

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D-0261]

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	Certifier	N. Hawkins

**Draft Guidance for Industry on Nucleic Acid Testing for Human Immunodeficiency Virus Type 1 and Hepatitis C Virus: Testing, Product Disposition, and Donor Deferral and Reentry; Availability**

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

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Industry: Nucleic Acid Testing (NAT) for Human Immunodeficiency Virus Type 1 (HIV-1) and Hepatitis C Virus (HCV): Testing, Product Disposition, and Donor Deferral and Reentry," dated July 2005. The draft guidance document provides information for blood and plasma establishments, manufacturers, and testing laboratories that are implementing a licensed method for NAT on pooled or individual samples of human blood and blood component donations for HIV-1 ribonucleic acid (RNA) and HCV RNA. The draft guidance document is intended to encourage more effective testing of whole blood and blood component samples, and improved product and donor management based on the results of NAT and concurrent serologic testing for markers of HIV and HCV infection on donated whole blood and blood components.

**DATES:** Submit written or electronic comments on the draft guidance by [*insert date 90 days after date of publication in the Federal Register*] to ensure their

adequate consideration in preparation of the final guidance. 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**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug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, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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, suite 200N, 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: Nucleic Acid Testing (NAT) for Human Immunodeficiency Virus Type 1 (HIV-1) and Hepatitis C Virus (HCV): Testing, Product Disposition, and Donor Deferral and Reentry" dated July 2005. There has been a dramatic reduction during the past decade in the transmission of HIV-1 and HCV by human blood and blood components. The reduction is a result of the implementation of sensitive tests for viral antibody, antigen (for HIV-1), and

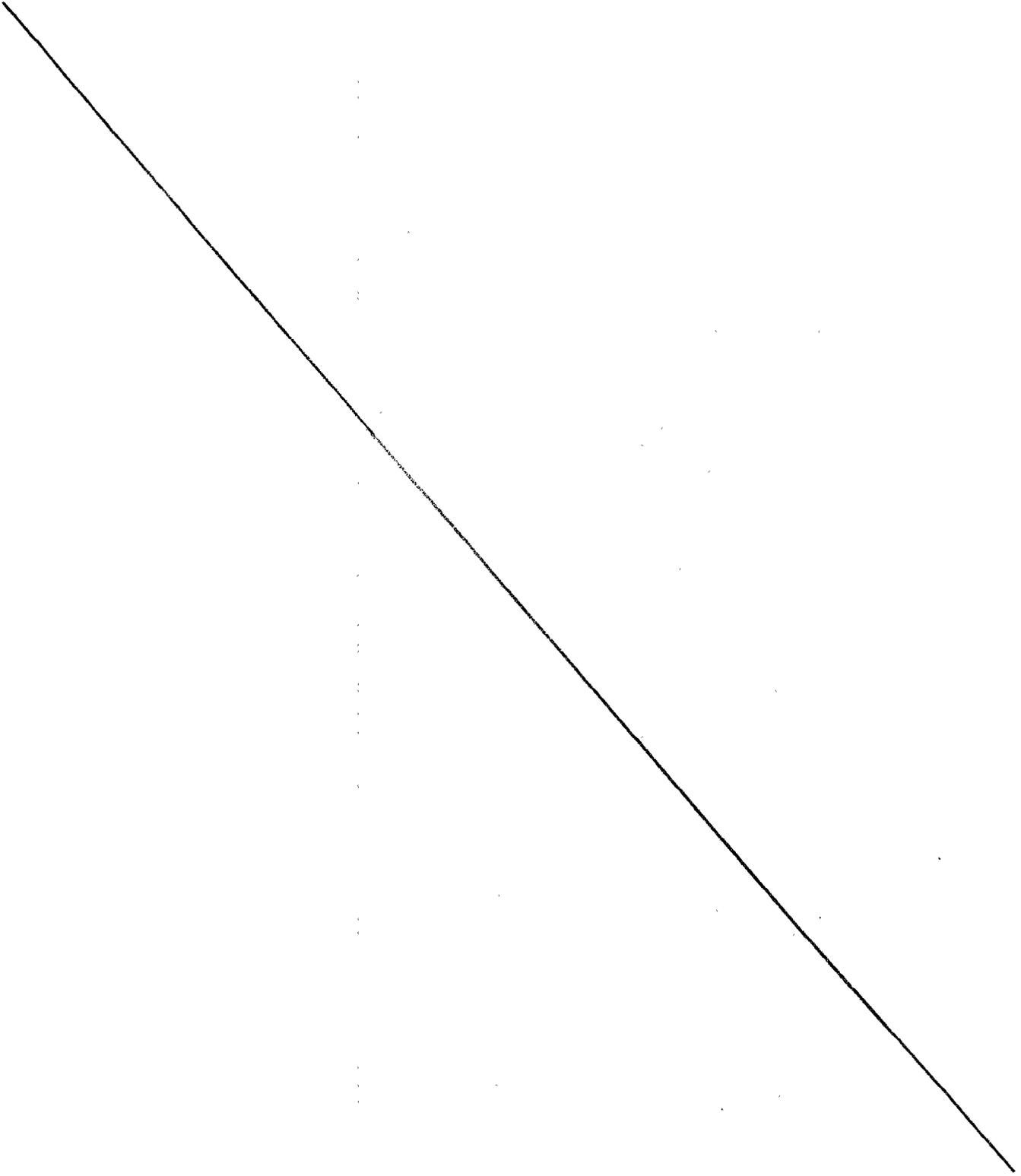
nucleic acids, and the use of effective virus removal and inactivation methods. The sources of remaining risk of HIV-1 and HCV transmission are marker-negative “window period” donations, donors infected with immunovariant viral strains, persistent antibody-negative (immunosilent) carriers, and laboratory test procedure errors. Because donations during the window period constitute most of the risk of HIV-1 and HCV transmission, measures to close the “window period” further could reduce significantly the low residual risk of HIV-1 and HCV transmission by human blood and blood components. Studies using seroconversion panels indicate the value of NAT in reducing the “window period” for HIV-1 and HCV.

The draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA’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**

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit written or electronic comments to ensure adequate consideration in preparation of the final guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the draft guidance and received comments are

available for public examination in the Division of Dockets Management  
between 9 a.m. and 4 p.m., Monday through Friday.



**III. Electronic Access**

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

Dated: 7/19/05  
July 19, 2005.

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Jeffrey Shuren,  
Assistant Commissioner for Policy.

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