

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.

Contact Person: Dr. Howard Berman, Scientific Review Administrator, 5333 Westbard Ave., Room 403D, Bethesda, MD 20892, (301) 594-7234.

Name of SEP: Clinical Sciences.

Date: March 20, 1995.

Time: 8:30 a.m.

Place: Holiday Inn, Chevy Chase, MD.

Contact Person: Ms. Jo Pelham, Scientific Review Administrator, 5333 Westbard Ave., Room 349, Bethesda, MD 20892, (301) 594-7254.

Name of SEP: Clinical Sciences.

Date: March 21, 1995.

Time: 8:30 a.m.

Place: Holiday Inn, Bethesda, MD.

Contact Person: Dr. Gopal Sharma, Scientific Review Administrator, 5333 Westbard Ave., Room 219C, Bethesda, MD 20892, (301) 594-7130.

Name of SEP: Chemistry and Related Sciences.

Date: March 21, 1995.

Time: 2:00 p.m.

Place: NIH, Westwood Building, Room 335, Telephone Conference.

Contact Person: Dr. Edward Zapolski, Scientific Review Admin., 5333 Westbard Ave., Room 335, Bethesda, MD 20892, (301) 594-7302.

Name of SEP: Clinical Sciences.

Date: March 22, 1995

Time: 8:30 a.m.,

Place: Holiday Inn, Bethesda, MD.

Contact Person: Dr. Gopal Sharma, Scientific Review Administrator, 5333 Westbard Ave., Room 219C, Bethesda, MD 20892, (301) 594-7130.

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

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the grant review cycle.

(Catalog of Federal Domestic Assistance Program Nos. 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 94.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: February 15, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95-4338 Filed 2-22-95; 8:45 am]

BILLING CODE 4140-01-M

National Cancer Institute; Notice of Meeting President's Cancer Panel

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the President's Cancer Panel, National Cancer Institute, March 28, 1995 at the National Institutes of Health, 9000 Rockville Pike, Building 31, Conference Room 6.

This meeting will be open to the public on March 28, 1995 from 8 a.m. to approximately 5 p.m. The topic will be: The Human Genome Project.

Individuals who plan to attend and need special assistance such as sign language interpretation or other reasonable accommodations should contact Ms. Nora Winfrey, (301-496-1148), in advance of the meeting.

Dr. Maureen O. Wilson, Executive Secretary, President's Cancer Panel, National Cancer Institute, Building 31, Room 4A34, National Institutes of Health, Bethesda, Maryland 20892 (301/496-1148) will provide a roster of the Panel members and substantive program information upon request.

Dated: February 15, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95-4337 Filed 2-22-95; 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 individual grant applications.

Name of SEP: Behavioral and Neurosciences.

Date: March 8, 1995.

Time: 8:30 a.m.

Place: OMNI Shoreham Hotel, Washington, DC.

Contact Person: Dr. Joseph Kimm, Scientific Review Administrator, 5333 Westbard Ave., Room 309, Bethesda, MD 20892, (301) 594-7257.

Name of SEP: Biological and Physiological Sciences.

Date: March 9, 1995.

Time: 2:30 p.m.

Place: NIH, Westwood Building, Room 418A, Telephone Conference.

Contact Person: Dr. Anne Clark, Scientific Review Administrator, 5333 Westbard Ave., Room 418A, Bethesda, MD 20892, (301) 594-7115.

Name of SEP: Multidisciplinary Sciences.

Date: March 9, 1995.

Time: 1:00 p.m.

Place: NIH, Westwood Building, Room 2A11, Telephone Conference.

Contact Person: Dr. Lee Rosen, Scientific Review Administrator, 5333 Westbard Ave., Room 2A11, Bethesda, MD 20892, (301) 594-7276.

Name of SEP: Behavioral and Neurosciences.

Date: March 14, 1995.

Time: 12:30 p.m.

Place: Holiday Inn, Chevy Chase, MD.

Contact Person: Dr. Herman Teitelbaum, Scientific Review Admin., 5333 Westbard Ave., Room 321, Bethesda, MD 20892, (301) 594-7245.

Name of SEP: Clinical Sciences.

Date: March 16, 1995.

Time: 8:30 a.m.

Place: NIH, Westwood Building, Room 203B, Telephone Conference.

Contact Person: Dr. H. M. Stiles, Scientific Review Administrator, 5333 Westbard Ave., Room 203B, Bethesda, MD 20892, (301) 594-7194.

Name of SEP: Biological and Physiological Sciences.

Date: March 22, 1995.

Time: 2:30 p.m.

Place: NIH, Westwood Building, Room 349, Telephone Conference.

Contact Person: Dr. Everett Sinnett, Scientific Review Admin., 5333 Westbard Ave., Room 349, Bethesda, MD 20892, (301) 594-7220.

Name of SEP: Microbiological and Immunological Sciences.

Date: March 27, 1995.

Time: 2:00 p.m.

Place: NIH, Westwood Building, Room 238, Telephone Conference.

Contact Person: Dr. Martin Slater, Scientific Review Admin., 5333 Westbard Ave., Room 238, Bethesda, MD 20892, (301) 594-7176.

Name of SEP: Biological and Physiological Sciences.

Date: March 28, 1995.

Time: 10:00 a.m.

Place: NIH, Westwood Building, Room 349, Telephone Conference.

Contact Person: Dr. Everett Sinnett, Scientific Review Admin., 5333 Westbard Ave., Room 349, Bethesda, MD 20892, (301) 594-7220.

Name of SEP: Chemistry and Related Sciences.

Date: March 28, 1995.

Time: 1:30 p.m.

Place: NIH, Westwood Building, Room 349, Telephone Conference.

Contact Person: Dr. Gopa Rakhit, Scientific Review Administrator, 5333 Westbard Ave., Room 349, Bethesda, MD 20892, (301) 594-7166.

Name of SEP: Multidisciplinary Sciences.

Date: April 6-7, 1995.

Time: 9:00 a.m.

Place: Marriott Hotel, Dulles, VA.

Contact Person: Dr. Harish Chopra, Scientific Review Admin., 5333 Westbard Ave., Room 2A18A, Bethesda, MD 20892, (301) 594-7342.

Name of SEP: Microbiological and Immunological Sciences.

Date: April 11, 1995.

Time: 10:00 a.m.