

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB

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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). At least one portion of the meeting will be closed to the public.

Name of Committee: Transmissible Spongiform Encephalopathies (TSE) 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 28, 2001, 8 a.m. to 5 p.m. and on June 29, 2001, 8 a.m. to 11:30 a.m.

Location: Holiday Inn, Versailles Ballroom I and II, 8120 Wisconsin Ave., Bethesda, MD.

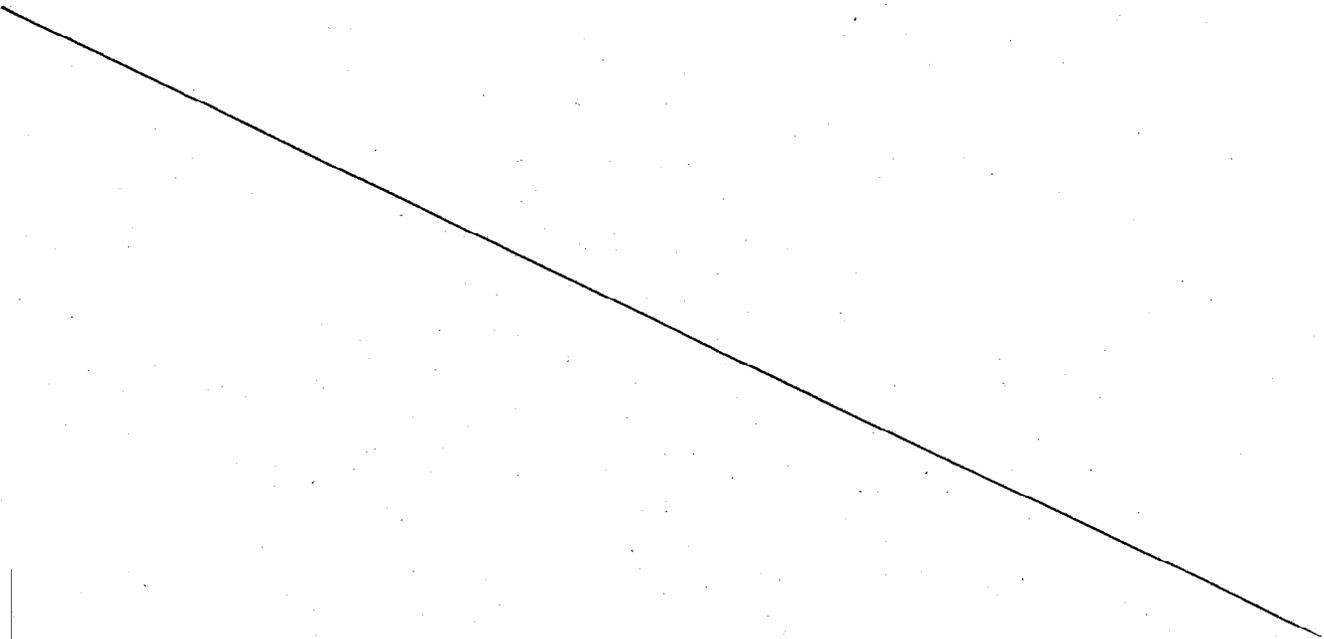
Contact: William Freas, or Sheila D. Langford, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12392. Please call the Information Line for up-to-date information on this meeting.

Agenda: On June 28, 2001, the committee will review and discuss the suitability of blood donors who have lived or traveled in various countries based on recent information concerning new-variant Creutzfeldt-Jakob disease and bovine spongiform encephalopathy in those countries. In the afternoon, the committee will discuss the safety of FDA-regulated plasma derivatives prepared in establishments proposing to use on the same manufacturing line, plasma which does and plasma which does not comply with current U.S. standards, with regard to donor deferral

for vCJB risk factors. On June 29, 2001, the committee will discuss the interim results of a new study on the inactivation of TSE agent by the manufacturing process for gelatin.

Procedure: On June 28, 2001, from 8 a.m. to 4:30 p.m. and June 29, 2001, from 8 a.m. to 11:30 a.m., the meeting is open to the public. 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 June 15, 2001. Oral presentations from the public will be scheduled between approximately 10:50 a.m. and 11:30 a.m., and between approximately 2:30 p.m. and 3:10 p.m. on June 28, 2001, and between approximately 10 a.m. and 10:30 a.m. on June 29, 2001. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 15, 2001, 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.

Closed Committee Deliberations: On June 28, 2001, from 4:30 p.m. to 5 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). This portion of the meeting will be closed to permit discussion of this material.



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

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[Redacted]

JUN - 5 2001

Dated:

June 5, 2001.

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

Linda A. Suydam

Linda A. Suydam,
Senior Associate Commissioner.

[Signature]

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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