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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier L. Corbin

Food and Drug Administration

[Docket No. 00D-1662]

“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 document entitled “Guidance for Industry: Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans” dated April 2003. The document provides guidance on the production, testing, and evaluation of products intended for use in xenotransplantation. The guidance announced in this notice finalizes the draft guidance document of the same title dated February 2001.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written or electronic requests for single copies of this 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 **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. 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

FDA is announcing the availability of a document entitled “Guidance for Industry: Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans” dated April 2003. The document provides guidance on the production, testing, and evaluation of products intended for use in xenotransplantation. The guidance document announced in this notice was revised based on public comments received on the draft guidance, and it finalizes the draft document of the same title dated February 2001 (66 FR 9348, February 7, 2001).

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). This 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

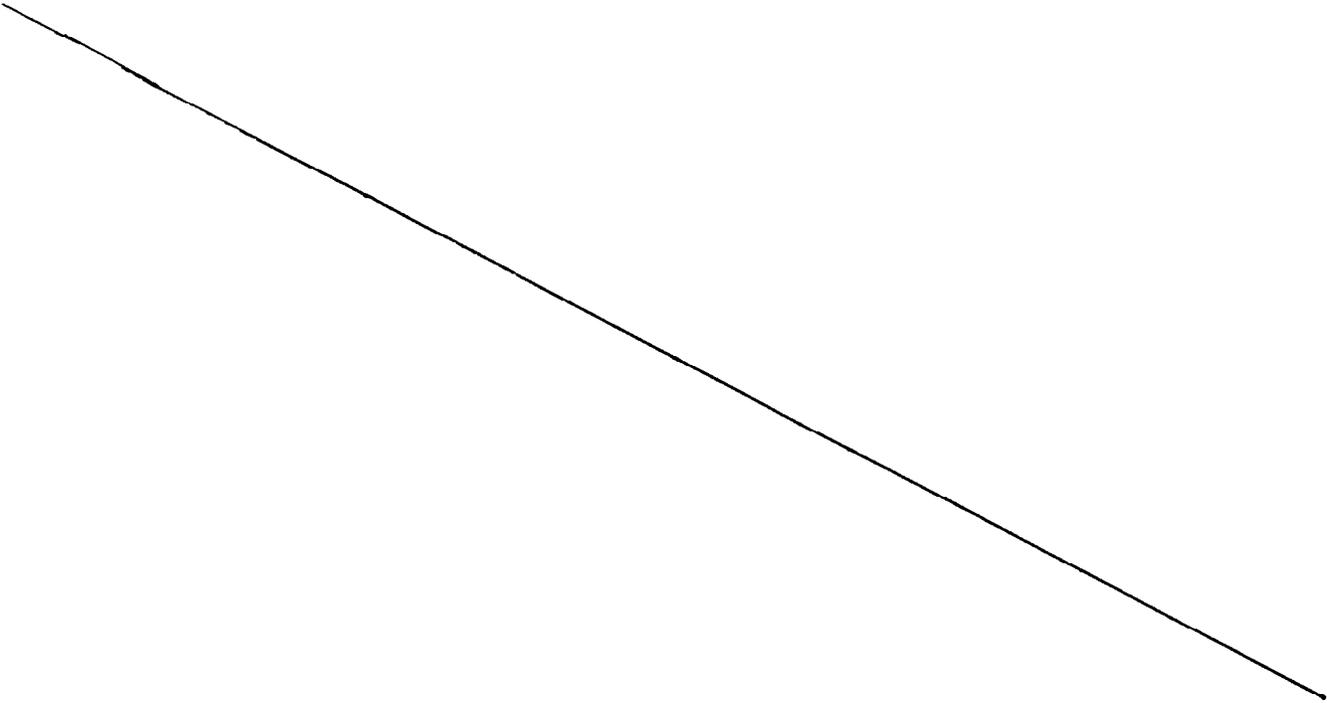
alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Comments

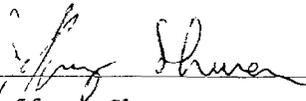
Interested persons may, at any time, submit written or electronic comments to the Dockets Management Branch (see **ADDRESSES**) regarding this guidance document. Two copies of any mailed comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket 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: 3/27/03
March 27, 2003.



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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