

Dated: January 19, 1996.
 Michael G. Beatrice,
*Deputy Director, Center for Biologics
 Evaluation and Research.*
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 BILLING CODE 4160-01-F

[Docket No. 95N-0369]

**Memorandum on the
 Recommendations for Donor
 Screening With a Licensed Test for
 HIV-1 Antigen; Availability**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a memorandum to all registered blood and plasma establishments, dated August 8, 1995. In the memorandum, the Center for Biologics Evaluation and Research (CBER) recommends the implementation of donor screening tests for human immunodeficiency virus, type 1 (HIV-1) antigen(s) using licensed tests that are approved for donor screening. FDA is recommending the implementation of HIV-1 antigen screening because of the benefit that it will provide to a small number of blood product recipients, as a partial preventive measure against the possibility of any increase in HIV-1 "window period" donations and to decrease the virus burden in plasma pools for fractionation. FDA expects HIV-1 antigen testing will reduce, but not eliminate, the residual risk of HIV-1 from transfusion and, therefore, regards such screening as only an interim measure pending the availability of more advanced test methodology.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the memorandum to the Congressional and Consumer Affairs Branch (HFM-12), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, or call FDA's automated information system at 800-835-4709. Send one self-addressed adhesive label to assist that office in

processing your requests. Submit written comments on the memorandum to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one copy. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the memorandum and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Persons with access to INTERNET may request the memorandum be sent by return E-mail by sending a message to "HIVANTIGEN@A1.CBER.FDA.GOV". The memorandum may also be obtained through INTERNET via File Transfer Protocol (FTP). Requestors should connect to the Center for Drug Evaluation and Research (CDER) using the FTP. CBER documents are maintained in a subdirectory called CBER on the server, "CDVS2.CDER.FDA.GOV" (150.148.24.202). The "READ.ME" file in that subdirectory describes the available documents which may be available as an ASCII text file (*.TXT), or a WordPerfect 5.1 document (*.w51), or both. A sample dialogue for obtaining the "READ.ME" file with a text-based FTP program would be:
 FTP CDVS2.CDER.FDA.GOV
 LOGIN: ANONYMOUS
 <ANY PASSWORD> <"Your E-mail address">
 BINARY
 CD CBER
 GET READ.ME
 EXIT

The memorandum may also be obtained by calling the CBER FAX Information System (FAX-ON-DEMAND) at 301-594-1939 from a touch tone telephone.

FOR FURTHER INFORMATION CONTACT: Paul A. Mied, Center for Biologics Evaluation and Research (HFM-310), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-3008.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a memorandum to all registered blood and plasma establishments, dated August 8, 1995, recommending the implementation of donor screening for HIV-1 antigen with a licensed test approved for this use. As of August 8, 1995, there were no tests for HIV-1 antigen(s) approved for donor screening. However, FDA issued these recommendations in advance of the availability of such tests in order to provide blood and plasma establishments with maximum time to prepare for implementation of this testing. These recommendations supersede some of the rationale/recommendations provided in a previous FDA memorandum dated October 4, 1989, following licensure of the first test for HIV-1 antigen(s).

Based on the data available in 1989, FDA did not approve HIV-1 antigen testing for routine donor screening. Recently, however, the role of HIV-1 antigen testing in the donor setting has been reconsidered for several reasons. For instance, there have been four documented instances of HIV-1 transmission by HIV-1 antigen positive blood donations from three HIV-1 antibody negative donors. Also, based on recent estimates of the antibody negative infectious "window period," the residual risk of HIV transmission by screened blood, and the efficacy of antigen testing to detect seronegative, infectious donations, it has been estimated that donor screening by HIV-1 antigen can be expected to prevent up to 25 percent of the current "window period" cases or about 5 to 10 cases of transfusion associated HIV infection per year.

