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 September 18, 2006, from 8 a.m. to 4:30 p.m. and September 19, 2006, from 8 a.m. to 1 p.m.

Location: Holiday Inn Gaithersburg, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: William Freas or Rosanna Harvey, 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 3014512392. Please call the Information Line for up-to-date information on this meeting.

oc06172

2006·4237

NM1

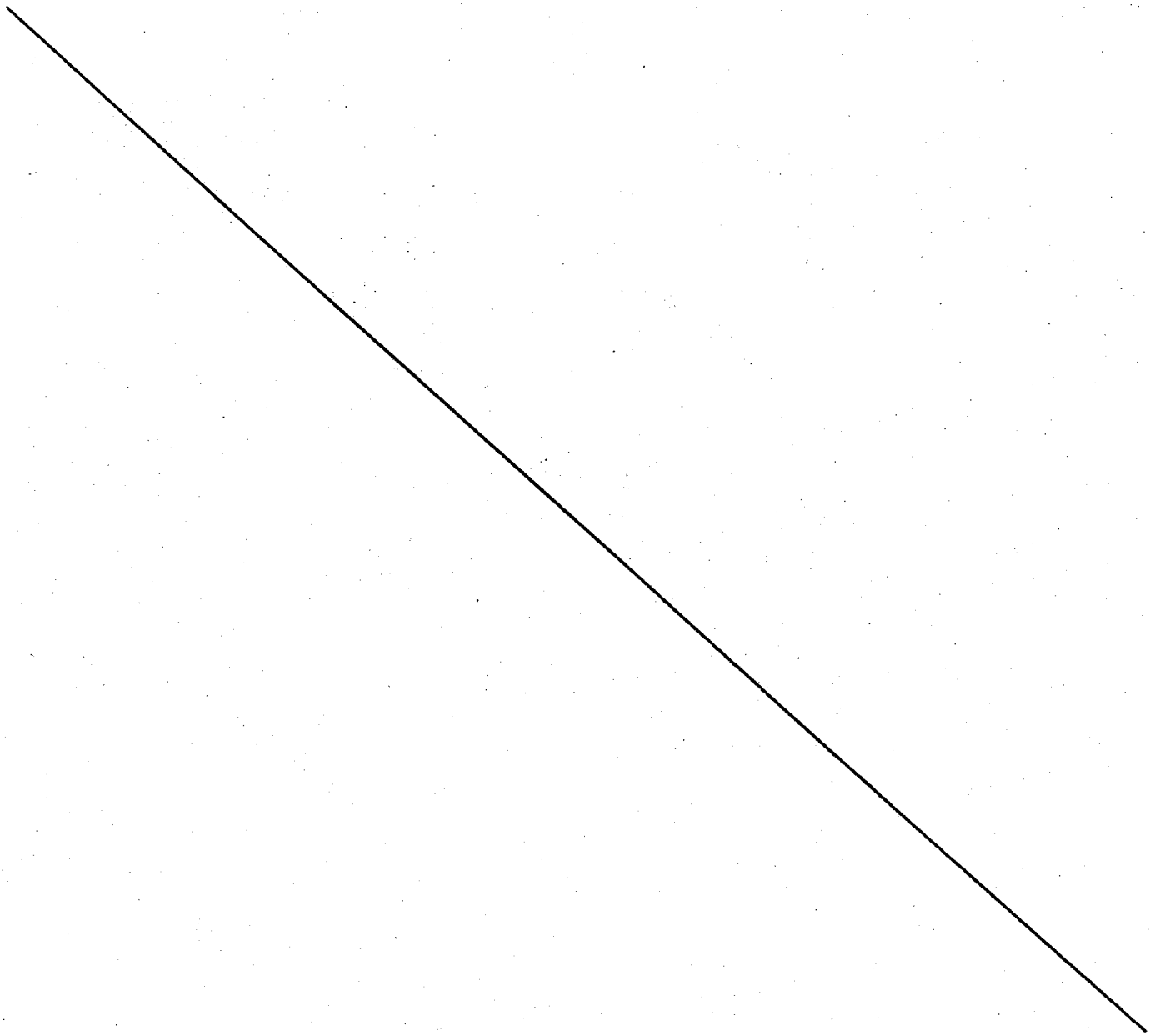
Agenda: On September 18, 2006, the committee will hear updates on the following topics: United States and worldwide bovine spongiform encephalopathies (BSE); variant Creutzfeldt-Jakob disease (vCJD) epidemiology and transfusion-transmission; blood and plasma donor deferral for transfusion in France since 1980 guidance; FDA's current assessment and plans regarding the potential exposure to vCJD from an investigational product, FXI, that was manufactured from UK donor plasma; and a summary of World Heath Organization Consultation on distribution of infectivity in tissues of animals and humans with transmissible spongiform encephalopathies. The committee will then discuss experimental clearance of transmissible spongiform encephalopathy infectivity in plasma-derived Factor VIII products. In the afternoon, the committee will discuss FDA's risk assessment for potential exposure to vCJD from human plasma-derived antihemophilic factor (FVIII) products and potential responses. On September 19, 2006, the committee will discuss possible criteria for approval of donor screening tests for vCJD.

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 September 6, 2006. Oral presentations from the public will be scheduled between approximately 10:45 a.m. and 11:15 a.m. and 2:30 p.m. and 3 p.m. on September 18, 2006, and between approximately 10:15 a.m. and 11:45 a.m. on September 19, 2006. Time allotted for each presentation may be limited. Those desiring to make 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 September 11, 2006.

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 Rosanna Harvey 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: 7/27/06
July 27, 2006.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 06–????? Filed ??–??–06; 8:45 am]

BILLING CODE 4160–01–S