Rockville, MD 20855. All presentations may be provided on Powerpoint (disk or CD, or e-mailed in advance to cvmmeet@cvm.fda.gov). No zip disks, slide presentations, or overheads can be accommodated.

If you need special accommodations due to a disability, please contact Vash Klein at least 7 days in advance.

Dated: April 4, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–8567 Filed 4–5–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0096]

Draft ''Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples From Donors of Whole Blood and Blood Components for Transfusion 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 and Individual Samples From Donors of Whole Blood and Blood Components for Transfusion to Adequately and Appropriately Reduce the Risk of Transmission of HIV–1 and HCV'' dated March 2002. The draft guidance document would inform all establishments that manufacture Whole Blood that FDA has licensed a nucleic acid test (NAT) to identify human immunodeficiency virus type 1 (HIV–1) and hepatitis C virus (HCV) in Whole Blood donations. The draft document recommends that manufacturers implement licensed HIV–1 and HCV NAT within 6 months of issuance of a final guidance and notify FDA of such implementation by specified procedures.

DATES: Submit written or electronic comments on the draft guidance to ensure their adequate consideration in preparation of the final document by July 8, 2002. 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ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug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, 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.

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 and Individual Samples From Donors of Whole Blood and Blood Components for Transfusion to Adequately and Appropriately Reduce the Risk of Transmission of HIV–1 and HCV,'' dated March 2002. FDA's final rule (66 FR 31146, June 11, 2001) entitled ''Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents'' became effective on December 10, 2001. Under 21 CFR 610.40(b), manufacturers ''must perform one or more such [screening] tests as necessary to reduce adequately and appropriately the risk of transmission of communicable disease'' (66 FR 31146 at 31162). In the preamble to the final rule, we said that the standard for adequate and appropriate testing will change as FDA approves new testing technology. We explained that, ''* * * 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 for adequately and appropriately reducing the risk of transmission of those diseases. The draft document recommends that manufacturers implement HIV–1 and HCV nucleic acid testing within 6 months of issuance of a final guidance. The draft guidance specifies how you should notify FDA of such implementation as required under 21 CFR 601.12.

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. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

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 (see **ADDRESSES**) 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 July 8, 2002. Two copies of any written 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 http://www.fda.gov/cber/guidelines.htm or http://www/fda.gov/ohrms/dockets/default.htm.

Dated: March 29, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–8464 Filed 4–8–02; 8:45 am]

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