

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

**FOR FURTHER INFORMATION CONTACT:**

Beth Duvall-Miller (CDER), Center for Drug Evaluation and Research (6411), Food and Drug Administration, 10903 New Hampshire Ave., bldg. 22, rm. 6466, Silver Spring, MD 20993, 301-796-0700; or

Robert Yetter (CBER), Center for Biologics Evaluation and Research (HFM-25), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301-827-0373.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a guidance for industry entitled "Reports on the Status of Postmarketing Study Commitments—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997." Section 506B ("Reports of Postmarketing Studies") of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 356b) provides FDA with additional authority for monitoring the progress of postmarketing studies that drug and biological applicants have made a commitment to conduct. Postmarketing studies are those studies conducted after approval to gather additional information about the safety, efficacy, or optimal use of the approved drug or biological product.

Under section 506B(a) of the act, an applicant who has entered into an agreement with FDA to conduct a postmarketing study is required to provide the agency with an annual report on the status of the study until FDA notifies the applicant, in writing, that all postmarketing study commitments established under the application(s) have either been fulfilled or have been released. The annual report must address the progress of the study or the reasons for the failure of the applicant to conduct the study. Section 506B(c) of the act directs FDA to develop and publish annually in the **Federal Register** a report on the status of postmarketing studies that applicants have made a commitment to conduct and for which status reports have been submitted. In the **Federal Register** of October 30, 2000 (65 FR 64607), the agency published a final rule to implement section 506B of the act. The final rule makes several changes to the existing regulations for approved human drugs and licensed biological products.

In the **Federal Register** of April 4, 2001 (66 FR 17912), FDA published a

notice announcing the availability of a draft guidance for industry entitled "Reports on the Status of Postmarketing Studies—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997." The notice gave interested persons an opportunity to submit comments by July 3, 2001. A number of comments were received in the docket for the 2001 draft guidance. After careful consideration of the comments, the draft guidance was revised. In addition to edits to improve clarity, the substantive changes made to the draft guidance included an update of the types of postmarketing studies currently required by FDA and an improved explanation of the procedures for establishing and revising study schedules.

This guidance is intended to provide information on the following: (1) Procedures concerning the submission of postmarketing study commitment status reports; (2) the content and format of a postmarketing study commitment status report; (3) timeframes for FDA's review of postmarketing study commitment final study reports; and (4) information about postmarketing study commitments that will be available to the public. This guidance applies to postmarketing study commitments for approved human drug products and licensed biological products that meet the definition of "drug" under the act. It does not apply to biological products that meet the definition of medical "device" under the act; or to veterinary drug products, which will be addressed separately.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the submission of postmarketing study commitment reports for approved human drug or licensed biological products. 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 requirements of the applicable statutes and regulations.

**II. Paperwork Reduction Act of 1995**

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR 314.81 and 601.70 have been approved under OMB control numbers 0910-0001 and 0910-0433.

**III. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Division of Dockets Management 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 either <http://www.fda.gov/cder/guidance/index.htm>, <http://www.fda.gov/cber/guidelines.htm>, or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: February 7, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**

[Docket No. FR-5041-N-03]

**Notice of Proposed Information Collection: Comment Request; Builder's Certification of Plans, Specifications, and Site**

**AGENCY:** Office of the Assistant Secretary for Housing-Federal Housing Commissioner, 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 Due Date:* April 17, 2006.

**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: Lillian Deitzer, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, SW., L'Enfant Plaza Building, Room 8001, Washington, DC 20410 or [Lillian\\_Deitzer@hud.gov](mailto:Lillian_Deitzer@hud.gov).

**FOR FURTHER INFORMATION CONTACT:** Margaret Burns, Director, Office of

Single Family Program Development, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410, telephone (202) 708-2121 (this is not a toll free number) for copies of the proposed forms and other available information.

**SUPPLEMENTARY INFORMATION:** The Department is submitting 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 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 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:* Builder's Certification of Plans, Specifications, and Site.

*OMB Control Number, if applicable:* 2502-0496.

*Description of the need for the information and proposed use:* HUD requires the builder to complete the certification (form HUD-92541) noting adverse site/location factor(s) of the property, including Floodplains. This certification is necessary so that HUD does not insure a mortgage on property that poses a risk to health or safety of the occupant.

*Agency form numbers, if applicable:* HUD-92541.

