

of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Transmissible Spongiform Encephalopathies 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 28, 2010, from 8:30 a.m. to approximately 5 p.m. and on October 29, 2010, from 8:30 a.m. to approximately 12:30 p.m.

Location: Holiday Inn, Gaithersburg, 2 Montgomery Village Ave., Gaithersburg, MD, 20879.

Contact Person: Bryan Emery or Rosanna Harvey, 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 3014512392. 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 October 28, 2010, the Committee will discuss: (1) FDA's risk assessment for potential exposure to the variant Creutzfeldt-Jakob disease (vCJD) agent in U.S.-licensed plasma-derived Factor VIII and (2) labeling of blood and blood components and plasma-derived products, including plasma-derived albumin and products containing plasma-derived albumin, to address the possible risk of transmission of vCJD. On October 29, 2010, the Committee will hear informational presentations related to FDA's geographic donor deferral policy to reduce the possible risk of transmission of CJD and vCJD by blood and blood products and human cells, and tissue and cellular and tissue based products. The Committee will also hear updates on the following topics: The development of devices to remove transmissible spongiform encephalopathy agents from blood components and chronic wasting disease.

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 21, 2010. Oral presentations from the public will be scheduled on October 28, 2010, between approximately 11 a.m. and 11:45 a.m. and between approximately 3:30 p.m. and 4 p.m. and on October 29, 2010, between approximately 10:30 a.m. and 11 a.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 13, 2010. 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 14, 2010.

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 Bryan Emery 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 7, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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: National Institute of General Medical Sciences Special Emphasis Panel, Phase II Clinical Trial in Septic Shock.

Date: October 7, 2010.

Time: 8:30 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN18K, Bethesda, MD 20892. (Telephone Conference Call.)

Contact Person: Brian R. Pike, PhD, Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN18B, Bethesda, MD 20892. 301-594-3907. pikbr@mail.nih.gov. (Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: September 8, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

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