Submit written requests for single copies of these draft GFI documents to the Communications and Education Team (HFV–12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855. Send two self-addressed adhesive labels to assist that office in processing your requests. Copies of these draft guidance documents may be obtained on the Internet from the CVM Home Page (http://www.cvm.fda.gov).

FOR FURTHER INFORMATION CONTACT:

Regarding the GFI's: William G. Marnane, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–0678. E-mail: wmarnane@bangate.fda.gov.

Regarding VICH: Sharon R. Thompson, Center for Veterinary Medicine (HFV–3), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1798. E-mail: sthompso@bangate.fda.gov.

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

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

The VICH meetings are held under the auspices of the Office International des Épizooties (OIE). During the initial phase of the VICH, an OIE representative chairs the VICH Steering Committee. The VICH Steering Committee is composed of member representatives from the European Commission; the European Medicines Evaluation Agency; the European Federation of Animal Health; the U.S. Food and Drug Administration; the U.S. Department of Agriculture; the Animal Health Institute; the Japanese Veterinary Pharmaceutical Association; and the Japanese Ministry of Agriculture, Forestry and Fisheries.

Four observers are eligible to participate in the VICH Steering Committee: One representative from the Government of Australia/ New Zealand, one representative from the industry in Australia/ New Zealand, one representative from MERCOSUR (Argentina, Brazil, Uruguay and Paraguay), and one representative from Federacion Latino-Americana de la Industria para la Salud Animal. 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.

At a meeting held on August 20 and 21, 1997, the VICH Steering Committee agreed that the draft GFI documents entitled ''Validation of Analytical Procedures: Definition and Terminology'' and ''Validation of Analytical Procedures: Methodology'' should be made available for public comment. These draft GFI documents were prepared by the VICH Quality Working Group and are based on the ICH Guidelines (Q2A and Q2B) that have already been adopted by FDA for human pharmaceuticals. With one exception, the deletion of the text ''(e.g. metered dose inhalers)'' included in the ICH guideline Q2B, Section 3, the documents are identical.

The draft GFI document entitled, ''Validation of Analytical Procedures: Definition and Terminology,'' discusses the characteristics that should be considered during the validation of the analytical procedures included in an application for registration of veterinary medicinal products in the European Union, Japan, and the United States. This document pertaining to ''Definition and Terminology'' is not intended to cover testing requirements or procedures, rather it is intended to serve as a collection of terms and definitions. These common definitions such as ''analytical procedures,'' ''specificity,'' ''precision,'' ''accuracy,'' etc., are meant to bridge the differences that often exist among various compendia and requirements of the European Union, Japan, and the United States. The draft GFI document entitled, ''Validation of Analytical Procedures: Methodology,'' discusses common analytical procedures and provides guidance and recommendations on how to consider various validation characteristics for each analytical procedure. It also indicates the data that should be included in an application for registration. Comments about these draft GFI documents will be considered by the FDA and the VICH Quality Working Group. Ultimately, FDA intends to adopt the VICH Steering Committee's final guidelines and publish them as future GFI documents.

If finalized, these documents will represent current FDA thinking on characteristics for consideration during the validation of the analytical procedures included as part of applications. The draft GFI documents will not create or confer any rights for or on any person and will not operate to bind FDA or the public. Alternate approaches may be used if they satisfy the requirements of applicable statutes, regulations, or both.

Interested persons may, on or before March 30, 1998, submit to the Dockets Management Branch (address above) written comments on the draft guidance document. 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 brackets in the heading of this document and with the full title of the guidance document. The comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. After review of these comments, FDA will implement the guidance document with any appropriate changes. Thereafter, interested persons may submit written comment on the guidance document directly to the CVM Communications and Education Team (address above).

Dated: January 20, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–1848 Filed 1–26–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

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

ACTION: Notice.

SUMMARY: The collection of information described below will be submitted to OMB for approval under the provisions

of the Paperwork Reduction Act of 1995. Copies of specific information collection requirements, related forms and explanatory material may be obtained by contacting the Service Information Collection Clearance officer at the address and/or phone numbers listed below.

DATES: Comments must be submitted on or before March 30, 1998.

ADDRESSES: Comments and suggestions on specific requirements should be sent to the Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, MS 222 ARLSQ, 1849 C Street, NW, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Stephen R. Vehrs, Refuge Program Specialist, Division of Refuges, 703/358–2397.

