D. Other Submission Requirements and Information

Several additional separate actions are required before an applicant institution/organization can submit an application.

Organizational DUNS—As of October 1, 2003, applicants are required to have a DUNS number to apply for a grant or cooperative agreement from the Federal Government. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number applicants should go to *http://www.grants.gov/RequestaDUNS*.

Central Contractor Registration—Applicants must register with the CCR database. This database is a government-wide warehouse of commercial and financial information for all organizations conducting business with the Federal Government. The preferred method for completing a registration is at *http://www.ccr.gov*. This Web site provides a CCR handbook with detailed information on data you will need prior to beginning the online preregistration as well as steps to walk you through the registration process. You must have a DUNS number to begin your registration. For foreign entities the Web site is *http://www.grants.gov/RequestaDUNS.gov*. In order to access Grants.gov an applicant will be required to register with the Credential Provider. Information about this is available at *https://apply.grants.gov/OrcRegister*.

A copy of the complete RFA can also be viewed on FDA's Center for Food Safety and Applied Nutrition Web site at *http://www.cfsan.fda.gov/list.html*.

Foreign Applications (Non-domestic (non-U.S.) Entity)

- Indicate how the proposed project has specific relevance to the mission and objectives of FDA and has the potential for significantly advancing sciences in the United States.
- Research grant applications from foreign or international organizations may not be funded unless approved by the National Cancer Institute National Advisory Board.

IV. Agency Contacts

A. Scientific/Research Contacts

For issues regarding the programmatic aspects of this document, contact Susan E. Carberry at 301–436–1269 or by e-mail: *susan.carberry@fda.hhs.gov*.

B. Financial or Grants Management Contacts

For issues regarding the administrative and financial management aspects, contact Gladys Melendez-Bohler at 301–827–7168 or by e-mail: *gladys.melendez-bohler@fda.hhs.gov*.

Dated: April 22, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–9251 Filed 4–25–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0233]

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); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''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)'' dated April 2008. This draft guidance is intended for establishments that collect Whole Blood and blood components intended for transfusion and establishments that make donor eligibility determinations for donors of human cells, tissues, and cellular and tissue-based products (HCT/Ps). The document 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 believes that the use of a licensed nucleic acid test (NAT) will reduce the risk of transmission of WNV, and therefore recommend use of a licensed NAT to screen donors of Whole Blood and blood components intended for transfusion and for testing donors of HCT/Ps for infection with WNV. FDA recommends the use of licensed NAT testing for WNV within 6 months after a final guidance is issued.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by July 28, 2008.

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.regulations.gov*.

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

FDA is announcing the availability of a draft document entitled ''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)'' dated April 2008. This draft guidance is intended for establishments that collect Whole Blood and blood components intended for transfusion and establishments that make donor eligibility determinations for donors of human cells, tissues, and cellular and tissue-based products HCT/Ps. The document provides recommendations for testing of donations of Whole Blood and blood components and HCT/P donor specimens for WNV using an FDA-licensed donor screening assay. FDA believes that the use of a licensed NAT will reduce the risk of transmission of WNV, and therefore recommend use of a licensed NAT to screen donors of Whole Blood and blood components intended for transfusion and for testing donors of HCT/Ps for infection with WNV. FDA recommends the use of licensed NAT testing for WNV within 6 months after a final guidance is issued.

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. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 collections of information in 21 CFR part 312 have been approved under 0910–0014; 21 CFR part 601 have been approved under 0910–0338; CFR part 606 have been approved under 0910–0116; and 21 CFR part 7, subpart C, have been approved under 0910–0249.

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 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.

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 comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

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.regulations.gov*.

Dated: April 22, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–9253 Filed 4–25–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0226]

Risk Communication Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Risk Communication Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on effective risk communication.

Date and Time: The meeting will be held on May 15, 2008, from 8 a.m. to 5 p.m. and May 16, 2008, from 8 a.m. to 2 p.m.

Addresses: Submit electronic comments and information to *http://www.regulations.gov* . Comments are to be identified with the docket number found in brackets in the heading of this document. Written comments should be submitted to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, by close of business on June 16, 2008. All comments received will be posted without change, including any personal information provided. Comments received on or before May 8, 2008, will be provided to the committee before or at the meeting; comments received after that time will still be considered in preparing the report that was specified in the FDA Amendments Act of 2007 (see docket and committee background for further information).

Location: Hilton Washington DC/Rockville Hotel & Executive Meeting Center, 1750 Rockville Pike, Rockville, MD, 20852–1699.

Contact Person: Lee L. Zwanziger, Office of the Commissioner, Office of Planning (HFP–60), Food and Drug Administration, 5600 Fishers Lane (for express delivery: rm. 15–22), Rockville, MD, 20857, 301–827–2895, FAX: 301–827–5340, Food and Drug Administration, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 8732112560. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that affect a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On May 15, 2008, the committee will meet for presentations and discussion of direct-to-consumer (DTC) advertising, including how it relates to communicating to subsets of the general population, such as the elderly, children, and racial and ethnic minority communities, and increased access to health information and decreased health disparities for these populations. On May 16, 2008, the committee will discuss studying the appropriateness of including, in televised DTC ads, a statement encouraging consumers to report negative side effects of prescription drugs to MedWatch, as is currently required for print DTC prescription drug ads.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2008 and scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before May 8, 2008. Written submissions may also be made to the docket at the address above (see the docket for further information on topics of particular interest for comment in connection with this meeting). Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on May 15th and between 10:30 a.m. and 11:30 a.m. on May 16th. Those desiring to make formal oral presentations should notify the contact person on or before May 8,