received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 22, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–3203 Filed 2–6–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1662]

Draft ''Guidance for Industry: Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans'' dated February 2001. The draft guidance document is intended to provide guidance on the production, testing, and evaluation of products intended for use in xenotransplantation.

DATES: Submit written comments on the draft guidance to ensure their adequate consideration in preparation of the final document by May 8, 2001.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled ''Guidance for Industry: Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans'' dated February 2001 to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, 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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Stephen Ripley, 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 guidance document entitled ''Guidance for Industry: Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans'' dated February 2001. For the purpose of the draft guidance ''xenotransplantation'' refers to any procedure that involves the transplantation, implantation, or infusion into a human recipient of either: (1) Live cells, tissues, or organs from a nonhuman animal source, or (2) human body fluids, cells, tissues, or organs that have had ex vivo contact with live nonhuman animal cells, tissues, or organs. This document is intended to provide guidance on the production, testing, and evaluation of products intended for use in xenotransplantation. The draft guidance includes scientific questions that should be addressed by sponsors during protocol development and during the preparation of submissions to FDA (e.g., investigational new drug application and biologics license application). The topics in the draft guidance include: Regulatory responsibility; source animal and xenotransplantation products characterization; microbiological testing of xenotransplantation products; manufacturing and process-related good manufacturing practice considerations for harvest and processing of xenotransplantation products; preclinical considerations for xenotransplantation products; and clinical issues in xenotransplantation.

FDA has previously announced the availability of the guidance document entitled ''Guidance for Industry: Public Health Issues Posed by the Use of Nonhuman Primate Xenografts in Humans'' dated April 1999, in the **Federal Register** of April 6, 1999 (64 FR 16743). FDA also announced the availability of the draft guidance document ''Guidance for Industry: Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products From Xenotransplantion Product Recipients and Their Contacts'' dated December 1999, in the **Federal Register** of December 30, 1999 (64 FR 73562). In the future, FDA intends to finalize the guidance. Furthermore, FDA is considering developing draft guidance to address various issues pertaining to FDA's regulation of transgenic animals.

This draft guidance is being issued consistent with FDA's good guidance practice regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). This draft guidance document represents the agency's current thinking with regard to the production, testing, and evaluation of products intended for use in xenotransplantation. 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 draft guidance document is intended to provide information and does not set forth requirements.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document. Submit written comments to ensure adequate consideration in preparation of the final document by May 8, 2001. 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 http://www.fda.gov/cber/guidelines.htm.

Dated: December 26, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–3202 Filed 2–6–01; 8:45 am]

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