

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April 30, 1999), and March 28 and 29, 2000 (65 FR 10811, February 29, 2000), and with other interested parties, the draft guidance has been revised and finalized.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.

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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 (BHP), 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.

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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