

entitled, "Draft Guidance for Industry: Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus From Donors of Whole Blood and Blood Components Intended for Transfusion and Donors of Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)," that published April 28, 2008. The agency is taking this action to allow interested persons to submit complete data from the 2008 West Nile Virus season concerning the criteria for converting from minipool nucleic acid tests (NAT) to individual donation NAT for donations of Whole Blood and blood components for transfusion.

DATES: Submit requested data by January 31, 2009.

ADDRESSES: Submit written data, identified by Docket No. FDA-2008-D-0233, to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit data in electronic format to <http://www.regulations.gov>. For additional information on submitting data, see the "Request for Data" heading of the **SUPPLEMENTARY INFORMATION** section of this document. Under 21 CFR 10.115(g)(5), comments on guidance documents can be submitted at any time; comments may be submitted to the addresses specified previously.

FOR FURTHER INFORMATION CONTACT: Tami Belouin, 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

In the **Federal Register** of April 28, 2008 (73 FR 22958), FDA published a notice announcing the availability of the draft guidance entitled, "Draft Guidance for Industry: Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus From Donors of Whole Blood and Blood Components Intended for Transfusion and Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)." The draft guidance provides recommendations for testing of donations of Whole Blood and blood components and HCT/P donor specimens for West Nile Virus (WNV) using an FDA-licensed donor screening assay. FDA requested that comments on this draft guidance be submitted within 90 days of publication. The 90-day comment period ends on July 28, 2008.

Based on FDA's consideration of input received to date, we believe that data collected during the 2008 WNV season will be important information that we should obtain prior to finalizing

recommendations on criteria for converting from minipool NAT to individual donation NAT for donations of Whole Blood and blood components for transfusion. However, the 2008 WNV season will extend beyond the 90-day comment period for this draft guidance. We are concerned that extending the comment period until the end of the WNV season would significantly delay finalization of the draft guidance, which contains additional recommendations regarding testing of donations of Whole Blood and blood components for transfusion and HCT/P donor specimens. Based on these considerations, FDA is retaining the 90-day comment period for the draft guidance (ending July 28, 2008). However, we do not intend to finalize the proposed recommendations on conversion from minipool NAT to individual donation NAT until obtaining additional data from the 2008 WNV season. We are requesting the submission, on or before January 31, 2009, of complete data collected during the 2008 WNV season relating to the criteria for converting from minipool NAT to individual NAT. FDA intends to finalize the draft guidance as soon as it is practicable, but may finalize the criteria for conversion to individual donation NAT in a subsequent guidance document after reviewing the additional 2008 data.

II. Request for Data

FDA requests the submission, on or before January 31, 2009, of complete data collected during the 2008 WNV season relating to the criteria for converting from minipool NAT to individual donation NAT. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic data. Submit a single copy of electronic data or two paper copies of any mailed data, except that individuals may submit one paper copy. Data are to be identified with the docket number found in brackets in the heading of this document. Received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic data or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

III. 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.regulations.gov>.

Dated: June 30, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Biomedical Library and Informatics Review Committee.

Date: November 6-7, 2008.

Time: November 6, 2008, 8 a.m. to 6 p.m.
Agenda: To review and evaluate grant applications.

Place: National Library of Medicine, Building 38, Board Room, 2nd Floor, 8600 Rockville Pike, Bethesda, MD 20892.

Time: November 7, 2008, 8 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Library of Medicine, Building 38, Board Room, 2nd Floor, 8600 Rockville Pike, Bethesda, MD 20892.

Contact Person: Arthur A Petrosian, PhD, Scientific Review Administrator, Division of Extramural Programs, National Library of Medicine, 6705 Rockledge Drive, Suite 301 Bethesda, MD 20892-7968, 301-496-4253, petrosia@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: June 26, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

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