

Rockville, MD 20855, 301-827-7576, e-mail: tletonja@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce the differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use for several years to develop harmonized technical recommendations 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 recommendations 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; the U.S. 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 Confederation Mondiale de L'Industrie de la Sante Animale (COMISA). A COMISA representative also participates in the VICH Steering Committee meetings.

II. Final Guidance on Effectiveness of Anthelmintics

In the **Federal Register** of December 18, 2000 (65 FR 79113), FDA published the notice of availability of these VICH draft guidances, giving interested persons until January 17, 2001, to submit comments. FDA received no comments. The final guidance was submitted to the VICH Steering Committee. At a meeting held on June 28, 2001, the VICH Steering Committee endorsed the final guidances for industry, VICH GL20 and VICH GL21.

These final guidances, VICH GL20 and VICH GL21 should be read in conjunction with the "Effectiveness of Anthelmintics: General Recommendations (EAGR)" which was published in the **Federal Register** of April 6, 2001 (66 FR 18257). The guidances for feline and poultry are part of the EAGR, and the aim of these final guidances is to: (1) Be more specific for certain issues not discussed in the general guidance, (2) highlight differences with the EAGR on effectiveness data recommendations, and (3) give explanations for disparities with the EAGR.

The final level 1 guidance documents, developed under the VICH process, are consistent with FDA's good guidance practices regulation (21 CFR 10.115). These documents do not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternate method may be used as long as it satisfies the requirements of applicable statutes and regulations. Information collected is covered under OMB control number 0910-0032.

III. Comments

As with all of FDA's guidances, the public is encouraged to submit written or electronic comments with new data or other new information pertinent to these guidances. FDA will periodically review the comments in the docket and, where appropriate, will amend the guidances. The agency will notify the public of any such amendments through a notice in the **Federal Register**.

Interested persons may submit written or electronic comments to the Dockets Management Branch (see **ADDRESSES**) regarding these guidance documents at any time. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. The guidances and received comments are available for public examination in the Dockets Management Branch between 9

a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Persons with access to the Internet may obtain the documents at <http://www.fda.gov/cvm>.

Dated: June 17, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02-15896 Filed 6-24-02; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Receipt of Applications for Permit

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of applications for permit.

SUMMARY: The public is invited to comment on the following applications to conduct certain activities with endangered species and/or marine mammals.

DATES: Written data, comments or requests must be received by July 25, 2002.

ADDRESSES: 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 30 days of the date of publication of this notice to: U.S. Fish and Wildlife Service, Division of Management Authority, 4401 North Fairfax Drive, Room 700, Arlington, Virginia 22203; fax 703/358-2281.

FOR FURTHER INFORMATION CONTACT: Division of Management Authority, telephone 703/358-2104.

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-057065

Applicant: Perlegen Sciences, Inc., Mountain View, California

The applicant request a permit to import cell lines from chimpanzees (*Pan troglodytes*) born both in the wild and captivity from Gabon and the Netherlands, respectively, for the purpose of scientific research.

PRT-698170

Applicant: Field Museum of Natural History, Chicago, IL

The applicant request a renewal of their permit to export and re-import endangered and threatened specimens already accessioned into the permittee's collection for scientific research. Permittee also request authorization to salvage dead endangered and threatened specimens found in the field. This notice covers activities by permittee for a period of five years.

PRT-055366

Applicant: Newton G. Beasley, Hampton, GA

The applicant requests a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus dorcus*) culled from a captive herd maintained under the management program of the Republic of South Africa for the purpose of enhancement of the survival of the species.

PRT-057588

Applicant: Fred C. Harteis, Harrisburg, PA

The applicant requests a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus dorcus*) culled from a captive herd maintained under the management program of the Republic of South Africa for the purpose of enhancement of the survival of the species.

PRT-055829

Applicant: Zoological Society of San Diego, San Diego, CA

The applicant requests a permit to import one captive-born male Cabot's tragopan (*Tragopan caboti*) from The Old House Bird Gardens Ltd., in Reading, United Kingdom, for the purpose of enhancement of the survival of the species through captive propagation.

PRT-054186 and 054188

Applicant: Philadelphia Zoological Garden, Philadelphia, PA

The applicant requests a permit to import (PRT-054186) three captive-born male cheetah (*Acinonyx jubatus*) from the Cango Wildlife Ranch, Oudtshoorn, South Africa for the purpose of enhancement of the species through captive propagation and conservation education. The second request is for a permit to import (PRT-054188) biological samples from these same

three specimens for the purpose of veterinary screening prior to importation of the living specimens.

Marine Mammals and Endangered Species

The public is invited to comment on the following application for a permit to conduct certain activities with endangered marine mammals. The application was submitted to satisfy requirements of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), the Endangered Species Act of 1973, as amended (16 U.S.C. 1531, *et seq.*), and the regulations governing marine mammals (50 CFR part 18) and endangered species (50 CFR part 17). 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-051399

Applicant: Diedrich Beusse, University of Florida, Gainesville, FL

Permit Type: Take for scientific research.

Name and Number of Animals: Florida manatee (*Trichechus manatus*), 50 per year.

Summary of Activity to be

Authorized: The applicant requests a permit to conduct passive hydrophone listening to sounds made by manatees and playback vocalizations using a boat at idle speed in the Intracoastal Waterway waters of Florida.

Source of Marine Mammals: Wild animals in the waters of Florida.

Period of Activity: Up to 5 years, if issued.

Concurrent with the publication of this notice in the **Federal Register**, the Division of Management Authority is forwarding copies of the above applications to the Marine Mammal Commission and the Committee of Scientific Advisors for their review.

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-057467

Applicant: Robert E. Cogar, West Salem, OH

The applicant requests a permit to import a polar bear (*Ursus maritimus*) sport hunted from the Northern Beaufort Seapolar bear population in Canada for personal use.

PRT-057708

Applicant: Robert Talley, Norman, OK

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.

The U.S. Fish and Wildlife Service has information collection approval from OMB through March 31, 2004, OMB Control Number 1018-0093. Federal Agencies may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a current valid OMB control number.

Dated: May 31, 2002.

Monica Farris,

Senior Permit Biologist, Branch of Permits, Division of Management Authority.

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Receipt of Application for Approval

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of application for approval.

SUMMARY: The public is invited to comment on the following application for approval to conduct certain activities with birds that are protected in accordance with the Wild Bird Conservation Act of 1992. This notice is provided pursuant to Section 112(4) of the Wild Bird Conservation Act of 1992, 50 CFR 15.26(c).

DATES: Written data, comments, or requests for a copy of this complete application must be received by July 25, 2002.

ADDRESSES: Written data, comments, or requests for a copy of this complete