

three responses) will contain information that the sponsor asserts is exempt from disclosure.

Based on FDA experience and information provided to the agency by industry, FDA estimates that approximately 700 hours on average

would be needed for the preparation of a fully releasable submission and 1,400 hours for that of a submission that contains information the respondent asserts is exempt from disclosure, including the time FDA expects it will take a sponsor to submit an electronic

version of the package. The total estimated burden hours under the draft guidance are 7,700. FDA invites comments on the analysis of information collection burdens.

FDA estimates the burden of this information collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN ¹

Submissions	No. of respondents	No. of responses per respondent	Total annual responses	Hours per response	Total hours
Fully releasable submissions	4	1.25	5	700	3,500
Submissions that contain material that is claimed to be exempt from disclosure	2	1.5	3	1,400	4,200
Total	6		8		7,700

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

III. Comments

This draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document and on the collection of information. Submit written comments to ensure adequate consideration in preparation of the final document by May 21, 2001. 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 brackets in the heading of this document. A copy of the 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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/cber/guidelines.htm>.

Dated: March 9, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01-6937 Filed 3-20-01; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4579-FA-05]

Announcement of Funding Award—Fiscal Year 2000, Office of Healthy Homes and Lead Hazard Control, National Center for Lead Safe Housing

AGENCY: Office of Healthy Homes and Lead Hazard Control, HUD.

ACTION: Announcement of funding award.

SUMMARY: In accordance with section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989, this announcement notifies the public of a funding decision made by the Department to the National Center for Lead Safe Housing. This announcement contains the name and address of the awardee and the amount of the award.

FOR FURTHER INFORMATION CONTACT: Joey Zhou, Department of Housing and Urban Development, 451, Seventh Street, SW, Washington, DC, 20410, telephone (202) 755-1785, ext. 153 (this is not a toll-free number). Hearing- or speech-impaired individuals may access this number by calling the Federal Information Relay Service TTY at 1-800-877-8339.

SUPPLEMENTARY INFORMATION: The Lead Hazard Control grant for the National Center for Lead Safe Housing was issued pursuant to Pub. L. 102-550, Title X; FY 2000 budget; House Appropriations Committee Report 2684-21.

This notice announces the award of \$750,000 to the National Center for Lead Safe Housing which will be used to provide funding to examine and disseminate innovative, lower cost hazard control and educational strategies and provide technical assistance for integrating lead safety in HUD programs.

The Catalog of Federal Domestic Assistance number for this program is 14.900.

In accordance with section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989 (103 Stat. 1987, 42 U.S.C. 3545), the Department is publishing the name, address, and amount of the award as follows: National Center for Lead Safe Housing,

10227 Wincopin Circle, Suite 205, Columbia, MD 21044, Amount of Grant: \$750,000.

Dated: March 13, 2001.

David E. Jacobs,

Acting Director, Office of Healthy Homes and Lead Hazard Control.

[FR Doc. 01-6933 Filed 3-20-01; 8:45 am]

BILLING CODE 4210-01-P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

Advisory Committee on Water Information; Notice of Reestablishment

This notice is published in accordance with section 9 (a) (2) of the Federal Advisory Committee Act (Pub. L. 92-463), 5 U.S.C. App. (1988). Following consultation with the General Services Administration, notice is hereby given that the Secretary of the Interior is reestablishing the Advisory Committee on Water Information (ACWI). OMB Memorandum 92-01 dated December 10, 1991, designated the U.S. Geological Survey (USGS) as the lead agency for the Water Information Coordination Program (WICP) and also designated all other Federal organizations using water resources information to assist the USGS in ensuring the implementation of an effective WICP.

The purpose of the Committee is to represent the interests of water-information users and professionals in advising the Federal Government on Federal water-information programs and their effectiveness in meeting the Nation's water-information needs. Member organizations will help to foster communications between the Federal and non-Federal sectors on sharing water information.

Membership represents a wide range of water resources interests and functions. Representation of the ACWI includes all levels of government—Tribes, public interest groups, academia, private industry, non-profit and professional organizations. Member organizations designate their representatives and alternatives. Membership is limited to a maximum of 35 organizations.

The Committee will function solely as an advisory body, and in compliance with the provisions of the Federal Advisory Committee Act. The Charter will be filed under the Act, 15 days from the date of publication of this notice.

Further information regarding the ACWI may be obtained from the Director, USGS, Department of the Interior, 12201 Sunrise Valley Drive, Reston, Virginia 20192. Certification of reestablishment is published below.

Certification

I hereby certify that the reestablishment of the Advisory Committee on Water Information is necessary and in the public interest in connection with the performance of duties by the Department of the Interior mandated pursuant to the OMB Memorandum 92-01.

Dated: March 12, 2001.

Gale A. Norton,

Secretary of the Interior.

