

National AIDS Clearinghouse, telephone (800) 458-5231).

The draft recommendations for HIV counseling and voluntary testing for pregnant women have been developed to provide a framework to enable pregnant women to know their HIV infection status; advise HIV-infected pregnant women of ways to prevent perinatal, sexual, and other transmission of HIV; facilitate appropriate follow up for HIV-infected women and their infants; and assist uninfected pregnant women in identifying methods to reduce their risk of acquiring HIV infection.

Dated: February 15, 1995.

**Jack Jackson,**

*Acting Director, Centers for Disease Control and Prevention (CDC).*

[FR Doc. 95-4368 Filed 2-22-95; 8:45 am]

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## Food and Drug Administration

[Docket No. 88N-0319]

### Home Specimen Collection Kit Systems Intended for Human Immunodeficiency Virus (HIV-1 and/or HIV-2) Antibody Testing; Revisions to Previous Guidance

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is revising its previous guidance for the approval of home specimen collection kit systems intended for the detection of antibodies to Human Immunodeficiency Virus type 1 (HIV-1), that was published in the **Federal Register** of February 17, 1989, and July 30, 1990.

**DATES:** Submit written comments by April 10, 1995.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Mary Gustafson, Center for Biologics Evaluation and Research (HFM-370), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-594-2012.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA announced in the **Federal Register** of February 17, 1989 (54 FR 7279), the scheduling of an open public meeting and invited written comments on blood collection kits and home test

kits designed to detect HIV-1 antibody. The document listed five factors that the agency was applying to the review of applications for premarket approval of blood collection kits labeled for HIV-1 antibody testing. At that time, FDA believed that blood collection kits labeled for HIV-related testing should be restricted to professional use in a health care environment. On April 6, 1989, FDA held an open public meeting to obtain comments on the issues related to applications for premarket approval of blood collection kits labeled for HIV-1 antibody testing. Comments also were solicited on kits for home collection and home testing of blood for evidence of HIV-1 infection.

In the **Federal Register** of July 30, 1990 (55 FR 30982), FDA announced the availability of a letter to firms and individuals who previously had asked FDA about the potential marketing of blood collection kits labeled for HIV-1 testing. In that document, which included the full text of the letter, FDA indicated its willingness to accept investigational device exemptions (IDE's) and to review applications for blood collection kits for HIV-1 testing intended for home use, but did not revise the list of factors, previously set forth in the February 17, 1989, **Federal Register** (54 FR 7279) document, that the agency would consider in evaluating the safety and effectiveness of specimen collection kits.

In light of scientific and technological developments and the changing nature of the HIV epidemic, FDA announced in the **Federal Register** of June 9, 1994 (59 FR 29814), that the agenda for FDA's Blood Products Advisory Committee meeting, scheduled for June 21 and 22, 1994, would include a discussion of issues related to home specimen collection kits labeled for HIV antibody testing, and that the discussion would reexamine FDA's approach to evaluating the safety and effectiveness of such kits. More than 60 members of the public, including potential product sponsors, academicians, physicians, clergy, HIV counselors, and representatives of various interest groups, made public presentations before the Blood Products Advisory Committee prior to the committee's discussion of these issues. Most of the advisory committee members believed that the potential benefits of over-the-counter (OTC) home specimen collection kits outweighed the potential risks.

##### II. The Revision

In this document, FDA is revising the previous guidance for blood sample collection kits labeled for HIV antibody testing set forth in the February 17,

1989, **Federal Register** document and in the July 30, 1990, **Federal Register** document. This revised guidance addresses only OTC products intended for the home collection of specimens (including blood and non-blood based specimens) for HIV antibody testing (including HIV-1 and/or HIV-2), and supersedes prior guidance about such home specimen collection kits. This revised guidance does not address professional use specimen collection kits for HIV testing or kits for home testing of specimens for evidence of HIV infection.

After significant consideration, including discussion at two public meetings, FDA has concluded that OTC home specimen collection kit system for HIV testing may be approvable. Each premarket approval application (PMA) for an OTC home specimen collection kit system labeled for HIV-1 and/or HIV-2 antibody testing will be evaluated for safety and effectiveness based on the proposed intended use. In general, sponsors should include information on the following points:

(1) Appropriate preclinical studies and clinical trials conducted under an approved IDE should validate all technical aspects of the home specimen collection and testing system and demonstrate the reproducibility, sensitivity, and specificity of test results in comparison with an approved, professional use system for the collection and testing of blood or any other appropriately validated specimen. Field trials should be conducted in a population likely to resemble the intended market for the collection kit. Lay comprehension of the instructions and educational materials, the ability of individual consumers to accurately identify whether the test is applicable to them, adequacy of home collection and shipment of the specimen by consumers, the adequacy of pretest and post-test counseling, and the ability of consumers to take appropriate followup action when indicated should be addressed. Safe handling and transport of the specimen and safe disposal of potentially hazardous materials also should be demonstrated. Sponsors additionally should document adequate quality assurance related to product manufacture, testing of the specimen (including laboratory proficiency controls) in a laboratory that is in compliance with the Clinical Laboratories Improvement Act of 1988 (CLIA), maintenance of test records, and a system for reporting of adverse events or device failures.

(2) The testing for all specimens collected using the home specimen collection kits should include the use of

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]

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## 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.