DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committees; Ad Hoc Advisory Committee on Creutzfeldt-Jakob Disease; Establishment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the establishment by the Secretary of Health and Human Services (the Secretary), of the Ad Hoc Advisory Committee on Creutzfeldt-Jakob Disease.

DATES: Authorization for the Committee being established will end on June 9, 1996.

FOR FURTHER INFORMATION CONTACT: Donna M. Combs, Committee Management Office (HFA–306), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–2765.

SUPPLEMENTARY INFORMATION: Under the Federal Advisory Committee Act of October 6, 1972, Pub. L. 92–463, as amended (5 U.S.C. app. 2), and 21 CFR 14.40(b), FDA is announcing the establishment by the Secretary of the Ad Hoc Advisory Committee on Creutzfeldt-Jacob Disease.

The Ad Hoc Advisory Committee on Creutzfeldt-Jakob Disease will review and evaluate available data concerning the safety of blood products obtained from, a donor who, after donation, was diagnosed with Creutzfeldt-Jakob Disease, and make recommendations regarding the disposition of such blood products to the Commissioner of Food and Drugs.

Dated: June 12, 1995.

David A. Kessler,

Commissioner of Food and Drugs.

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BILLING CODE 4160–01–F

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1–800–741–8138 or 301–443–0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETINGS: The following advisory committee meeting is announced:

Ad Hoc Advisory Committee on Creutzfeldt-Jakob Disease

Date, time, and place. June 22, 1995, 8 a.m., Marriott Hotel—Bethesda, Congressional Salons I, II, and III, 5151 Pooks Hill Rd., Bethesda, MD.

Type of meeting and contact person. Open committee discussion, 8 a.m. to 11:50 p.m.; open public hearing, 11:50 a.m. to 12:50 p.m., unless public participation does not last that long; open committee discussion, 12:50 p.m. to 5 p.m.; Linda A. Smallwood, Office of Blood Research and Review, Center for Biologics Evaluation and Research (HFM–350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–6700, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Ad Hoc Advisory Committee on Creutzfeldt-Jakob Disease code 12388.

General function of the committee. The Committee will review and evaluate available data concerning the safety of blood products obtained from, or prepared from one or more donations from, a donor who, after donation, was diagnosed with Creutzfeldt-Jakob Disease and make appropriate recommendations to the Commissioner of Food and Drugs regarding the appropriate disposition of such blood products.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before June 16, 1995, 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 required to make their comments.

Open committee discussion. The committee reviews and provides recommendations on the public health issue of Creutzfeldt-Jakob Disease concerning blood products, especially those derived from pooled plasma.

FDA is giving less than 15 days public notice of this Ad Hoc Advisory Committee meeting because of the urgent need to address the potential risk of this disease to public health safety. The agency decided that it was in the public interest to hold this scientific discussion on June 22, 1995, even if there was not sufficient time for the customary 15-day public notice.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this **Federal Register** notice. Changes in the agenda will be announced at the