**Federal Register Proposed Rules, Notices - Title 21**
**Vol. 67 No. 122 Tuesday, June 25, 2002**
**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.**

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**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 The draft guidance document provides information that would assist manufacturers of human cellular and tissue-based products in minimizing the possible risk of transmission of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DATES: Submit written or electronic comments on the draft guidance to ensure their adequate consideration in preparation of the final document by December 23, 2002.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ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers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

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SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance.

Submit written comments on the document to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

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 help human cellular and tissue-based product manufacturers minimize the possible risk of transmission of CJD/vCJD by HCT/Ps through deferral of donors with possible exposure to the agents causing CJD and vCJD.

The draft guidance document represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statute, regulations, or both. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

This draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons

may submit to the Dockets Management Branch (see ADDRESSES) written or electronic comments regarding this draft guidance document. Submit written or electronic comments to ensure adequate consideration in preparation of the final document by December 23, 2002. Two copies of any written comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/cber/guidelines.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: June 13, 2002.
Margaret M. Dotzel,
Associate Commissioner for Policy.
[FR Doc. **02**-**15898 Filed** 6-24-**02**; 8:45 am]

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