

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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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 14, 2004, from 8 a.m. to 5:30 p.m.

Location: Hilton Hotel, 8727 Colesville Rd., Silver Spring, MD 20910.

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, 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 14, 2004, the committee will hear updates on the following issues: USDA-licensed tests for the diagnosis of bovine spongiform

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encephalopathy (BSE) and other transmissible spongiform encephalopathies (TSE), review of the worldwide BSE situation, new FDA/Center for Food Safety and Applied Nutrition BSE-food safety rules, and labeling claims for TSE clearance studies for plasma derivative products. The committee will then discuss and make recommendations regarding presumptive transfusion transmissions of variant Creutzfeldt Jakob Disease (vCJD) and current FDA-recommended safeguards.

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 5, 2004. Oral presentations from the public will be scheduled between approximately 9:20 a.m. and 9:50 a.m., and 2:45 p.m. and 3:15 p.m. on October 14, 2004. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 7, 2004, 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 D. 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: 9-15-04

September 15, 2004.

Sheila Dearybury Walcott

Sheila Dearybury Walcott,
Associate Commissioner for External Relations.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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