In September 1994, FDA sponsored a "Conference on the Feasibility of Genetic Technology to Close the HIV Window in Donor Screening." Although the majority of participating experts expressed the opinion that genetic techniques were not ready for use in mass screening, the meeting did spark renewed interest in considering other direct viral detection methods for donor screening, such as HIV-1 antigen testing as an interim measure to further reduce current low risk of

HIV-1 transmission through transfusions of blood and blood products. To further address direct viral detection methods, FDA brought the issue of donor screening for HIV-1 antigen to a public meeting of the Blood Products Advisory Committee (BPAC) in June 1995. After hearing the most recent available data on HIV-1 risk in the blood supply, the estimated efficacy of antigen screening, and other issues bearing on a risk/benefit assessment, 9 of the 15 BPAC members present were of the opinion that donor screening for HIV-1 antigen by candidate test kits is not likely to provide a significant public health benefit which outweighs the potential risks. After considering the available information and the opinions of the BPAC members, FDA recommended that blood establishments should implement donor screening for HIV-1 antigen using licensed tests that are approved for this indication. FDA recommended implementation of HIV-1 antigen screening because of the benefit that it will provide to a small number of blood product recipients, as a partial preventive measure against the possibility of any increase in HIV-1 "window period" donations and to decrease the virus burden in plasma pools for fractionation.

FDA recommended that the screening for HIV-1 antigen(s) be implemented within 3 months of the commercial availability of the first such test approved for donor screening for all donations of Whole Blood, blood components, Source Leukocytes and Source Plasma, and all such inventoried units available for release. FDA also recommended that consigned within-date units intended for transfusion and still in the consignee's inventory be either replaced with screened units or tested for HIV-1 antigen(s) as soon as feasible. The memorandum included additional recommendations and information on the following: (1) Disposition and labeling of units; (2) donor deferral; (3) Public Health Service recommendations for donor notification and counseling; (4) exclusion/retrieval of potentially contaminated units from prior collections and notification of consignees; and (5) notification of consignees of neutralization test results.

Because HIV-1 antigen testing will reduce, but not eliminate, the residual risk of HIV-1 from transfusion, FDA regards such screening as an interim measure pending the availability of better technology for this purpose. FDA encourages continued development of new methods to further reduce the risk of HIV transmissions in the "window period."

As with other memoranda, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The memorandum is intended to provide information and does not set forth new requirements. The procedures cited in the memorandum are recommendations. FDA anticipates that blood and plasma establishments may develop alternative procedures and discuss them with FDA. FDA may find those alternative procedures acceptable. FDA recognizes that the scientific technology for controlling the risk of transmission of HIV by blood and blood products may continue to advance and that this document may become outdated as those advances occur. The memorandum does not bind FDA and does not create or confer any rights, privileges, or benefits on or for any private person, but is intended merely for guidance.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the memorandum. 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. A copy of the memorandum and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Received comments will be considered in determining whether further revisions to the memorandum are warranted.

Dated: January 22, 1996.
William K. Hubbard,
*Associate Commissioner for Policy
Coordination.*

[FR Doc. 96-1657 Filed 1-29-96; 8:45 am]

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[Docket No. 93D-0398]

**Microbiological Testing for
Antimicrobial Food-Animal Drugs;
Final Guidance; Availability**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled "Microbiological Testing of Antimicrobial Drug Residues in Food." The availability of the draft guideline was announced on January 6, 1994; this final guidance document addresses the comments submitted on the draft

guideline. The final guidance document, which was prepared by the Center for Veterinary Medicine (CVM), addresses human food safety issues that may be associated with food-animal antimicrobial drug products. This guidance document also provides points to consider when determining which antimicrobials may require supplemental testing and recommends test procedures for establishing that antimicrobial drug residues will not cause intestinal microflora perturbations in the consumer.

DATES: Written comments on the guidance document may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the final guidance document "Microbiological Testing of Antimicrobial Drug Residues in Food," to the Communications and Education Branch (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1755. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the guidance document and received comments may be seen at the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Haydee Fernandez, Center for Veterinary Medicine (HFV-154), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1684.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of the final guidance document entitled "Microbiological Testing of Antimicrobial Drug Residues in Food." In evaluating the safety of new animal drugs, the agency must determine, among other things, their cumulative effect in man or other animal as required by section 512(d)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(d)(2)(B)). The guidance document describes the testing that may be necessary to establish that antimicrobial drug residues in food will be safe and will not cause intestinal microflora perturbations in the consumer.

In the Federal Register of January 6, 1994 (59 FR 754), FDA issued a notice of availability of the draft guideline entitled "Microbiological Testing of