SUPPLEMENTARY INFORMATION: The Service proposes to submit the following information collection clearance requirements to OMB for review and approval under the Paperwork Reduction Act of 1995, Pub. L. 104–13. Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of burden, including the validity of the methodology and assumptions used; (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 those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

The issuance of a Permit by the Fish and Wildlife Service for access to units of the National Wildlife Refuge System Administration Act (16 U.S.C. 668dd–668ee *et seq.*) as amended; the Refuge Recreation Act (16 U.S.C. 460K–3); the National Wildlife Refuge System Improvement Act of 1997 (Pub. L. 105–57); and as implemented by regulations in 50 CFR 25–38.

The information requested prior to issuing the Permit is required to obtain a benefit, and will assist the Service in administering System programs in accordance with the above statutory authorities. The Improvement Act requires that a wildlife dependent recreational use or any other uses of a refuge that, in the sound professional judgment of the Director, will not materially interfere with or detract from the fulfillment of the mission of the System or the purposes for which the refuge was established. The information is needed by the Service to make this determination before a permit can be issued.

The permit is required for any person entering a national wildlife refuge, unless otherwise provided under the provisions of 50 CFR, subchapter C. The permittee must abide by all the terms and conditions set forth in the permit.

Information collected in submitting an application for a permit, prior to issuing a permit, may be used to evaluate and conclude the eligibility of, or merely document, permit applicants. The Service will require the use of permits as a condition in new and revised regulations pursuant to the Refuge Improvement Act.

The Service will provide Special Use Permit forms as requested by interested citizens. The required written forms and/or verbal application information will be sued by the Service to ensure that the applicant is eligible to receive a Permit.

Title: United States Department of the Interior, Fish and Wildlife Service, Special Use Permit.

Bureau form number: 3–1383.

Frequency of collection: On occasion.

Description of respondents: Individuals or households; State, local, or Tribal governments; businesses or other for profit and not-for-profit institutions.

Number of respondents: 10,000.

Estimated completion time: The reporting burden for FWS Form 3–1383 (Special Use Permit) is estimated to be 30 minutes.

Burden estimate: 5,000 hours.

Dated: January 15, 1998.

Carolyn A. Bohan,

Acting Assistant Director for Refuges and Wildlife.

[FR Doc. 98–1862 Filed 1–26–98; 8:45 am]

BILLING CODE 4310–55–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Endangered and Threatened Species Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of application.

The following applicant has applied 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.*).

PRT–697830

Applicant: Assistant Regional Director, Ecological Services, Region 3, U.S. Fish and Wildlife Service, Fort Snelling, Minnesota.

The applicant requests to renew and amend his current permit to take the following species for scientific purposes and the enhancement of propagation or survival of the species in the wild in accordance with listing, recovery outlines, recovery plans, and/or other Service work for those species:

Mammals

bat, gray (*Myotis grisescens*)
bat, Indiana (*Myotis sodalis*)
bat, Ozark big-eared (*Plecotus townsendii ingens*)
wolf (*Canis lupus*)

Birds

eagle, bald (*Haliaeetus leucocephalus*)
falcon, peregrine (*Falco peregrinus*)
plover, piping (*Charadrius melodus*)
tern, least tern (*Sterna antillarum*)
warbler, Kirtland's (wood) (*Dendroica kirtlandii*)

Reptiles

snake, copperbelly water (northern population) (*Nerodia erythrogaster neglecta*)

Fish

cavefish, Ozark (*Amblyopsis rosae*)
darter, Niangua (*Etheostoma nianguae*)
madtom, Scioto (*Noturus trautmani*)
madtom, Neosho (*Noturus placidus*)
sturgeon, pallid (*Scaphirhynchus albus*)

Clams

clubshell (*Pleurobema clava*)
fanshell [*Cyprogenia stegaria* (=*irrorata*)]
mussel, ring pink (=golf stick pearly) (*Obovaria retusa*)
mussel, winged mapleleaf (*Quadrula fragosa*)
pearlymussel, cracking [*Hemistena* (=*Lastena*) *lata*]
pearlymussel, Curtis' [*Epioblasma* (=*Dysnomia*) *florentina curtisi*]
pearlymussel, Higgins' eye (*Lampsilis higginsi*)
pearlymussel, orange-foot pimple back (*Plethobasus cooperianus*)
pearlymussel, pink mucket [*Lampsilis* (=*abrupta*) *orbiculata*]
pearlymussel, purple cat's paw pearly mussel [*Epioblasma* (=Dysnomia) *obliquata obliquata* (=*sulcata sulcata*)]
pearlymussel, tubercled-blossom [*Epioblasma* (=*Dysnomia*) *torulosa torulosa*]
pearlymussel, turgid-blossom [*Epioblasma* (=*Dysnomia*) *turgidula*]
pearlymussel, white cat's paw [*Epioblasma* (=*Dysnomia*) *obliquata perobliqua*]
pearlymussel, white wartyback (*Plethobasus cicatricosus*)