[FR Doc. 01-7053 Filed 3-20-01; 8:45 am]

BILLING CODE 4310-YZ-M

DEPARTMENT OF THE INTERIOR

FISH AND WILDLIFE SERVICE

Notice of Availability of an Environmental Assessment/Habitat Conservation Plan and Receipt of an Application for a Permit for the Incidental Take of the Houston Toad (*Bufo houstonensis*) During Construction of One Single-Family Residence on Approximately 0.5 Acres of a 6.631-Acre Property on Lake Mist Road, Bastrop County, Texas

SUMMARY: Scott and Linda Bell (Applicant) have applied to the U.S. Fish and Wildlife Service (Service) for an incidental take permit pursuant to Section 10(a) of the Endangered Species Act (Act). The Applicant has been assigned permit number TE-039440-0. The requested permit, which is for a period of 5 years, would authorize the incidental take of the endangered Houston toad (*Bufo houstonensis*). The proposed take would occur as a result of the construction and occupation of one single-family home on

approximately 0.5 acres of a 6.631-acre property on Lake Mist Road, Bastrop County, Texas.

The Service has prepared the Environmental Assessment/Habitat Conservation Plan (EA/HCP) for the incidental take application. A determination of jeopardy to the species or a Finding of No Significant Impact (FONSI) will not be made until at least 30 days from the date of publication of this notice. This notice is provided pursuant to section 10(c) of the Act and National Environmental Policy Act regulations (40 CFR 1506.6).

DATES: Written comments on the application should be received on or before April 20, 2001.

ADDRESSES: Persons wishing to review the application may obtain a copy by writing to the Regional Director, U.S. Fish and Wildlife Service, P.O. Box 1306, Room 4201, Albuquerque, New Mexico 87103. Persons wishing to review the EA/HCP may obtain a copy by contacting Clayton Napier, U.S. Fish and Wildlife Service, 10711 Burnet Road, Suite 200, Austin, Texas 78758 (512/490-0057). Documents will be available for public inspection by written request, by appointment only, during normal business hours (8:00 to 4:30) at the U.S. Fish and Wildlife Service, Austin, Texas. Written data or comments concerning the application and EA/HCP should be submitted to the Supervisor, U.S. Fish and Wildlife Service, Austin, Texas, at the above address. Please refer to permit number TE-039440-0 when submitting comments.

FOR FURTHER INFORMATION CONTACT:

Clayton Napier at the above U.S. Fish and Wildlife Service, Austin Office.

SUPPLEMENTARY INFORMATION: Section 9 of the Act prohibits the "taking" of endangered species such as the Houston toad. However, the Service, under limited circumstances, may issue permits to take endangered wildlife species incidental to, and not the purpose of, otherwise lawful activities. Regulations governing permits for endangered species are at 50 CFR 17.22.

Applicant: Scott and Linda Bell plan to construct a single-family residence on approximately 0.5 acres of a 6.631-acre property on Lake Mist Road, Bastrop County, Texas. This action will eliminate 0.5 acres or less of Houston toad habitat and result in indirect impacts within the lot. The Applicants propose to compensate for this incidental take of the Houston toad by providing \$2,000.00 to the National Fish and Wildlife Foundation for the specific purpose of land acquisition and

management within Houston toad habitat, as identified by the Service.

Geoffrey L. Haskett,

*Acting Regional Director, Region 2
Albuquerque, New Mexico.*

[FR Doc. 01-6954 Filed 3-20-01; 8:45 am]

BILLING CODE 4510-55-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Issuance of Permit for Incidental Take of Threatened Species for the Harding Property, Douglas County, CO

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of issuance of permit for incidental take of endangered species.

SUMMARY: On November 22, 2000, a notice was published in the **Federal Register** (Vol. 65 No. 226 FR 70359), that an application had been filed with the U.S. Fish and Wildlife Service (Service) by Susan K. Harding, Douglas County, Colorado, for a permit to incidentally take, pursuant to section 10(a)(1)(B) of the Endangered Species Act of 1973 (16 U.S.C. 1539), as amended (Act), Preble's meadow jumping mouse (*Zapus hudsonius preblei*) on the Harding Property, 101 Allis Ranch Road, Sedalia, Colorado 80135, pursuant to the terms of the Environmental Assessment/Habitat Conservation Plan.

Notice is hereby given that on March 1, 2001, as authorized by the provisions of the Act, the Service issued a permit (PRT-TE035844-0) to the above named party subject to certain conditions set forth therein. The permit was granted only after the Service determined that it was applied for in good faith, that granting the permit will not be to the disadvantage of the threatened species, and that it will be consistent with the purposes and policy set forth in the Act, as amended.

Additional information on this permit action may be requested by contacting the Colorado Field Office, 755 Parfet Street, Suite 361, Lakewood, Colorado 80215, telephone (303) 275-2370 between the hours of 7:00 am and 4:30 pm weekdays.

Dated: March 8, 2001.

Ralph O. Morgenweck,

Regional Director, Region 6.

[FR Doc. 01-6976 Filed 3-2-01; 8:45 am]

BILLING CODE 4310-55-M