DATES: Submit written 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. Send one self-addressed adhesive label to assist that office in processing your requests. 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: Karen L. Davis Bruno, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 3108, Silver Spring, MD 20993–0002, 301–796–2290.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Nonclinical Safety Evaluation of Pediatric Drug Products.'' Many therapeutics marketed in the United States and used in pediatric patients lack adequate information in the labeling for use in that population. Recent FDA regulations have focused attention on current practices for evaluating drug safety in this population. Traditionally, safety data from clinical studies in adults, supported by nonclinical studies in adult animals, have been used to support the use of a drug in pediatric patients. These studies may not always assess possible drug effects on developmental processes specific to pediatric age groups. Some effects may be very difficult to detect in clinical trials or during routine postmarketing surveillance.

In the **Federal Register** of February 3, 2003 (68 FR 5301), FDA announced the availability of a draft version of this guidance entitled ''Nonclinical Safety Evaluation of Pediatric Drug Products.'' Interested persons had the opportunity to submit comments. Based on the public comments received, changes to wording have been added for clarity and the guidance has been finalized. This document provides guidance on the role and timing of animal studies in the safety evaluation of therapeutics intended for the treatment of pediatric patients. It is intended to serve as a resource for general considerations in testing and provide specific recommendations based on available science and pragmatic considerations. The scope of this guidance is limited to safety effects that cannot be reasonably, ethically, and safely assessed in pediatric clinical trials.

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 nonclinical safety evaluation of pediatric drug 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. 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. 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: February 8, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–2139 Filed 2–14–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (pursuant to the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)), the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Assessment of the Engagement of Historically Black Colleges and Universities in Campus and Community-based Activities To Eliminate Health Disparities (NEW)

The Health Resources and Services Administration (HRSA) plans to conduct a survey of 525 university administrators at Historically Black Colleges and Universities (HBCUs) to collect information not otherwise available about the extent to which HBCUs have engaged in health promoting activities on campus and in their surrounding communities that are designed to eliminate health disparities among African Americans. The results of this survey will be used by HRSA's Office of Minority Health and Health Disparities (OMHHD) to obtain information regarding the engagement of HBCUs in health disparities activities. The results of the survey will also permit OMHHD (1) to describe the origins, structure, content, and intensity of such activities, (2) to document the level of support for campus and community activities among administrative leaders at HBCUs, (3) to document the factors that facilitate or hinder the ability of HBCUs to engage in campus and community activities to eliminate health disparities, and (4) to determine whether there is a need among HBCUs for additional assistance that will allow them to expand their role and improve their effectiveness in addressing health disparities.

The survey process will include a web-based survey to be completed by targeted respondents. Follow-up

telephone calls will be conducted with respondents who do not complete the online survey. Approximately 5 administrators will be surveyed at each of the 105 recognized HBCUs. The types of administrators to be surveyed include Presidents, Deans of Faculty, Deans of Students, and staff and/or faculty that are leaders for programs that are associated with eliminating health disparities. The estimated burden of data collection is as follows:

The burden estimate for this project is as follows:

Form	Number of respondents	Average number of responses per respondent	Total responses	Hours per response	Total burden hours
Survey	525	1	525	0.50	262.5

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 10–33 Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. Written comments should be received within 60 days of this notice.

Dated: February 9, 2006.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. E6–2069 Filed 2–14–06; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

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

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Application for the National Health Service Corps (NHSC) Scholarship Program (OMB No. 0915–0146): Extension

The National Health Service Corps (NHSC) Scholarship Program's mission is to ensure the geographic representation of physicians and other health practitioners in the United States. Under this program, health professions students are offered scholarships in return for service in a federally designated Health Professional Shortage Area (HPSA). The Scholarship Program provides the NHSC with the health professionals it requires to carry out its mission of providing primary health care to HPSA populations in areas of greatest need. Students are supported who are well qualified to participate in the NHSC Scholarship Program and who want to assist the NHSC in its mission, both during and after their period of obligated service. Scholars are selected for these competitive awards based on the information provided in the application and during the semi-structured personal interview that is conducted by a team of two interviewers who use a structured scoring procedure. Awards are made to applicants who demonstrate a high potential for providing quality primary health care services.

The estimated response burden is as follows:

Form	Number of respondents	Responses per respondent	Hours per response	Total burden hours
Application	1800	1	1	1800
Interview	900	1	1	900
Total	2700			2700

Written comments and recommendations concerning the proposed information collection should be sent within 60 days of this notice to: Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 10857.

Dated: February 9, 2006.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. E6–2072 Filed 2–14–06; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.