The reporting burden is estimated to average 2 minutes per respondent for the Migratory Bird Harvest Information Program, 8 minutes per respondent for the Waterfowl Hunter Survey, 4 minutes per respondent for the Migratory Bird Hunter Survey, and 50 minutes per respondent for the Parts Collection Survey.

The Total Annual Burden is 138,917 hours.

Total Annual Responses: About 3,600,000 individuals are expected to participate in the Migratory Bird Harvest Information Program. Recent Service experience indicates that about 30,000 hunters will respond to the Waterfowl Hunter Survey each year, about 11,400 hunters will respond to the
the purpose of enhancing the survival of
Recreation Area, Marin County, CA, for
San Francisco, Golden Gate National
controlled burning, on the Presidio of
invasive exotic plant removal and
Restoration and Enhancement, including
permit amendment to remove/reduce to
San Francisco, California.

et seq.

10(a)(1)(A) of the Endangered Species
endangered species pursuant to section

Pursuant to this renewal, comments
are invited on: (1) Whether the
Collection of information is necessary
of the functions of the agency, including
whether the information will have
practical utility; (2) the accuracy of the
agency’s estimate of the burden of the
Collection of information; (3) ways to
enhance the quality, utility, and clarity
of the information to be collected; and,
(4) ways to minimize the burden of the
Collection of information on
respondents. The information
collections in this program will be part
of a system of a record covered by the

Rebecca A. Mullin,
Information Collection Officer, Fish and
Wildlife Service.

[FR Doc. 01–21656 Filed 8–27–01; 8:45 am]

BILLING CODE 4310–55–M

DEPARTMENT OF THE INTERIOR
Fish and Wildlife Service
Endangered Species Permit Applications

AGENCY: Fish and Wildlife Service.
ACTION: Notice of receipt of permit applications.

SUMMARY: The following applicants have
applied for a scientific research permit
to conduct certain activities with
Endangered species pursuant to section
10(a)(1)(A) of the Endangered Species
Act of 1973, as amended (16 USC 1531
et seq.).

 Permit No. TE–027427.
Applicant: Jeff Alvarez, Sacramento,
California.

The applicant requests a permit to
take (capture, mark, radio-tag) Alameda
whipsnakes (Masticophis lateralis
euryxanthus) throughout the species
range in conjunction with surveys and
Ecological research for the purpose of
enhancing its survival.

 Permit No. TE–045733.
Applicant: Bureau of Land
Management, Burns District, Hines,
Oregon.

The applicant requests a recovery
permit to remove/reduce to possession
of the Malheur wire lettuce
(Stephanomeria malheurensis)
throughout the species’ range, in
conjunction with various recovery
activities as outlined in the Recovery
Plan, for the purpose of enhancing its
survival.

 Permit No. TE–045937.
Applicant: Alan Hastings, Ph.D. et al.,
Dept. of Environmental Studies,
University of California at Davis, Davis,
California.

The applicant requests a recovery
permit to take (harm, harass) salt marsh
harvest mouse (Reithrodontomys
raviventris) and California Clapper Rail
(Rallus longirostris obsoletus) within the
San Francisco estuary, Alameda and
San Mateo Counties, California, in
conjunction with an ecological study of
invasive cordgrass (Spartina alterniflora
x Spartina foliosa hybrids) in tidal
marshes, in order to ascertain how the
cordgrass is altering the ecosystem, for
the purpose of enhancing their survival.

 Permit No. TE–045994.
Applicant: U. S. Geological Service,
Biological Resources Division, Western
Ecological Research Center, San Diego
Field Station, San Diego, California.

The applicant requests a recovery
permit to take (conduct surveys,
capture, and collect for voucher
specimens) up to 20 each of unarmored
threespine stickleback (Gasterosteus
aculeatus), Santa Ana sucker
(Catostomus sanctaeanoe), and Mojave tui
chub (Gila bicolor mojavensis) and to
take (conduct surveys, capture, take
tissue samples, and salvage unlimited
numbers of dead, sick, or malformed)
desert slender salamander
(Batrachoseps aridus), California redlegged frog (Rana aurora), and the
California arroyo toad (Bufo
microscaphus californicus) on
Department of Interior lands in Los
Angeles, Riverside, and San Bernardino
Counties, California, in conjunction
with population demographic studies,
determining parasites present, and
genetic studies, for the purpose of
enhancing their survival.

DATES: Written comments on these
permit applications must be received
within 30 days of the date of publication
of this notice.

ADDRESSES: Written data or comments
should be submitted to the Chief,
Endangered Species, Ecological
Services, Fish and Wildlife Service, 911
NE. 11th Avenue, Portland, Oregon
97232–4181; Fax: (503) 231–6243.
Please refer to the respective permit
number for each application when
submitting comments. All comments
received, including names and
addresses, will become part of the
official administrative record and may
be made available to the public.

FOR FURTHER INFORMATION CONTACT:
Documents and other information
submitted with these applications are
available for review, subject to the
requirements of the Privacy Act and
Freedom of Information Act, by any
party who submits a written request for
a copy of such documents within 20
days of the date of publication of this
notice to the address above; telephone:
(503) 231–2063. Please refer to the
respective permit number for each
application when requesting copies of
documents.

Rowan W. Gould,
Acting Regional Director, Region 1, Portland,
Oregon.

[FR Doc. 01–21662 Filed 8–27–01; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR
Fish and Wildlife Service
Aquatic Nuisance Species Task Force
Western Regional Panel

AGENCY: Fish and Wildlife Service, Interior.
ACTION: Notice of workshop and
meeting.

SUMMARY: This notice announces a
meeting of the Aquatic Nuisance
Species (ANS) Task Force Western
Regional Panel and an Invasive Species
Screening Process workshop. The
meeting topics and workshop agenda
are identified in the SUPPLEMENTARY
INFORMATION.

DATES: The Invasive Species Screening
Process workshop will be held from
8:30 a.m. to 4:30 p.m., Tuesday,
September 25, 2001, and 9 a.m. to noon,
Wednesday, September 26, 2001. The