DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Advisory Committee on Minority Health

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of Public Health and Science, Office of Minority Health.

ACTION: Notice of meeting.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (DHHS) is hereby giving notice that the Advisory Committee on Minority Health (ACMH) will hold a meeting. This meeting is open to the public. Preregistration is required for both public attendance and comment. Any individual who wishes to attend the meeting and/or participate in the public comment session should e-mail acmh@osophs.dhhs.gov.

DATES: The meeting will be held on August 11, 2008 from 9 a.m. to 5 p.m. and August 12, 2008 from 9 a.m. to 1 p.m.

ADDRESSES: The meeting will be held at the Doubletree Hotel, 1515 Rhode Island Ave., NW., Washington, DC 20005.


SUPPLEMENTARY INFORMATION: In accordance with Public Law 105–392, the ACMH was established to provide advice to the Deputy Assistant Secretary for Minority Health in improving the health of each racial and ethnic minority group and on the development of goals and specific program activities of the Office of Minority Health.

Topics to be discussed during this meeting will include strategies to improve the health of racial and ethnic minority populations through the development of health policies and programs that will help eliminate health disparities, as well as other related issues.

Public attendance at the meeting is limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the designated contact person at least fourteen business days prior to the meeting. Members of the public will have an opportunity to provide comments at the meeting. Public comments will be limited to three minutes per speaker. Individuals who would like to submit written statements should mail or fax their comments to the Office of Minority Health at least seven business days prior to the meeting. Any members of the public who wish to have printed material distributed to ACMH committee members should submit their materials to Garth Graham, M.D., M.P.H., Executive Secretary, ACMH, Tower Building, 1101 Wootton Parkway, Suite 600, Rockville, Maryland 20852, prior to close of business August 4, 2008.

Dated: June 30, 2008.

[FR Doc. E8–15264 Filed 7–3–08; 8:45 am]
BILLING CODE 4150–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

Board of Scientific Counselors, Coordinating Office for Terrorism Preparedness and Emergency Response (BSC, COTPER)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–589), CDC announces the following meeting of the aforementioned committee:

Name: Board of Scientific Counselors, Coordinating Office for Terrorism Preparedness and Emergency Response. Times and Dates: 1 p.m.–4:45 p.m., August 5, 2008, 8:30 a.m.–5:30 p.m., August 6, 2008. Place: CDC, 1600 Clifton Road, NE., Global Communications Center, Building 19, Auditorium B, Atlanta, Georgia 30333. Status: Open to the public for observation and comment, limited only by the space available. The meeting room accommodates approximately 50 people. The public comment period is planned for 3 p.m. Wednesday, August 6, 2008. Conference phone access is available for the meeting. All participants must register. Those desiring to participate by phone will be sent call access information following registration. The call line will not be interactive.

Purpose: This Board is charged with advising the Secretary of HHS and Director of CDC concerning strategies and goals for the programs and research within COTPER, monitoring the strategic direction and focus of the Divisions, and conducting peer review of scientific programs. The agenda will include briefings of the BSC members about COTPER’s mission, strategy, and operations, establishing the BSC procedures for external peer review, determining which COTPER programs will be peer reviewed in Fiscal Year 2009, reviewing the Federal Advisory Board Act requirements, and determining appropriate protocols and procedures under which the Board will pursue their Charter.

Agenda items are subject to change as priorities dictate.

Additional Information: In order to expedite the security clearance process at CDC/Roybal Campus located on Clifton Road, All attendees are required to register online at http://www2a.cdc.gov/nip/COTPER/Registration.asp. Please complete all required fields before submitting your registration and submit no later than July 14, 2008 for non-U.S. citizens and July 20, 2008 for U.S. citizens.

Please Note: In addition to completing the registration form on-line, all non-U.S. citizens are required to complete the “Access Request Form” which will be e-mailed to you upon registration. The completed access request form should be sent by e-mail directly to dmanheim@cdc.gov no later than July 15, 2008. Those planning to participate by conference phone will be sent access information following registration.

Contact Person for More Information: Barbara Ellis, Coordinating Office for Terrorism Preparedness and Emergency Response, CDC, 1600 Clifton Road, NE., Mailstop D–44, Atlanta, Georgia 30333; Telephone (404) 639–1528, FAX: (404) 639–7977. E-mail: COTPER.BSC.Questions@cdc.gov.

The Director, Management Analysis and Service Office, has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities for both CDC and Agency for Toxic Substances and Disease Registry.

Dated: June 30, 2008.
Elaine L. Baker,
Director, Management Analysis and Service Office, Centers for Disease Control and Prevention.

[FR Doc. E8–15247 Filed 7–3–08; 8:45 am]
BILLING CODE 4150–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration


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; Request for Data

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for data.

SUMMARY: The Food and Drug Administration (FDA) is requesting submission of data related to certain recommendations in 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 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.


ADDRESSES: Submit written data, identified by Docket No. FDA–2008–D–0234, 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.


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 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.

[FR Doc. E8–15368 Filed 7–3–08; 8:45 am]