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