

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 July 17, 2003, from 8 a.m. to 6 p.m., and on July 18, 2003, from 8 a.m. to 4:30 p.m.

Location: Holiday Inn Select, 8120 Wisconsin Ave., Bethesda, MD, 301-652-2000.

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 12392. Please call the Information Line for up-to-date information on this meeting.

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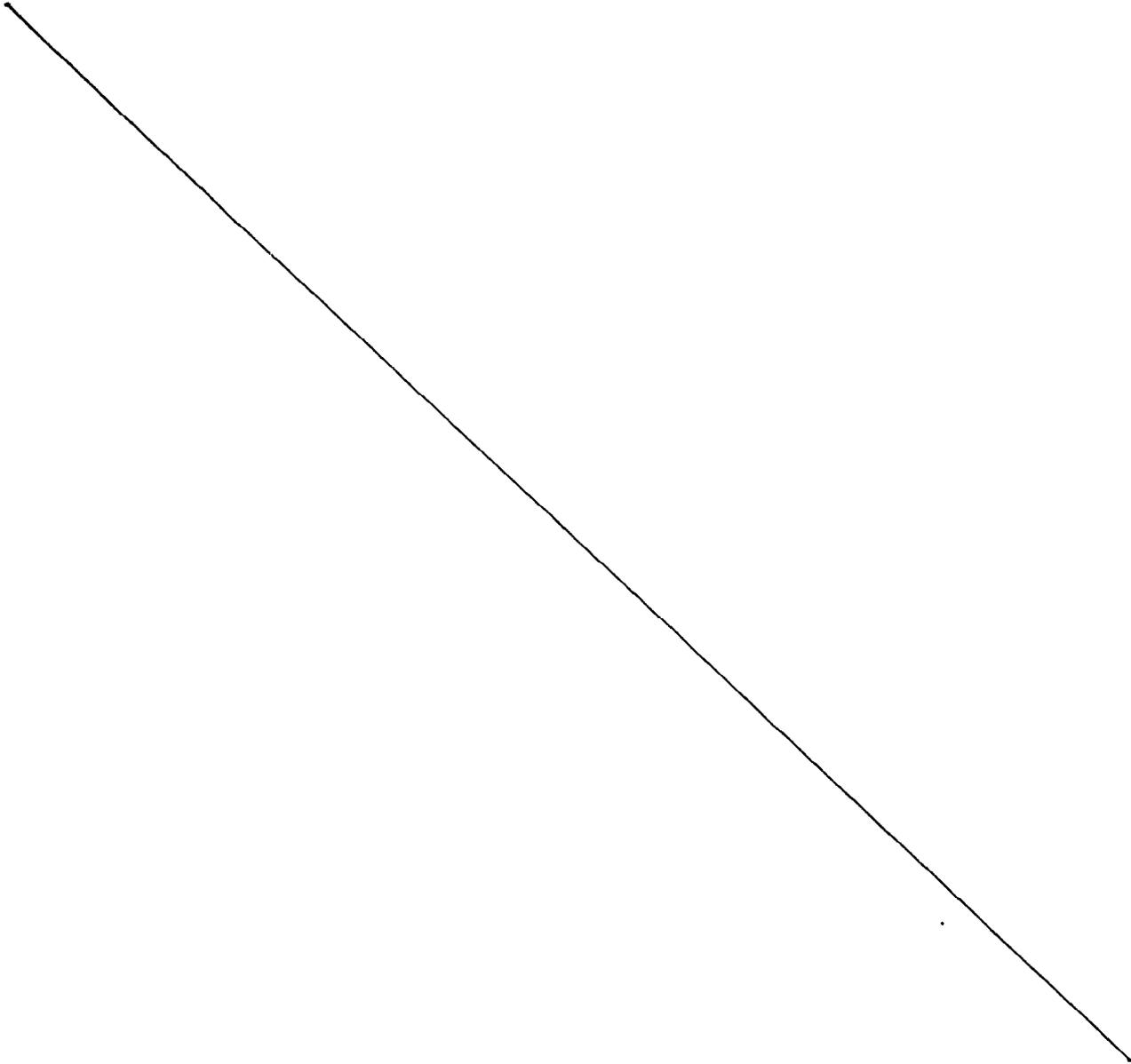
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Agenda: On July 17, 2003, the committee will discuss the safety of bovine bone gelatin in oral and topical drugs, food and cosmetics. The committee will then discuss bovine spongiform encephalopathy in Canada and potential implications for FDA-regulated products. In the afternoon, the committee will hear presentations on transmissible spongiform encephalopathies (TSEs) and decontamination of medical equipment and facilities. On Friday, July 18, 2003, the committee will discuss designing, interpreting, and validating studies to evaluate reprocessing methods for removing TSE contamination from medical devices. In the afternoon, the committee will discuss methods to decontaminate facilities and equipment used to prepare human cellular and tissue products, and human blood products, including plasma derivatives, to reduce the theoretical risk of transmitting TSE agents.

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 July 10, 2003. Oral presentations from the public will be scheduled between approximately 11:35 a.m. and 11:55 a.m., and 1:55 p.m. and 2:25 p.m. on July 17, 2003; and between approximately 9:50 a.m. and 10:20 a.m., and 1:30 p.m. and 2 p.m. on July 18, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 11, 2003, 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: 6/9/03
June 9, 2003.

Peter J. Pitts
Peter J. Pitts,
Associate Commissioner for External Relations.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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