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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D-0584]

Draft "Guidance for Industry: Use of Nucleic Acid Tests on Pooled Samples From Source Plasma Donors to Adequately and Appropriately Reduce the Risk of Transmission of HIV-1 and HCV;" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Industry: Use of Nucleic Acid Tests on Pooled Samples From Source Plasma Donors to Adequately and Appropriately Reduce the Risk of Transmission of HIV-1 and HCV" dated December 2001. The draft guidance document, when finalized, would inform all establishments that manufacture Source Plasma that FDA has approved nucleic acid tests (NAT) to identify human immunodeficiency virus type 1 (HIV-1) and hepatitis C virus (HCV) in Source Plasma donations. The draft document recommends that manufacturers submit a prior approval supplement to a biologics license application (BLA) to implement HIV-1 and HCV NAT by a specified date.

DATES: Submit written or electronic comments on the draft guidance to ensure their adequate consideration in preparation of the final document by *[insert date 90 days after date of publication in the Federal Register]*. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville,

1-30-02
1-31-02
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MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

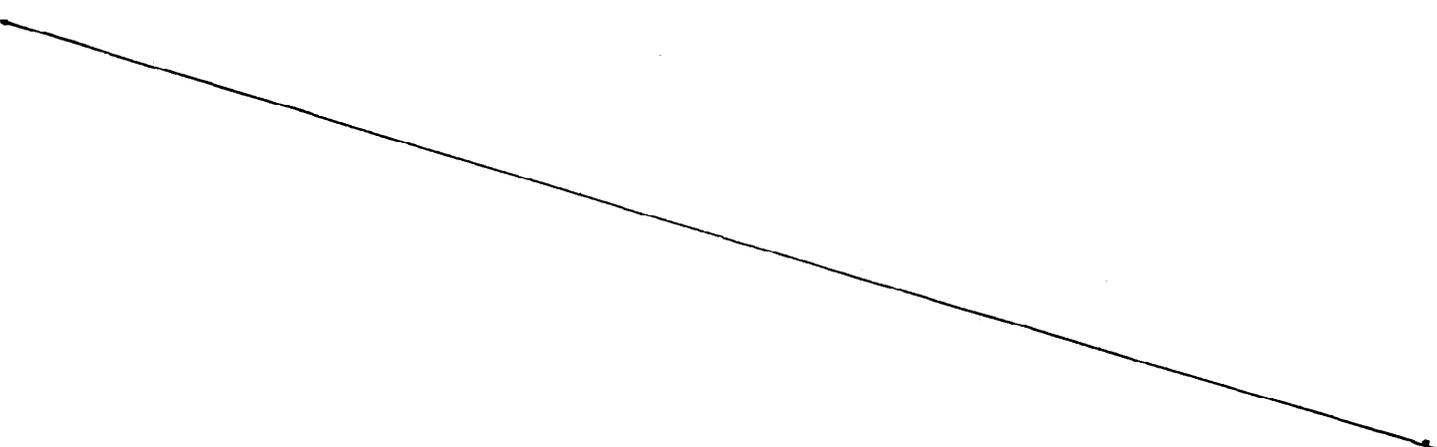
FDA is announcing the availability of a draft document entitled “Guidance for Industry: Use of Nucleic Acid Tests on Pooled Samples From Source Plasma Donors to Adequately and Appropriately Reduce the Risk of Transmission of HIV–1 and HCV” dated December 2001. FDA’s final rule (66 FR 31146, June 11, 2001) entitled “Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Diseases” became effective on December 10, 2001. The provision in 21 CFR 610.40(b) of the rule provides that manufacturers “must perform one or more screening tests to adequately and appropriately reduce the risk of transmission of communicable disease agents” (66 FR 31146 at 31162). As we noted in the preamble to the final rule, the standard for adequate and appropriate testing will change as new testing technology is approved by FDA. We explained, “we intend to regularly issue guidance describing those tests that we believe would adequately and appropriately reduce the risk of transmission of communicable disease agents” (66 FR 31146 at 31149).

The availability of NAT to identify HIV-1 and HCV will change the testing protocol that should be used to adequately and appropriately reduce the risk of transmission of those diseases. The draft document recommends that manufacturers submit a prior approval supplement to a BLA to implement HIV-1 and HCV NAT by a specified date.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance document represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Comments

This draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this draft guidance document. Submit written or electronic comments to ensure adequate consideration in preparation of the final document by *[insert date 90 days after date of publication in the **Federal Register**]*. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

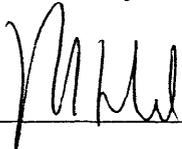


III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: 1/23/02

January 23, 2002.



Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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