

DATES: Written comments may be submitted at any time, however, comments should be submitted by October 18, 1999, to ensure adequate consideration in preparation of a revised document, if warranted. The agency is soliciting public comment, but is implementing this guidance document immediately because of the public health concerns related to the possible risk of transmission of CJD and nvCJD by blood and blood products.

ADDRESSES: Submit written requests for single copies of the guidance document entitled "Guidance for Industry: Revised Precautionary Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and New Variant Creutzfeldt-Jakob Disease (nvCJD) by Blood and Blood Products" 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 that office in processing your requests. The guidance 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 guidance document.

Submit written comments on the guidance document to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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

FDA is announcing the availability of a guidance document entitled "Guidance for Industry: Revised Precautionary Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and New Variant Creutzfeldt-Jakob Disease (nvCJD) by Blood and Blood Products." The guidance document is intended to replace the FDA guidance entitled "Revised Precautionary Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) by Blood and Blood Products" sent by mail to blood and plasma establishments and plasma derivatives manufacturers on December

11, 1996. See notice of availability (62 FR 49694, September 23, 1997).

Recommendations addressed in the guidance document include: (1) Donor screening questions and deferral criteria, (2) disposition of implicated products, (3) consignee notification and recipient counseling, and (4) product labeling.

The guidance document represents the agency's current thinking on precautionary measures to reduce the possible risk and to assure that blood and blood products are not adulterated or misbranded, within the meaning of the Federal Food Drug and Cosmetic Act, and are safe, pure and potent within the meaning of the Public Health Service Act. 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 requirements 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 guidance document is intended to provide information and does not set forth requirements.

II. Comments

The agency is soliciting public comment, but is implementing this guidance document immediately because of the public health concerns related to the possible risk of transmission of CJD and nvCJD by blood and blood products. Additionally, the guidance presents a less burdensome policy for the management of blood components and plasma derivatives in cases where the donor has classic CJD or CJD risk factors. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this guidance document. Written comments may be submitted at any time, however, comments should be submitted by October 18, 1999, to ensure adequate consideration in preparation of a revised document, if warranted. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the guidance document and received comments are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the guidance document using the World Wide Web (WWW). For WWW access, connect to CBER at "http://www.fda.gov/cber/guidelines.htm".

Dated: August 4, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99-21251 Filed 8-16-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-2407]

Evaluation and Processing of Post Donation Information Reports; Compliance Policy Guide; Guidance for FDA Personnel; Availability; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a new compliance policy guide (CPG) entitled "Evaluation and Processing of Post Donation Information Reports" (section 230.140). This document provides guidance to FDA field and headquarters staff regarding FDA's policy related to the evaluation and processing of post donation information reports for blood and blood components.

DATES: Written comments may be provided at any time.

ADDRESSES: Submit written requests for single copies of the CPG entitled "Evaluation and Processing of Post Donation Information Reports" (section 230.140) to the Director, Division of Compliance Policy (HFC-230), Office of Enforcement, Office of Regulatory Affairs (ORA), 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your requests, or you may fax your request to 301-827-0482. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document. Written comments should be identified with the docket number found in brackets in the heading of this document and should be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Sharon O'Callaghan, Center For Biologics Evaluation and Research (CBER) (HFM-650), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-594-1191.

SUPPLEMENTARY INFORMATION:**I. Background**

CBER issued a memorandum to blood establishments on December 10, 1993, that provided guidance concerning process control procedures that should be established and maintained for the receipt, evaluation, investigation, and followup of post donation information reports. Post donation information includes information provided by the donor or other source and received or obtained following a donation, or at a subsequent donation during the health history screening process that relates to the suitability of the donor or of the blood or blood component. This CPG provides regulatory guidance relative to the evaluation and processing of this information.

This Level 2 guidance document is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on the evaluation and processing of post donation reports. 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 requirements of the applicable statutes, regulations, or both.

II. Request for Comments

Written comments concerning the guidance may be submitted to the Dockets Management Branch (address above) at any time. Two copies of any comments are to be submitted, except that individuals may submit one copy. Written comments and requests for copies are to be identified with the docket number found in brackets in the heading of this document. A copy of the CPG and received comments are available for public examination in the office above between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

An electronic version of the CPG (section 230.140) is also available on the Internet by connecting to the ORA home page at "http://www.fda.gov/ora/compliance_ref/default.htm".

Dated: August 9, 1999.

Dennis E. Baker,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 99-21255 Filed 8-16-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. 99D-2405]

Draft "Guidance for Industry: Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act;" 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: Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act." This draft guidance is intended to provide guidance to industry on the use of certain types of letters by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) as part of the review of marketing applications for certain drug and biological products. **DATES:** Written comments may be submitted at any time, however, comments should be submitted by November 15, 1999, to ensure their adequate consideration in preparation of the final document.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled "Guidance for Industry: Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act" to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self addressed adhesive label to assist the office in processing your request. The document may also be obtained by mail by calling the CBRE 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 document to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Murray M. Lumpkin, Center for Drug Evaluation and Research (HFD-2), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5400; or

Robert A. Yetter, Center for Biologics Evaluation and Research (HFM-10), 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-0373.

SUPPLEMENTARY INFORMATION:**I. Background**

FDA is announcing the availability of a draft document entitled "Guidance for Industry: Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act." In a November 1997 letter to Congress regarding the reauthorization of the Prescription Drug User Fee Act (PDUFA) as part of the Food and Drug Administration Modernization Act of 1997 (Public Law 105-115), the Secretary of Health and Human Services (the Secretary) committed FDA to certain user fee performance goals and additional procedures related to the review of products in human drug applications as defined in section 735(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g(1)) (PDUFA products). As one of the additional procedures intended to help expedite the development of drugs and biologics, the Secretary specified that FDA intends to provide early agency thoughts on possible deficiencies to applicants in a letter as each discipline finishes its initial review of its portion of the pending application. The procedures and policies described in this draft guidance are intended to explain how the agency will issue and use information request letters and discipline review letters during the review of PDUFA products.

This draft guidance document represents the agency's current thinking on information request letters and discipline review letters under PDUFA. 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 requirements 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