

- 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;
- Recommends new deferral periods for donors who are diagnosed with or suspected of WNV infection; and

- Describes the use of the investigational nucleic acid test (NAT) for WNV in deferring reactive donors.

This guidance supersedes "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, and finalizes the draft "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.

In the **Federal Register** of April 20, 2005 (70 FR 20575), FDA announced the availability of the draft guidance of the same title. FDA received several comments on the April 2005 draft guidance and those comments were considered when finalizing the guidance. A summary of changes to the guidance includes the following items: (1) Modifies recommendations on followup testing and reentry of reactive donors, (2) adds recommendations on component retrieval and quarantine for presumptive viremic donors, and (3) discusses preliminary laboratory data indicating WNV infectivity in blood cultures of NAT reactive individuals who were also seropositive for WNV antibodies. In addition, editorial changes were made to improve clarity. Elsewhere in this issue of the **Federal Register**, FDA is withdrawing the guidance entitled "Guidance for Industry: Discontinuation of Donor Deferral Related to Recent Fever with Headache as a Symptom of West Nile Virus Infection," dated May 2005. The May 2005 guidance is no longer necessary because the guidance that is the subject of this notice does not contain the recommendation to defer donors based on recent fever with a headache as a symptom of WNV infection.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents 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 requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This 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 collection of information in this guidance was approved under OMB control number 0910–0338; 21 CFR 606.170(b) has been approved under OMB control number 0910–0116; and 21 CFR 606.171 has been approved under OMB control number 0910–0458.

III. Comments

Interested persons may, at any time, submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**) regarding this 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 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 guidance at either <http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: June 24, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–12960 Filed 6–29–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D–0467]

“Guidance for Industry: Discontinuation of Donor Deferral Related to Recent Fever with Headache as a Symptom of West Nile Virus Infection”; Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of a guidance entitled “Guidance for Industry: Discontinuation

of Donor Deferral Related to Recent Fever with Headache as a Symptom of West Nile Virus Infection” (May 2005 guidance) that was issued on May 6, 2005. A guidance entitled “Guidance for Industry: Assessing Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection,” dated June 2005, is being announced elsewhere in this issue of the **Federal Register**, and supersedes the May 2003 guidance entitled “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” (May 2003 guidance) (68 FR 25897).

DATES: June 30, 2005.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of May 23, 2005 (70 FR 29529), FDA announced the availability of the May 2005 guidance. This guidance removed FDA's previous recommendation concerning deferral of donors of Whole Blood and blood components for transfusion and for further manufacturing use on the basis of a specific donor question related to West Nile Virus infection (i.e., to defer donors each year between June 1 and November 30 when the donor reports a history of fever with headache in the past week). Donor deferral based on this information was originally recommended in the May 2003 guidance. The guidance entitled “Guidance for Industry: Assessing Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection,” dated June 2005, announced elsewhere in this issue of the **Federal Register**, supersedes the May 2003 guidance and does not recommend donor deferral based upon a reported history of fever with headache in the week prior to donation. Therefore, the May 2005 guidance is being withdrawn because it is no longer necessary.

Dated: June 24, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–12961 Filed 6–29–05; 8:45 am]

BILLING CODE 4160–01–S