800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1512) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

To receive a hard copy or electronic copy of ''Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices,'' you may either send a fax request to 301–443–8818, or send an e-mail request to *gwa@cdrh.fda.gov*. Please use the document number (1512) to identify the guidance you are requesting.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information, including text, graphics, and files that may be downloaded to a personal computer with Internet access. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120). The labeling provisions addressed in the guidance have been approved by OMB under OMB control number 0910–0485.

V. 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 any 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 4, 2005.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 05–8468 Filed 4–27–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1999D–1540] (formerly Docket No. 99D–1540)

Guidance for Reviewers on Evaluating the Risks of Drug Exposure in Human Pregnancies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for reviewers entitled ''Reviewer Guidance: Evaluating the Risks of Drug Exposure in Human Pregnancies.'' This guidance is intended to help FDA staff evaluate human fetal outcome data generated after medical product exposures during pregnancy. The goal of such evaluations is to assist in the development of product labeling that is useful to medical care providers when they care for patients who are pregnant or planning pregnancy. The review of human pregnancy drug exposure data and assessment of fetal risk (or lack of risk) requires consideration of human embryology and teratology, pharmacology, obstetrics, and epidemiology. Consequently, FDA staff also are encouraged to consult with experts in these fields, as appropriate.

The guidance announced in this document finalizes the draft guidance entitled ''Guidance for Reviewers: Evaluation of Human Pregnancy Outcome Data'' announced in the **Federal Register** of June 4, 1999.

DATES: Submit written comments or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or 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 either office in processing your requests. The guidance may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Dianne L. Kennedy, Center for Drug Evaluation and Research (HFD–020), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5162, e-mail: *kennedyd@cder.fda.gov*, or Toni M. Stifano, Center for Biologics Evaluation and Research (HFM–602), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6190, e-mail: *stifano@cber.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for reviewers entitled ''Reviewer Guidance: Evaluating the Risks of Drug Exposure in Human Pregnancies.'' The guidance provides FDA staff with critical factors to consider when evaluating data on the effects of drug exposure during human pregnancies. It also describes the sources of human data on gestational drug exposures and available resources for more information. The guidance is intended to provide FDA reviewers with a standardized and scientific approach to the evaluation of the effects of human gestational drug exposures.

In the **Federal Register** of June 4, 1999 (64 FR 30040), FDA announced the availability of a draft version of the guidance entitled ''Guidance for Reviewers: Evaluation of Human Pregnancy Outcome Data.'' When the draft guidance was published, FDA requested comments on the document. Three public comments were received. The comments were supportive of the agency's efforts to provide this type of guidance. However, the comments also recommended revision/clarification of several sections, as well as provided a number of suggestions of a more technical nature. Additionally, comments regarding the draft guidance raised the following three broader concerns: (1) That it contained redundant information already presented in the guidance for industry entitled ''Establishing Pregnancy Exposure Registries'' (draft: 64 FR

30040, June 4, 1999; final: 67 FR 59528, September 23, 2002), (2) that it focused too much on general epidemiologic issues, and (3) that it overemphasized the utility of pregnancy registries without a balanced review of the strengths of other data sources for evaluating pregnancy outcome data.

Based on these comments and discussions with FDA's Pregnancy Labeling Subcommittee of the Advisory Committee for Reproductive Health Drugs on June 3, 1999 (64 FR 23340, April 30, 1999), and March 28 and 29, 2000 (65 FR 10811, February 29, 2000), and with other interested parties, the draft guidance has been revised and finalized. The name has been changed from ''Evaluating Pregnancy Outcome Data'' to ''Evaluating the Risks of Drug Exposure in Human Pregnancies'' to reflect more accurately the information contained in the guidance.

This guidance is being issued consistent with FDA's good guidance practice regulation (21 CFR 10.115). The guidance represents the agency's current thinking with regard to evaluating data on the effects of drug exposure during pregnancy. 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. 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 any 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. 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: April 19, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–8466 Filed 4–27–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: The National Health Service Corps (NHSC) Recruitment and Retention Assistance Application (OMB No. 0915–0230)—Revision

The National Health Service Corps (NHSC) of the Bureau of Health Professions (BHPr), HRSA, is committed to improving the health of the Nation's underserved by uniting communities in need with caring health professionals and by supporting communities' efforts to build better systems of care.

The Application for NHSC Recruitment and Retention Assistance submitted by sites or clinicians, requests information on the practice site, sponsoring agency, recruitment contact, staffing levels, service users, charges for services, employment policies, and fiscal management capabilities. Assistance in completing the application may be obtained through the appropriate State Primary Care Offices, State Primary Care Associations and NHSC Contractors. The information on the application is used for determining eligibility of sites and to verify the need for NHSC providers. Sites must apply once every three years.

Estimates of annualized reporting burden are as follows:

Type of report	Number of respondents	Response per respondents	Hours per response	Total burden hours
Application	2900	1	.5	1450

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: John Kraemer, Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: April 22, 2005.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 05–8509 Filed 4–27–05; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Training in Primary Care Medicine and Dentistry; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Advisory Committee on Training in Primary Care Medicine and Dentistry.

Date and Time: May 19, 2005, 8:30 a.m.–4:30 p.m. and May 20, 2005, 8 a.m.–2 p.m.

Place: The Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, Maryland 20814.

Status: The meeting will be open to the public.

Purpose: The Advisory Committee provides advice and recommendations on a broad range of issues dealing with programs and activities authorized under section 747 of the Public Health Service Act as amended by The Health Professions Education Partnership Act of 1998, Public Law 105–392. At this meeting the Advisory Committee will continue to work on its fifth report which will be submitted to Congress and to the Secretary of the Department of Health and Human Services in November 2005 and which focuses on measuring outcomes of Title VII, section 747 grant programs.

Agenda: The meeting on Thursday, May 19, will begin with opening comments from the Chair of the Advisory Committee. A plenary session will follow in which Advisory Committee members will discuss various sections of the fifth report. The Advisory Committee will divide into