resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before October 23, 1997, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: August 26, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–25180 Filed 9–22–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0318]

Revised Precautionary Measures to Reduce the Possible Transmission of Creutzfeldt-Jakob Disease (CJD) by Blood and Blood Products; Guidance Document; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Revised Precautionary Measures to Reduce the Possible Transmission of Creutzfeldt-Jakob Disease (CJD) by Blood and Blood Products,'' dated December 11, 1996. The guidance document is intended to provide recommendations to the blood industry and may include information useful to other interested persons.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of ''Revised Precautionary Measures to Reduce the Possible Transmission of Creutzfeldt-Jakob Disease (CJD) 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. Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Joseph Wilczek, Center for Biologics Evaluation and Research (HFM–350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3514.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance document entitled ''Revised Precautionary Measures to Reduce the Possible Transmission of Creutzfeldt-Jakob Disease (CJD) by Blood and Blood Products,'' dated December 11, 1996, and sent to all registered blood and plasma establishments and all establishments engaged in manufacturing plasma derivatives.

The guidance document updates and supersedes the FDA guidance documents of August 8, 1995, entitled ''Disposition of Products Derived from Donors Diagnosed with, or at Known High Risk for, Creutzfeldt-Jakob Disease'' and ''Precautionary Measures to Further Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease by Blood and Blood Products,'' and the November 25, 1987, guidance document entitled ''Deferral of Donors Who Have Received Human Pituitary-Derived Growth Hormone.''

The guidance document presents recommendations for donor deferral, product disposition, recipient notification, and labeling. The recommendations were developed after considering donor and product risk factors and the impact such recommendations could have on the availability of blood and blood products. Topics addressed in the guidance document include: (1) Recommended questions that will help identify donors at an increased risk for CJD; (2) recommended actions to take when a donor is identified to be at an increased risk for developing CJD; (3) recommended actions to take when a donor is subsequently diagnosed with CJD; (4) recommendations for recipient notification and counseling; (5) recommendations for disposition of implicated products; and (6) recommendations for the labeling of implicated products intended for research or further manufacture into non-injectable products. The guidance document also includes FDA's recommendations regarding ''lookback'' notification of persons possibly exposed to CJD contaminated blood or blood products.

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. It is intended to provide recommendations and does not set forth requirements. In response to public comment, development of suitable alternatives or other new information, FDA may revise the guidance document at anytime to improve its usefulness. Any revisions to this guidance document will be announced in the **Federal Register**. The recommendations in the guidance document represent the agency's current thinking on precautionary measures to use to reduce the possible transmission of CJD by blood and blood products. 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.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the guidance document. 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. Any comments previously submitted to the Division of Blood Applications (HFM–370), CBER, FDA, do not have to be resubmitted. Comments previously submitted will be filed with the Dockets Management Branch (address above) under the docket number in the heading of this document. The guidance document and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Received comments will be considered in determining whether further revision is warranted.

Persons with access to the Internet may obtain the guidance document

using the World Wide Web (WWW). For WWW access, connect to CBER's site at ''http://www.fda.gov/cber/memo.htm''.

Dated: September 16, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–25181 Filed 9–22–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0319]

Interim Recommendations for Deferral of Donors at Increased Risk for HIV–1 Group O Infection; Guidance Document; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Interim Recommendations for Deferral of Donors at Increased Risk for HIV–1 Group O Infection,'' dated December 11, 1996. The guidance document, which discusses the appearance in 1996 of two cases of HIV–1 Group O infection in the United States, is intended to provide interim measures to reduce the risk of HIV–1 Group O transmission by blood and blood products pending the licensure of test kits specifically labeled for detection of antibodies to HIV–1 Group O viruses. The guidance document recommends adding three questions to screening questionnaires used to exclude donors at high risk of HIV–1 infection.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of ''Interim Recommendations for Deferral of Donors at Increased Risk for HIV–1 Group O Infection'' 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. Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. 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.

FOR FURTHER INFORMATION CONTACT: Joseph Wilczek, Center for Biologics Evaluation and Research (HFM–350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3514.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance document entitled ''Interim Recommendations for Deferral of Donors at Increased Risk for HIV–1 Group O Infection.'' It was dated December 11, 1996, and sent to all registered blood and plasma establishments. The guidance document, which discusses the appearance in 1996 of two cases of HIV–1 Group O infection in the United States, recommends adding three questions to screening questionnaires used to exclude donors at high risk for HIV–1 infection. These recommendations are intended to be interim measures to reduce the risk of HIV–1 Group O transmission by blood and blood products pending the licensure of test kits specifically labeled for detection of antibodies to HIV–1 Group O viruses.

As with other guidance documents, FDA does not intend this guidance document to be all-inclusive and cautions that not all information may be applicable to all situations. It is intended to provide recommendations and does not set forth requirements. In response to public comment, development of suitable alternatives or other new information, FDA may revise this guidance document at any time to improve its usefulness. Any revisions to this document will be announced in the **Federal Register**. The recommendations in the document represent the agency's current thinking on screening and deferral of donors at increased risk for HIV–1 Group O infection. 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.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the guidance document. 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. Any comments previously submitted to the Division of Blood Applications (HFM–370), CBER, FDA, do not have to be resubmitted. Comments previously submitted will be filed with the Dockets Management Branch (address above) under the docket number in the heading of this document. The document and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Received comments will be considered in determining whether further revision is warranted.

Persons with access to the Internet may obtain the document by using the World Wide Web (WWW). For WWW access, connect to CBER's site at ''http://www.fda.gov/cber/memo.htm''.

Dated: September 16, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–25128 Filed 9–22–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0381]

Guidance for Industry on Archiving Submissions in Electronic Format—NDA's; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Archiving Submissions in Electronic Format—NDA's.'' This guidance is intended to describe how to submit records and other documents in electronic format to the Center for Drug Evaluation and Research (CDER) for archival purposes. Guidance is provided on submitting case report forms and case report tabulations as part of new drug applications (NDA's). This is the first in a series of guidances for industry that will address archiving NDA submissions in electronic format. Guidance for industry on other submission types will be made available as they are completed. The submission of records in electronic format should reduce the amount of paperwork for applicants and the agency. Submissions in electronic format are voluntary.

DATES: Written comments may be submitted at any time.