MSC 7890, Bethesda, MD 20892, 301–435–2514, *stassid@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: September 21, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–23240 Filed 9–28–09; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0443]

Anti-Infective Drugs 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: Anti-Infective Drugs Advisory Committee.

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 October 26, 2009, from 8:30 a.m. to 4 p.m.

Addresses: Electronic comments should be submitted to *http://www.regulations.gov*. Enter ''FDA–2009–N–0443'' and follow the prompts to submit your statement. 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. All comments received will be posted without change, including any personal information provided. Comments received on or before October 5, 2009, will be provided to the committee before the meeting.

Location: Hilton Washington DC/Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD. The hotel phone number is 301–589–5200.

Contact Person: Minh Doan, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *Minh.Doan@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington DC area), code 3014512530. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact 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: The committee will discuss updating susceptibility test information in systemic antibacterial drug product labeling.

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/AdvisoryCommittees/Calendar/default.htm*. 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 October 16, 2009. Oral presentations from the public will be scheduled between approximately 12:45 p.m. and 1:45 p.m. Those desiring to make formal oral presentations should notify the contact person 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 on or before October 9, 2009. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 12, 2009.

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 Minh Doan at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

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

Dated: 9/23/09.

David Horowitz,

Assistant Commissioner for Policy

[FR Doc. E9–23437 Filed 9–28–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Blood Products 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Blood Products Advisory Committee.

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 November 16, 2009, from 8 a.m. to 5:30 p.m. and on November 17, 2009, from 8 a.m. to 5 p.m.

Location: Bethesda Marriott Hotel, 5151 Pooks Hill Rd., Bethesda, MD 20814.

Contact Person: William Freas or Pearline K. Muckelvene, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike (HFM–71), 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. A notice in the **Federal Register** about last minute modifications that impact 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 November 16, 2009, in the morning the Committee will hear updates on the following topics: the HHS Advisory Committee on Blood Safety and Availability, Dengue virus outbreak, and 2009 A/H1N1 Pandemic and the impact on blood safety and availability. The Committee will then discuss blood donor deferral for malaria risk associated with travel to Mexico. In the afternoon the Committee will discuss the design of a new phase III study of pathogen inactivation of human platelets using the Cerus, INTERCEPT Blood System. On November 17, 2009, in the morning the Committee will discuss blood pressure and pulse as blood donor eligibility criteria, and in the afternoon the committee will discuss the public health need and performance characteristics of over-the-counter home-use HIV test kits.

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/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee link.

Procedure: On November 16, 2009, from 8 a.m. to 5:30 p.m. and on November 17, 2009, from 8 a.m. to 3:15 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 committee. Written submissions may be made to the contact person on or before November 9, 2009. Oral presentations from the public will be scheduled between approximately 11 a.m. and 11:30 a.m. and between 4 p.m. and 4:30 p.m. on November 16, 2009, and between approximately 10:30 a.m. and 11 a.m., and 2:15 and 2:45 p.m. on November 17, 2009. Those desiring to make formal oral presentations should notify the contact person 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 on or before October 30, 2009. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 2, 2009.

Closed Committee Deliberations : On November 17, 2009, from approximately 3 p.m. until 5 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)). The committee will hear presentations and discuss sponsor, trade secret and confidential information.

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 Pearline K. Muckelvene at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

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

Dated: September 23, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–23434 Filed 9–28–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

''CORRECTED Version of Request for Information Regarding Development and Operation of a Transplantation Sentinel Network''

AGENCY: Office of Blood, Organ and Other Tissue Safety, Division of Healthcare Quality Promotion, Center for Preparedness, Detection, and Control of Infectious Diseases, Centers for Disease Control and Prevention, Department of Health and Human Services.

ACTION: Request for information notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC) is seeking information on development and operation of a national transplantation sentinel network (TSN) for the United States, including resources needed for management of such a system. The purpose of the network is to detect and prevent disease transmission from organ and tissue allografts recovered for transplantation.

In June 2005, the CDC announced a Request for Application (RFA) through a cooperative agreement for development of a TSN for organizations that recover, process, distribute, and implant organs and tissues. The overall goal of the system was to improve patient safety for organ and tissue recipients. The RFA objectives were to: (1) Identify and track organs and tissues to facilitate intervention following recognition of infections among recipients or donors; (2) improve communication among those in the transplant community, healthcare facilities and public health agencies concerning potential risks for transmission of infections; and (3) improve pathologic and microbiologic capabilities on cadaveric donor specimen samples through shared resources. Development and field testing of the prototype was completed in 2008.

For this RFI, respondents are asked to describe experiences, plans or opinions regarding aspects of completing and operating a TSN system; system governance, security, and marketing; user training; and operational and infrastructure management. Responses need not address every aspect of this RFI; responses may be limited to address specific components or portions of a section. The specific sections requested for comments are: (1) Transition of Transplantation Transmission Sentinel Network (TTSN) Prototype to Full Production; (2) Standardization and Compatibility Issues; (3) Reporting Criteria; (4) Interoperability and Interfacing with Existing Data Sources; (5) System Operation and Infrastructure Management; (6) Analysis Plan including Feedback to Users; (7) Patient Health Information Privacy and Security; and (8) System Governance.

DATES: Comments must be submitted on or before December 11, 2009.

ADDRESSES: The entire TSN RFI can be accessed at *http://www.cdc.gov/ncidod/dhqp/pdf/ttsn/RFI_TSN_FedRegDoc_9909.pdf*. Electronic responses are preferred and should be sent to *TransplantRFI@cdc.gov*. Responses sent in hard copy format must be securely bound and sent to Debbie Seem, Office of Blood, Organ and Other Tissue Safety, Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention, Building 16, MS–A07, 1600 Clifton Road, NE., Atlanta, GA 30329–4018, Telephone number: 404–639–3234, E-mail Address: *gqi4@cdc.gov*.

SUPPLEMENTARY INFORMATION: Each year in the United States, more than 28,000 solid organs and 2 million tissues are transplanted, including heart, lung, liver, kidneys, pancreas, intestine, bone, skin, heart valves, tendons, fascia and corneas. Donor-derived infections have been identified as a source of morbidity and mortality among both solid organ and tissue transplant recipients.

Infectious transmission identified in the past few years among solid organs have reflected a broad array of viruses, bacteria, and parasites, resulting in a high proportion of mortality amongst infected recipients; examples include HIV, hepatitis C virus (HCV), lymphocytic choriomeningitis virus, *Mycobacterium tuberculosis, Pseudomonas aeruginosa, Strongyloides* spp, and *Trypanosoma cruzi,* the etiologic agent of Chagas Disease. Malignancies also have been transmitted by solid organs. The Health Resources and Services Administration (HRSA) oversees the transplantation of solid organs through the Organ Procurement and Transplantation Network (OPTN) administered by the United Network for Organ Sharing (UNOS). OPTN policy requires reporting of all potential donor-derived infections to UNOS and