4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Transmissible Spongiform Encephalopathies 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: 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 June 1, 2015, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm.1503), Silver Spring, MD 20993-0002. For those unable to attend in person, the meeting will also be available via Webcast. The Webcast will be available at the following link: https://collaboration.fda.gov/cbertseac/. When accessing the Webcast please enter as a guest. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.

Contact Person: Bryan Emery or Rosanna Harvey, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 6132, Silver Spring, MD 20993-0002, 240-402-8054 or 240-402-8072; or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). 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 at http://www.fda.gov/AdvisoryCommittees/default.htm and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On June 1, 2015, the Transmissible Spongiform Encephalopathies Advisory Committee will meet in open session to hear update presentations on the following topics: 1) The variant Creutzfeldt-Jakob Disease (vCJD) situation worldwide and an update on the United Kingdom's Transfusion Medicine Epidemiological Review; 2) vCJD in the United States; and, 3) the bovine spongiform encephalopathy (BSE) situation worldwide and the United States Department of Agriculture's regulatory approaches to reduce the risk of food-borne exposure of BSE. Following the update presentations, in open session, the committee will hear presentations from FDA on current measures to reduce risk of vCJD from transfusion in the U.S., and a mathematical model of the risk reduction achievable under the current and alternative geographically based donor deferral policies when implemented in conjunction with the use of leukocyte reduction of blood components. The committee will then discuss FDA's geographically based donor deferral policies and other strategies, including leukocyte reduction

of blood components, to reduce the risk of transfusion-transmitted vCJD. FDA will seek advice from the committee in developing future recommendations to reduce this risk.

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 meeting 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 25, 2015. Oral presentations from the public will be scheduled between approximately 2:30 p.m. and 3:30 p.m. Those individuals interested in making 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 May 15, 2015. 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 May 18, 2015.

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: April 24, 2015.

Peter Lurie,

Associate Commissioner for Public Health Strategy and Analysis.

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