I. Background

FDA is announcing the availability of a guidance for industry entitled ''Handling and Retention of BA and BE Testing Samples.'' Following the generic drug crisis in the 1980s, FDA issued regulations to prevent possible bias and fraud in BA and BE testing by study sponsors and/or drug manufacturers (58 FR 25918, April 28, 1993). In the preamble to the final rule, the agency stated that the study sponsor should not separate out the reserve samples of the test article and reference standard prior to sending the drug product to the testing facility. This is to ensure that the reserve samples are in fact representative of the same batches provided by the study sponsor for the testing.

FDA's Division of Scientific Investigations and field investigators from the Office of Regulatory Affairs conduct inspections of clinical and analytical sites that perform BA and BE studies for sponsors and/or drug manufacturers seeking approval of generic and new drug products. A frequent finding from these inspections is the absence of reserve samples at the testing facility. In the **Federal Register** of August 21, 2002 (67 FR 54219), the agency issued a draft guidance entitled ''Handling and Retention of Bioavailability and Bioequivalence Testing Samples'' to clarify the responsibilities of the involved parties for retention of samples used in BA and BE studies. That draft guidance included recommendations for sampling techniques and responsibilities in various study settings. All comments received during the comment period have been carefully reviewed and changes were made to this final guidance where appropriate.

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 retention of BA and BE testing samples. 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 on the guidance at any time. Two copies of any mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination 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: May 18, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–11828 Filed 5–25–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Maternal and Child Health Research Grants Review Committee; 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: Maternal and Child Health Research Grants Review Committee.

Dates and Times: June 15 , 2004, 8:30 a.m. to 9:30 a.m.—open, June 15, 2004, 9:30 a.m. to 5 p.m.—closed, June 16, 2004, 8:30 a.m. to 5 p.m.—closed, June 17, 2004, 8:30 a.m. to 5 p.m.—closed.

Place: Hilton Garden Inn, 815 14th Street, NW., Washington, DC 20005.

Status: The meeting will be open to the public on Tuesday, June 15, 2004, from 8:30 a.m. to 9:30 a.m. The remainder of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(6), title 5 U.S.C., and the Determination of the Acting Deputy Associate Administrator for Management and Program Support, Health Resources and Services Administration (HRSA), pursuant to section 10(d) of the Federal Advisory Committee Act (Pub. L. 92–463).

Purpose: To review research grant applications in the program areas of maternal and child health, administered by HRSA's Maternal and Child Health Bureau (MCHB).

Agenda: The open portion of the meeting will cover opening remarks by the Director, Division of Research, Training and Education, MCHB, HRSA, who will report on program issues, congressional activities, and other topics of interest to the field of maternal and child health. The closed portion of the meeting will involve the review, discussion, and evaluation of grant applications containing information of a personal nature, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

For further information contact: Anyone wishing to obtain a roster of members, minutes of meetings, or other relevant information should write or contact Stella Yu, Sc.D., M.P.H., Executive Secretary, Maternal and Child Health Research Grants Review Committee, Room 18A–55, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–0695.

Dated: May 19, 2004.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 04–11829 Filed 5–25–04; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meeting

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 meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Eye Institute Special Emphasis Panel, Review of Conference Applications (R13s).

Date: May 24, 2004.

Time: 10 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892.

Contact Person: Houmam H. Araj, PhD, Scientific Review Administrator, Division of Extramural Research, National Eye Institute, NIH, 5635 Fishers Lane, Suite 1300, Bethesda, MD 20892–9602, 301–451–2020, *haraj@mail.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institute of Health, HHS)

Dated: May 18, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–11836 Filed 5–25–04; 8:45 am]

BILLING CODE 4140–01–M