a licensed screening test for HIV–1 and/or HIV–2 antibodies and, for those specimens testing repeatedly reactive by the screening test, the use of a licensed, more specific test (e.g., Western blot, immunofluorescence assay, or comparable test). Both the screening and confirmatory tests should be validated and labeled for use on the particular home specimen collection kit system specimens.

(3) Results of testing should be reported to test subjects by persons appropriately trained in HIV notification and counseling. Counseling of persons with confirmed positive test results should include referral to medical and social support services in the area where the person lives.

(4) The sponsor should also consider the gathering and reporting of demographic data as appropriate. In addition, the sponsor should discuss proposals for appropriate postmarketing studies to assess the public health impact of OTC home specimen collection kit systems for HIV testing.

FDA approval of a PMA would be based upon a finding that information and data submitted in the PMA demonstrate the safety and effectiveness of the home specimen collection kit system (including counseling), and that facility inspections (including any dedicated testing and counseling sites) demonstrate compliance with current good manufacturing practices for medical devices.

This document represents current agency guidance on OTC products intended for the home collection of specimens (including blood and non-blood based specimens) for HIV antibody testing. Other guidance may be developed over time in response to developing technology, public health concerns, consumer preferences, and product submissions.

A manufacturer who wishes to pursue the marketing of a home specimen collection kit system for HIV–1 and/or HIV–2 antibody testing is invited to consult with FDA about the information that should be included in the IDE and PMA submissions. For further information contact Mary Gustafson, Director, Division of Blood Applications, Center for Biologics Evaluation and Research, FDA, at 301–594–2012.

III. Request for Comments

Interested persons may, on or before April 10, 1995, submit to the Dockets Management Branch (address above) written comments regarding the modifications to this guidance. Two copies of any 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 15, 1995.

Linda A. Suydam,

Interim Deputy Commissioner for Operations.

[FR Doc. 95–4465 Filed 2–22–95; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

National Institute of General Medical Sciences, 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:

Committee Name: National Institute of General Medical Sciences Special Emphasis Panel—Pharmacology.
Date: March 7.
Time: 9:30 a.m.—adjournment.
Place: Sheraton International Airport Hotel, Baltimore-Washington Airport, Baltimore, MD 20805.
Contact Person: Dr. Helen Sunshine, Scientific Review Administrator, NIGMS, 45 Center Drive, Room 1AS-13F, Bethesda, MD 20892-6200.
Purpose: To review and evaluate grant applications.

Committee Name: National Institute of General Medical Sciences, Special Emphasis Panel—Chemistry.
Date: March 8.
Time: 8:30 a.m.—adjournment.
Place: Plaza Hotel and Conference Center, 1900 E. Speedway Blvd., Tucson, AZ 85719.
Contact Person: Dr. Arthur Zachary, Scientific Review Administrator, 45 Center Drive, Room 1AS–13, Bethesda, MD 20892–6200.
Purpose: To review and evaluate grant applications.

Committee Name: National Institute of General Medical Sciences, Special Emphasis Panel—Pharmacology.
Date: March 11.
Time: 7 a.m.—adjournment.
Place: Radisson Hotel, Clayton, 7750 Carondelet, Clayton, MO 63105.
Contact Person: Dr. Irene Glowinski, Scientific Review Administrator, 45 Center Drive, Room 1AS–13J, Bethesda, MD 20892–6200.
Purpose: To review and evaluate grant applications.

Name of Committee: National Institute of General Medical Sciences, Special Emphasis Panel—Trauma and Burn.
Date: March 14.
Time: 9:30 a.m.—adjournment.
Place: Hyatt Regency Hotel, Bethesda, One Bethesda Metro Center, Bethesda, MD 20814.
Contact Person: Dr. Bruce Wetzel, Scientific Review Administrator, 45 Center Drive, Room 1AS–19K, Bethesda, MD 20892–6200.
Purpose: To review and evaluate grant applications.

The meetings will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 522b(c)(6), title 5, U.S.C. The discussions of these applications could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Nos. 93.821, Biophysics and Physiological Sciences; 93.859, Pharmacological Sciences; 93.862, Genetics Research; 93.863, Cellular and Molecular Basis of Disease Research; 93.880, Minority Access Research Careers [MARC]; and 93.375, Minority Biomedical Research Support [MBRS].

Dated: February 15, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95–4339 Filed 12–22–95; 8:45 am]

BILLING CODE 4140–01–M

Division of Research Grants; 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 Division of Research Grants Special Emphasis Panel (SEP) meetings:

Purpose/Agenda: To review Small Business Innovation Research Program grant applications.
Name of SEP: Behavioral and Neurosciences.
Date: March 15–16, 1995.
Time: 9:00 a.m.
Place: Renaissance Hotel, Washington, DC.
Contact Person: Dr. Anita Sostek, Scientific Review Administrator, 5333 Westbard Ave., Room 319C, Bethesda, MD 20892, (301) 594–7358

Purpose/Agenda: To review individual grant applications.
Name of SEP: Microbiological and Immunological Sciences.
Date: March 8, 1995.
Time: 10:00 a.m.
Place: NIH, Westwood Building, Room 403D, Telephone Conference.
Contact Person: Dr. Howard Berman, Scientific Review Administrator, 5333 Westbard Ave., Room 403D, Bethesda, MD 20892, (301) 594–7234.

Name of SEP: Microbiological and Immunological Sciences.
Date: March 9, 1995.
Time: 3:00 p.m.
Place: NIH, Westwood Building, Room 403D, Telephone Conference.