

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D-0133]

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Certifier	D. Hawkins

**Draft "Guidance for Industry: Assessing Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection;" 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: Assessing Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection," dated April 2005. The draft guidance document provides revisions to the previously published recommendations for assessing donor suitability and product safety when donors are diagnosed with or suspected of West Nile Virus (WNV) infections based on symptoms and laboratory tests. This draft guidance proposes revised deferral periods for such donors, and updates information on product retrieval and quarantine. When finalized, this guidance will supersede "Guidance for Industry: Revised Recommendations for the Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection," dated May 2003.

**DATES:** Submit written or electronic comments on the draft guidance by *[insert date 30 days after date of publication in the Federal Register]*, to ensure their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**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug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, 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 The draft guidance may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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:** Brenda R. Friend, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft document entitled "Guidance for Industry: Assessing Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection," dated April 2005. FDA developed the information in this draft guidance after consulting with other Public Health Service agencies of the Department of Health and Human Services.

This draft guidance:

- Applies to donors of blood and blood components intended for transfusion;
- Applies to donors of blood components intended for use in further manufacturing into injectable products or noninjectable products, including recovered plasma, Source Leukocytes, and Source Plasma;
- Provides updated scientific data;
- Removes the current recommendation for donor deferral based upon a reported history of headache with fever in the week before donation;
- Proposes new deferral periods for donors who are diagnosed with or suspected of WNV infections;
- Describes the use of the investigational nucleic acid test (NAT) for WNV in deferring reactive donors; and
- Provides information about the use of individual donor NAT testing to re-enter reactive donors if a blood establishment, at its discretion, chooses to reenter such donors.

This draft guidance, when finalized, will supersede “Guidance for Industry: Revised Recommendations for the Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection,” dated May 2003.

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 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. Paperwork Reduction Act of 1995**

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The information collection provisions in this guidance for 21 CFR 601.12 were approved under OMB control number 0910–0338; 21 CFR 606.170(b) was approved under OMB control number 0910–0116; and 21 CFR 606.171 was approved under OMB control number 0910–0458.

## **III. 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.

**IV. Electronic Access**

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

Dated: 4/13/05  
April 13, 2005.



Jeffrey Shuren,  
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