

**ADDRESSES:** Submit written requests for single copies of the guidance document entitled "Guidance for Industry: Public Health Issues Posed by the Use of Nonhuman Primate Xenografts in Humans" to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance document may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800, or by fax by calling the FAX Information System at 1-888-CBER-FAX or 301-827-3844.

See the **SUPPLEMENTARY**

**INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance document to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

Valerie A. Butler, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a guidance document entitled "Guidance for Industry: Public Health Issues Posed by the Use of Nonhuman Primate Xenografts in Humans." The document provides guidance to industry concerning: (1) The potential public health risks posed by nonhuman primate xenografts; (2) the need for further scientific research and evaluation of these risks, particularly infectious agents; and (3) the need for public discussion concerning these issues.

Concerns have arisen in the last few years about the potential infectious disease and public health risks associated with xenotransplantation, particularly nonhuman primate xenotransplantation. For the purpose of this guidance document, xenotransplantation is defined as any procedure that involves the use of live cells, tissues, or organs from a nonhuman animal source transplanted or implanted into a human, or used for ex vivo contact with human body fluids, cells, tissues, or organs that are subsequently given to a human recipient. In addition, defined for the purpose of this document, xenografts

include live cells, tissues, or organs from a nonhuman animal source used for xenotransplantation.

In developing the guidance, FDA considered numerous sources of information, including concerns raised in public comments to the "Draft Public Health Service (PHS) Guideline on Infectious Disease Issues in Xenotransplantation" (61 FR 49920, September 23, 1996) and concerns voiced by the scientific and lay community at the public workshops on xenotransplantation entitled "Cross-Species Infectivity and Pathogenesis" held on July 21 and 22, 1997, and "Developing U.S. Public Health Service Policy in Xenotransplantation" held on January 21 and 22, 1998, sponsored by PHS.

The approach outlined in the guidance document has been accepted by the other PHS agencies including the National Institutes of Health, the Centers for Disease Control and Prevention, and the Health Resources and Services Administration, as well as the Department of Health and Human Services Working Group on Xenotransplantation. The agency is aware that other species of animals have been used and are proposed as future sources of xenografts and may pose infectious disease risks. The public health issues raised by xenotransplantation, regardless of source animal species, will continue to receive scientific evaluation and discussion by appropriate Federal agencies and advisory committees.

The guidance document represents the agency's current thinking on the potential public health risks posed by the use of nonhuman primate xenografts in humans, and the consequent need for further scientific evaluation and public discussion of this issue. 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 requirement of the applicable statute, regulations, or both. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

**II. Comments**

The agency notes that measures taken during the production of some nonhuman primate xenografts products, such as extensive preclinical xenotransplant product testing for infectious agents, genetic engineering, enclosure of the product in a

semipermeable barrier, and/or the use of well-characterized cell lines which have been handled in a manner to avoid the introduction of new pathogens, could potentially provide greater control of infectious disease risks. The agency specifically solicits comments on the potential for such measures, alone or in combination, to substantially reduce the risks posed by nonhuman primate xenotransplantation. The agency is soliciting public comment but is implementing this guidance document immediately because of the public health concerns related to the use of live cells, tissues and organs from nonhuman primate xenografts in humans.

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this guidance document. Written comments may be submitted at any time, however, comments should be submitted by July 6, 1999, to ensure adequate consideration in preparation of a revised document, if warranted. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

**III. Electronic Access**

Persons with access to the Internet may obtain the document using the World Wide Web (WWW). For WWW access, connect to CBER at "http://www.fda.gov/cber/guidelines.htm".

Dated: March 30, 1999.

**William K. Hubbard,**

*Acting Deputy Commissioner for Policy.*

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**DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**

**[Docket No. FR-4442-N-09]**

**Notice Of Proposed Information Collection for Public Comment**

**AGENCY:** Office of the Assistant Secretary for Policy Development and Research, HUD.

**ACTION:** Notice.

**SUMMARY:** The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for

review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

**DATES:** Comments are due June 7, 1999.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Reports Liaison Officer, Office of Policy Development & Research, Department of Housing and Urban Development, 451-7th Street, SW, Room 8226, Washington, DC 20410-6000.