*Estimation of the total numbers of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response:* The estimated total number of hours needed to prepare the information collection is 15,744; the number of respondents is approximately 1,600 generating approximately 65,600 annual responses; the frequency of response is on occasion; and the estimated time needed to prepare the response varies from 5 minutes to 10 minutes.

*Status of the proposed information collection:* This is an extension of a currently approved collection.

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

Dated: February 9, 2006.

**Frank L. Davis,**

*General Deputy Assistant Secretary for Housing-Deputy Federal Housing Commissioner.*

[FR Doc. E6-2183 Filed 2-15-06; 8:45 am]

**BILLING CODE 4210-27-P**

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## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

#### Draft National Bald Eagle Management Guidelines

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

**ACTION:** Notice of availability.

**SUMMARY:** This notice advises the public that draft National Bald Eagle Management Guidelines are available for public review. Comments and suggestions are requested.

**DATES:** We will accept written comments on the Draft National Bald Eagle Management Guidelines until May 17, 2006.

**ADDRESSES:** Copies of the Draft National Bald Eagle Management Guidelines can be obtained by writing to U.S. Fish and Wildlife Service, Division of Migratory Bird Management, 4401 North Fairfax Drive, Mail Stop MBSP-4107, Arlington, VA 22203. The draft guidelines may also be obtained via the Internet at: <http://www.fws.gov/migratorybirds/BaldEagle.htm>. Written comments can be sent to the mailing address above, or e-mailed to [BaldEagle\\_ManagementGuidelines@fws.gov](mailto:BaldEagle_ManagementGuidelines@fws.gov). All comments must include the name and full mailing address of the person submitting the comments. All comments received, including names and addresses, will become part of the public record. You may inspect comments by appointment during normal business hours at the address above.

**FOR FURTHER INFORMATION CONTACT:**

Eliza Savage, Division of Migratory Bird Management, (see **ADDRESSES** section); or via e-mail at: [Eliza\\_Savage@fws.gov](mailto:Eliza_Savage@fws.gov); telephone: (703) 358-2329; or facsimile: (703) 358-2217.

**SUPPLEMENTARY INFORMATION:** The U.S. Fish and Wildlife Service has proposed to remove the bald eagle from the list of threatened species under the Endangered Species Act (16 U.S.C. 1531 *et seq.*) (see our re-opening of the public comment period on the proposed rule to delist the bald eagle, published separately in this part of today's **Federal**

**Register**). If the bald eagle is delisted, the Bald and Golden Eagle Protection Act (BGEPA) (16 U.S.C. 668-668d) will become the primary law protecting bald eagles. BGEPA prohibits take of bald and golden eagles and provides a statutory definition of "take" that includes "disturb."

To provide guidance to land managers, landowners, and others, the Service has developed draft National Bald Eagle Management Guidelines. In the event the bald eagle is delisted, the guidelines will provide the public with information on how to avoid disturbing bald eagles. Secondly, the guidelines include recommended additional practices that can benefit bald eagles. The draft guidelines are based on the definition of "disturb" that we are making available for public comment in a proposed rule published separately in this part of today's **Federal Register**.

Dated: October 31, 2005.

**H. Dale Hall,**

*Director.*

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## DEPARTMENT OF THE INTERIOR

### Bureau of Indian Affairs

#### Advisory Board for Exceptional Children

**AGENCY:** Bureau of Indian Affairs, Interior.

**ACTION:** Notice of meeting.

**SUMMARY:** In accordance with the Federal Advisory Committee Act, the Bureau of Indian Affairs announces that the Advisory Board for Exceptional Children will hold its next meeting in Casa Blanca, Arizona. The purpose of the meeting is to discuss the impact of the Individuals with Disabilities Education Improvement Act Amendments of 2004 on Indian children with disabilities.

**DATES:** The Board will meet Sunday, March 19, 2006, from 6 p.m. to 9 p.m.; Monday, March 20, 2006, from 7:30 a.m. to 4:30 p.m.; and, Tuesday, March 21, 2006, from 8 a.m. to 4 p.m. (MST).

**ADDRESSES:** The meetings will be held at the Francisco Grande Hotel and Golf Resort, 26000 West Gila Bend Highway, Casa Blanca, Arizona. Written statements may be submitted to Mr. Edward F. Parisian, Director, Office of Indian Education Programs, Bureau of Indian Affairs, 1849 C Street, NW., Mail Stop 3609-MIB, Washington, DC 20240; Telephone (202) 208-6123; Fax (202) 208-3312.