

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D-0318]

DMB

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Certifier	<i>Skese</i>

Draft "Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products;" Availability; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of the comment period.

SUMMARY: The Food and Drug Administration (FDA) previously requested that comments on the draft entitled "Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products" dated August 2001 be submitted by September 28, 2001, to ensure their adequate consideration in preparation of the final document (66 FR 45683, August 29, 2001). The agency has determined that it will have adequate time to consider, in preparation of the final guidance, comments received by October 28, 2001. FDA is taking this action in response to a request that the agency allow interested parties additional time to review and to submit comments.

DATES: Submit written or electronic comments on the draft guidance to ensure their adequate consideration in preparation of the final document by October 28, 2001. 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ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug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

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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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance document to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

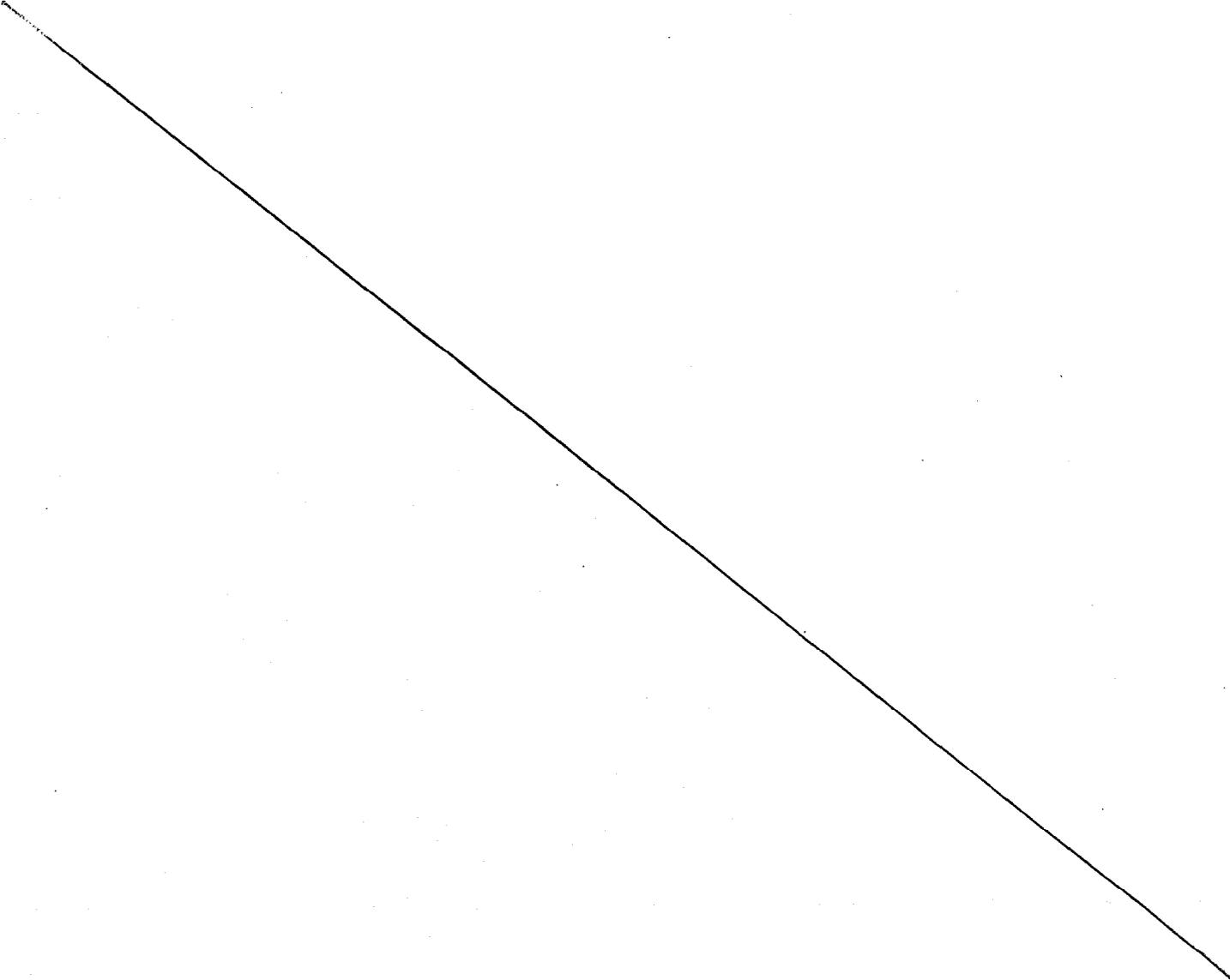
I. Background

In the **Federal Register** of August 29, 2001 (66 FR 45683), FDA published a notice announcing the availability of a draft guidance document entitled “Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products.” The draft guidance document provides comprehensive current recommendations to all registered blood and plasma establishments for deferral of donors with possible exposure to the agent of vCJD. The agency asked interested persons to submit written or electronic comments on the draft guidance to ensure their adequate consideration in preparation of the final document by September 28, 2001.

On September 19, 2001, a comment from America’s Blood Centers was submitted to the docket requesting that FDA consider comments received after September 28, 2001. The comment stated that blood establishment obligations related to the recent terrorist attack has delayed the review of the guidance by a number of blood establishments. The agency has determined that it will have adequate time to consider comments received by October 28, 2001.

II. Comments

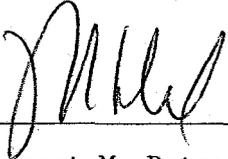
Interested persons should submit to the Dockets Management Branch (address above) written or electronic comments regarding the draft guidance document by October 28, 2001, to ensure consideration of comments in FDA's preparation of a final guidance. Two copies of any comments are to be submitted, except 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: 9/21/01
September 21, 2001.



Margaret M. Dotzel,
Associate Commissioner for Policy.

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

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Suzette N. Reese