

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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 October 31, 2005, from 8 a.m. to 5:30 p.m.

Location: Holiday Inn Select, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: William Freas or Sheila D. Langford, 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.

Agenda: On October 31, 2005, the committee will hear updates on the following topics: Current status of bovine spongiform encephalopathy (BSE)

in the United States, incidence and prevalence worldwide of variant Creutzfeldt-Jakob Disease (vCJD), and a summary of FDA's device panel discussion on September 27, 2005, on criteria for considering label claims of effective decontamination for surgical instruments exposed to transmissible spongiform encephalopathy (TSE) agents. The committee will then discuss progress in development of a risk assessment model for vCJD in U.S.-licensed human plasma-derived Antihemophilic Factor (Factor VIII). The latter discussion will focus on selection of input parameters for the model. In the afternoon, the committee will discuss labeling claims for TSE clearance studies for blood component filters.

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 by October 21, 2005. Oral presentations from the public will be scheduled between approximately 12:30 p.m. and 1 p.m., and 4:15 p.m. and 4:45 p.m. on October 31, 2005. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 25, 2005, 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.

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 Sheila Langford at least 7 days in advance of the meeting.

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

Dated: October 6, 2005.

Jason Brodsky,

Acting Associate Commissioner for External Relations.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

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