

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 22, 2005, from 8 a.m. to 5 p.m.

Location: Holiday Inn Gaithersburg, Two Montgomery Village Ave., Gaithersburg, MD 20879.

Contact Person: William Freas or Pearlline K. Muckelvene, Center for Biologics Evaluation and Research, (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014519516. Please call the Information Line for up-to-date information on this meeting.

Agenda: On July 22, 2005, the subcommittee will listen to presentations to further a dynamic, responsive, and cutting edge research program at the Office of Blood Research and Review, Center for Biologics Evaluation and Research (CBER), that facilitates development of safe and effective biological products. The subcommittee's recommendations will be publicly discussed at a future meeting of the Blood Products Advisory Committee. Information regarding CBERS scientific program is outlined in its Strategic Plan of 2004 and is available to the public on the Internet at: <http://www.fda.gov/cber/inside/mission.htm>. Information regarding FDA's Critical Path to New Medical Products is available to the public on the Internet at: <http://www.fda.gov/oc/initiatives/criticalpath/>.

Procedure: On July 22, 2005, from 8 a.m. to 1:15 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by July 14, 2005. Oral presentations from the public will be scheduled between approximately 12:15 p.m. and 1:15 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person by July 14, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Subcommittee Deliberations: On July 22, 2005, from 2:15 p.m. to 5 p.m., the meeting will be closed to the public. The meeting will be closed to

permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)) and to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). The subcommittee will discuss the internal research programs in the Office of Blood Research and Review, CBERS.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact William Freas or Pearlline K. Muckelvene at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 23, 2005.

Sheila Dearybury Walcott,
Associate Commissioner for External Relations.

[FR Doc. 05-12962 Filed 6-29-05; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D-0133]

“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.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a 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 June 2005. This 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) infection based on symptoms and laboratory tests. This guidance revises recommended deferral periods for such donors, and updates information on component retrieval and quarantine. This guidance 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 and supersedes the final “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. 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.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, 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 guidance may also be obtained by mail by calling CBERS at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the 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 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 June 2005. FDA developed the information in this guidance after consulting with other Public Health Service Agencies of the Department of Health and Human Services.

This guidance does the following things:

- 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]

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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:

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: 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]

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