became effective on November 10, 1989, but upon reviewing the application, FDA determined that VITREON should be regulated as a device, not a drug, and transferred the application to the Center for Devices and Radiological Health (CDRH) on April 13, 1990. The application was renumbered as an investigational device exemption (IDE) application (IDE G900050). FDA's initial determination of the regulatory review period for VITREON used April 13, 1990, as the effective date for the investigational application (63 FR 69633, December 17, 1998). However, the applicant later claimed in its request for a revision of the regulatory review period dated February 16, 1999 (Docket No. 98E–0489), that FDA's initial determination failed to take into account that the original IND became effective on November 10, 1989, because VITREON was initially considered to be a drug rather than a device. The applicant argued that FDA did not object to the November 10, 1989, submission and that November 10, 1989, should remain valid as the effective date of the investigational application because under both the IND and IDE regulations, an investigational application becomes effective 30 days after submission unless FDA notifies the applicant. Therefore, the applicant requested that the agency correct the date the investigational application became effective to November 10, 1989, the effective date of IND 33,858.

FDA reviewed its records and confirmed that IND 33,858 became effective on November 10, 1989. This application was subsequently transferred to CDRH because the agency decided to regulate the product as a device rather than a drug. Though the transfer of IND 33,858 to IDE G900050 occurred for administrative reasons the application was sufficiently complete to permit a substantive review. For this reason, FDA now accepts the date of November 10, 1989, submitted by the applicant in its request, as the date that the investigational application for VITREON became effective. Therefore, the applicable regulatory review period for the VITREON application is 2,883 days. Of this time, 757 days occurred during the testing phase of the regulatory review period, while 2,126 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date a clinical investigation involving this device was begun*: November 10, 1989. November 10, 1989, is the date that IND 33,858 became effective. The application was subsequently transferred to CDRH because FDA decided to regulate VITREON as a device rather than a drug. IND 33,858 was renumbered as IDE G900050 on April 13, 1990. This transfer occurred only for administrative reasons because IND 33,858, later designated IDE G900050, was sufficiently complete to permit a substantive review. For this reason, FDA accepts the date of November 10, 1989, as the date that a clinical investigation involving this device was begun.

2. *The date the application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e)*: December 6, 1991. FDA has verified the applicant's claim that the premarket approval application (PMA) for VITREON (PMA P910068) was initially submitted December 6, 1991.

3. *The date the application was approved*: September 30, 1997. FDA has verified the applicant's claim that PMA P910068 was approved on September 30, 1997.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,826 days of patent term extension.

Any interested person may petition FDA, on or before September 15, 2003, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch. Three copies of any information 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. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 3, 2003.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 03–6226 Filed 3–14–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4815–N–12]

Notice of Submission of Proposed Information Collection to OMB; Emergency Comment Request; Grant Application Standard Logic Model; Notice of Proposed Information Collection for Public Comment

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice of proposed information collection.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for emergency review and approval, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* March 31, 2003.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments must be received within fourteen (14) days from the date of this Notice. Comments should refer to the proposal by name/or OMB approval number) and should be sent to: Lauren Wittenberg, HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; e-mail: *Lauren_Wittenberg@omb.eop.gov;* fax: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, AYO, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; e-mail *Wayne_Eddins@HUD.gov;* telephone (202) 708–2374. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: This Notice informs the public that the U.S. Department of Housing and Urban Development (HUD) has submitted to OMB, for emergency processing, a proposed revision to the currently approved information collection for selecting applicants for the Fair Housing Initiatives (FHIP) Program grants.

This Notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the

accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Grant Application Standard Logic Model.

Description of Information Collection: Applicants of HUD Federal Financial Assistance will be required to indicate intended results and impacts. Grant recipients will be required to report against their baseline performance standards. This process will replace various, current progress reporting requirements and reduce reporting burdens. It will also promote greater emphasis on performance and results in grant programs.

OMB Control Number: 2535-pending.

Agency Form Numbers: HUD-pending.

Members of Affected Public: Individuals, Not-for-profit institutions, State, Local or Tribal Government, Business or other for-profit.

Estimation of the total numbers of hours needed to prepare the information collection including number of respondents, frequency of responses, and hours of response: This information collection is estimated to total one hour per submission. Of the estimated 11,000 grant applicant/recipients, approximately 6,600 report quarterly and 4,400 report annually. Total annual reporting burden is estimated at 30,800 hours.

Status of the Proposed Information Collection: New Collection.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35, as amended.

Dated: March 11, 2003.

Wayne Eddins,

Departmental Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 03–6321 Filed 3–14–03; 8:45 am]

BILLING CODE 4210–72–P

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 April 16, 2003.

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).

Applicant: Hawthorn Corporation, Grayslake, IL.

The applicant requests permits to export captive-born tigers (*Panthera tigris*) to worldwide locations for the purpose of enhancement of the species through conservation education. This notification covers the import of any potential progeny born while overseas. The permit numbers are 068349, Rook; 068350, Segal; 068351, Rajee; 068352, Kali; 068353, Pashawn; 068354, Maja; 068355, Sjiba; and 068356, Ice. This notification covers activities conducted by the applicant over a three years period.

PRT–066160

Applicant: Hawthorn Corporation, Grayslake, IL

The applicant requests a permit to export three captive-born tigers (*Panthera tigris*) to the Ouwehands Zoo, Rhenen, the Netherlands for the purpose of enhancement of the species through conservation education.

PRT–810465

Applicant: A.R. Galloway Exotic Ranch, Pearsall, TX

The applicant requests renewal of a permit to authorize interstate and foreign commerce, export, and cull of excess male barasingha (*Cervus duvauceli*) and Eld's deer (*Cervus eldi*) from their captive herd for the purpose of enhancement of the survival of the species. This notification covers activities conducted by the applicant over a five year period. Permittee must apply for renewal annually.

PRT–067307

Applicant: Shark Reef at Mandalay Bay, Las Vegas, NV

The applicant requests a permit to authorize the transfer in interstate commerce of three sub-adult, captive-bred Komodo monitors (*Varanus komodensis*) from the Miami Metrozoo, Miami, Florida, for the purpose of conservation education and enhancement of the survival of the species.

PRT–067128

Applicant: Smithsonian Institution, Washington, DC

The applicant requests a permit to import biological samples collected from maned wolves (*Chrysocyon brachyurus*) in Noel Kempff Mercado National Park, Bolivia for the purpose of scientific research to aid species conservation. This notification covers activities conducted by the applicant over a five year period. Permittee must apply for renewal annually.

PRT–001904

Applicant: U.S. Fish and Wildlife Service, Mexican Wolf Reintroduction Project, Region 2, Albuquerque, NM

The applicant requests renewal of a permit to import, export and reexport live Mexican or lobo wolves (*Canis lupus baileyi*) for breeding and reintroduction and to import biological samples for genetic studies for the enhancement of the propagation or survival of the species. This notification covers activities conducted by the applicant over a five year period.

Marine Mammals

The public is invited to comment on the following applications for a permit to conduct certain activities with marine mammals. The applications were 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