I. Background
On December 21, 2001, FDA issued a draft guidance document that outlined the agency’s current recommendations for effectively achieving a 5-log pathogen reduction in juice. The purpose of this draft guidance was to encourage processors who are not subject to the juice HACCP rule and who are performing a 5-log pathogen reduction to attain exemption from the warning label requirement to apply effective 5-log pathogen reduction treatments based upon FDA’s most current scientific understanding. In the Federal Register notice of December 21, 2001 (66 FR 65978), announcing the availability of the draft guidance document, FDA provided a 60-day period for comment on the draft guidance.

FDA received four comments in response to the December 21, 2001, draft guidance document. These comments represented the views of trade associations representing small farm family citrus operations, commercial fresh citrus shippers, juice and juice beverage producers and suppliers, and a public health group. The comments suggested changes or modifications to FDA’s revised recommendations for effectively achieving a 5-log pathogen reduction. FDA has considered the submitted comments and determined that the suggested changes or modifications are beyond the scope of this guidance or are not consistent with FDA’s current scientific understanding of pathogen reduction. On its own initiative, FDA is making certain editorial changes in the guidance.

II. Conclusion
The agency is adopting the revised recommendations for effectively achieving a 5-log pathogen reduction that is the basis for exempting juice products from the warning label requirement as presented in the draft guidance document. After considering the comments the agency received, the agency has determined that no changes are warranted.

The guidance entitled “Guidance for Industry: Exemptions from the Warning Label Requirement for Juice—Recommendations for Effectively Achieving a 5-Log Pathogen Reduction” is being issued as a level 1 guidance, consistent with FDA’s good guidance practices regulation (21 CFR 10.115). This guidance represents the agency’s current recommendations for effectively achieving a 5-log pathogen reduction in juice. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Comments
Interested persons may, at any time, submit written or electronic comments to the Dockets Management Branch (see ADDRESSES) on this guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. The guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access
Persons with access to the Internet may obtain the document at http://www.cfsan.fda.gov/~dms/guidance.html.
Dated: September 27, 2002.
Margaret M. Dotzel,
Associate Commissioner for Policy.
[FR Doc. 02–25341 Filed 10–4–02; 8:45 am]
BILING CODE 4160–01–S
SUPPLEMENTARY INFORMATION:

Endangered Species
The public is invited to comment on the following application(s) for a permit to conduct certain activities with endangered species. This notice is provided pursuant to Section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531, et seq.). Written data, comments, or requests for copies of these complete applications should be submitted to the Director (address above).

PRT–016881
Applicant: Hawthorn Corporation, Grayslake, Illinois
The applicant requests a permit to export, re-export, and re-import captive-born tigers (Panthera tigris) and future progeny born outside of the United States currently held by the applicant and any animals acquired in the United States by the applicant from worldwide locations to enhance the survival of the species through conservation education. This notification covers activities conducted by the applicant over a three year period.

PRT–062075
Applicant: The Hawthorn Corporation, Grayslake, IL
The applicant requests a permit to export, re-export, and re-import captive-born tigers (Panthera tigris) and future progeny born outside of the United States currently held by the applicant and any animals acquired in the United States by the applicant from worldwide locations to enhance the survival of the species through conservation education. This notification covers activities conducted by the applicant over a three year period.

PRT–062056
Applicant: Columbus Zoo and Aquarium, Powell, Ohio
The applicant requests a permit to transfer from the Miami Metro Zoo, Miami, Florida to the Columbus Zoo and Aquarium, Powell, Ohio, live Komodo island monitors (Varanus komodoensis) for the purpose of enhancement of the species through conservation for a period of five years.

PRT–050415
Applicant: Big Game Alaska Inc, Portage Glacier, AK
The applicant requests a permit to import 5 live captive-born wood bison from LaPrarie Woodland Bison Ranch, Whitehorse, Yukon Territory, Canada, for the purpose of enhancement of the survival of the species through propagation.

PRT–058654
Applicant: Oregon Graduate Institute, Beaverton, OR
The applicant requests a permit to import biological samples (trunk mucus) taken from two captive held Asian elephants (Elephas maximus) that were born in the wild. The elephants are current residents of the Auckland Zoo, Auckland, New Zealand, their samples will be used for scientific research purposes. This notification covers activities conducted by the applicant for a five-year period.

PRT–058905
Applicant: Oregon Graduate Institute, Beaverton, OR
The applicant requests a permit to export and re-import non-living museum specimens of endangered and threatened species of plants and animals previously accessioned into the permittee’s collection for scientific research. This notification covers activities conducted by the applicant for a five year period.

Marine Mammals
The public is invited to comment on the following application(s) for a permit to conduct certain activities with marine mammals. The application(s) was submitted to satisfy requirements of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 et seq.) and the regulations governing marine mammals (50 CFR Part 18). Written data, comments, or requests for copies of the complete applications or requests for a public hearing on these applications should be submitted to the Director (address above). Anyone requesting a hearing should give specific reasons why a hearing would be appropriate. The holding of such a hearing is at the discretion of the Director.

PRT–061116
Applicant: James L. Scull, Jr., Rapid City, SD
The applicant requests a permit to import a polar bear (Ursus maritimus) sport hunted from the Lancaster Sound polar bear population in Canada for personal use.

PRT–062382
Applicant: Eddie R. Simone, Ogden UT
The applicant requests a permit to import the sport-hunted trophy of one male bontebok (Damaliscus pygargus dorcas) culled from a captive herd maintained under the management program of the Republic of South Africa.