

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 The total estimated burden hours under the draft guidance are 7,700.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 <sup>1</sup>

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

<sup>1</sup> 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This draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document and on the collection of information.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.