

agency has compiled these comments into a plan for further discussion by the committee.

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 2, 2002. Oral presentations from the public will be scheduled between approximately 1 p.m. and 1:30 p.m. on July 10, 2002, and between approximately 1 p.m. and 2 p.m. on July 11, 2002. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 2, 2002, 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 Tara Turner 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: June 17, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committees: Filing of Annual Reports

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that, as required by the Federal Advisory Committee Act, the agency has filed with the Library of Congress the annual reports of those FDA advisory committees that held closed meetings.

ADDRESSES: Copies are available from the Dockets Management Branch (HFA-305), Food and Drug Administration,

5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 301-827-6860.

FOR FURTHER INFORMATION CONTACT:

Linda Ann Sherman, Advisory Committee Oversight and Management Staff, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1220.

SUPPLEMENTARY INFORMATION: Under section 13 of the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR 14.60(c), FDA has filed with the Library of Congress the annual reports for the following FDA advisory committees that held closed meetings during the period October 1, 2000, through September 30, 2001:

Center for Biologics Evaluation and Research:

Biological Response Modifiers Advisory Committee;

Blood Products Advisory Committee; and

Vaccines and Related Biological Products Advisory Committee.

Center for Drug Evaluation and Research:

Anti-Infective Drugs Advisory Committee;

Arthritis Advisory Committee;

Cardiovascular and Renal Drugs Advisory Committee;

Dermatologic and Ophthalmic Drugs Advisory Committee; and

Oncologic Drugs Advisory Committee.

Center for Devices and Radiological Health:

Medical Devices Advisory Committee.

National Center for Toxicological Research:

Science Advisory Board to the National Center for Toxicological Research.

Annual reports are available for public inspection between 9 a.m. and 4 p.m., Monday through Friday at the following locations:

(1) The Library of Congress, Madison Bldg., Newspaper and Current Periodical Reading Room, 101 Independence Ave. SE., rm. 133, Washington, DC; and (2) The Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Dated: June 14, 2002.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D-0266]

Draft "Guidance for Industry: Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps);" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Industry: Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)" dated June 2002. The draft guidance document provides information that would assist manufacturers of human cellular and tissue-based products in minimizing the possible risk of transmission of CJD/vCJD by HCT/Ps through deferral of donors with possible exposure to the agents of CJD and vCJD. Because there is no readily available demographic information about the HCT/P donor population, FDA encourages establishments to submit with their comments study data concerning the effect that implementation of these recommendations could have on the HCT/P supply.

DATES: Submit written or electronic comments on the draft guidance to ensure their adequate consideration in preparation of the final document by December 23, 2002. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800, or by fax by calling the FAX Information System at 1-888-CBER-FAX or 301-827-3844. See the