**FOR FURTHER INFORMATION CONTACT:** Laurent V. Hodes or Robert W. Gray, Office of Policy Development and Research, Department of Housing and Urban Development, 451 7th St., SW, Room 8154, Washington, DC 20410-6000, telephone 202-708-5537 extension 5736 or 5732. (This is not a toll-free number.) A copy of the proposed forms and other available documents to be submitted to OMB may be obtained from Mr. Hodes or Mr. Gray.

**SUPPLEMENTARY INFORMATION:** The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This notice is soliciting comments from members of the public and affected 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 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:* Reinstatement, "Customer-Survey of Households Living in Federally Assisted Units," OMB Control Number: 2528-0170, Expired 04/30/98.

*Description of the Need for the Information and Proposed Use:*

HUD recently developed and tested a cost-effective mail survey instrument for assessing resident satisfaction with, and rating of, housing units assisted through HUD programs. This survey, which

elicits renters' ratings of their housing, provided high response rates and high levels of agreement with independent condition ratings by professional inspectors. HUD plans to implement this survey as an ongoing tool to assess customer ratings of housing assisted through the Section 8 Certificate and Voucher programs. For limited evaluative or comparative purposes, HUD may also use this survey to assess resident ratings of other Federal housing assistance programs.

This survey will provide feedback to help local housing agencies improve their Section 8 programs, and will help HUD to focus its monitoring and technical assistance resources where program performance most needs improvement. It will also provide HUD's policy, budget, and program managers with improved measures for tracking national housing conditions over time.

*Members of the affected public:* Households receiving assistance from the Section 8 Certificate or Voucher Programs.

*Estimation of the total number of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response:* Information will be collected by an annual mail survey of 267,000 of the 1.4 million households who are assisted through the Section 8 Certificate and Voucher programs. The survey will take approximately 15 minutes to complete for an annual total of 66,750 hours of respondent burden. Because the survey will be administered to a sample of households, and because of turnover in the Section 8 programs, most households will not be asked to complete the survey two years in a row.

*Status of the proposed information collection:* The original information collection was suspended at the termination of HUD's pilot testing. This proposed reinstatement is pending submission to the Office of Management and Budget (OMB) for review and clearance.

**Authority:** Sec. 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: March 29, 1999.

**Lawrence L. Thompson,**  
General Deputy Assistant Secretary for Policy Development and Research.

[FR Doc. 99-8399 Filed 4-5-99; 8:45 am]

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## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

#### Receipt of an Application for an Incidental Take Permit for Construction on a Single-Family Lot, in Volusia County, FL

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice.

**SUMMARY:** Linda B. Walters (Applicant), is seeking an incidental take permit (ITP) from the Fish and Wildlife Service (Service), pursuant to section 10(a)(1)(B) of the Endangered Species Act of 1973 (Act), as amended. The ITP would authorize incidental take of the Florida scrub-jay (*Aphelocoma coerulescens*) and the eastern indigo snake (*Drymarchon corais couperi*), both threatened species, on a single family lot for a period of twenty (20) years. The proposed taking is incidental to land clearing and other activities associated with the construction of a single family home on a .685-acre lot in Volusia County, Florida (Project). Surveys on the Project site indicate that one family of Florida scrub-jays occupies the Project site. No eastern indigo snakes have been reported on the property; however, the Applicant has requested that the eastern indigo snake be included in the ITP based on the chance that this species could occur on the project site. A description of the mitigation and minimization measures outlined the Applicant's Habitat Conservation Plan (HCP) to address the effects of the Project to the protected species is as described further in the **SUPPLEMENTARY INFORMATION** section below.

Further, the Service has determined that the Applicant's HCP qualifies as a "low-effect" HCP as defined by the Service's Habitat Conservation Planning Handbook (November 1996). The Service has further determined that approval of the HCP qualifies as a categorical exclusion under the National Environmental Policy Act (NEPA), as provided by the Department of Interior Manual (516 DM 2, Appendix 1 and 516 DM 6, Appendix 1).

Copies of the Applicant's HCP may be obtained by making a request to the Regional Office (see **ADDRESSES**). Requests must be in writing to be processed. This notice is provided pursuant to Section 10 of the Act and NEPA regulations (40 CFR 1506.6).

The Service specifically requests information, views, opinions from the public via this Notice, including information regarding the adequacy of