

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96M-0311]

*DMB*

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Publication Date	<i>1-29-01</i>
Certifier	<i>AJ</i>

**“PHS Guideline on Infectious Disease Issues in Xenotransplantation;” Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** On behalf of the U.S. Public Health Service (PHS), the Food and Drug Administration (FDA) is announcing the availability of a guideline entitled “PHS Guideline on Infectious Disease Issues in Xenotransplantation” dated January 19, 2001. This guideline was developed by the PHS to identify general principles for the prevention and control of infectious diseases associated with xenotransplantation that may pose a hazard to public health. The guideline is intended to provide general guidance to local review bodies evaluating proposed xenotransplantation protocols and to sponsors in developing xenotransplantation protocols, in preparing submissions to FDA and the Secretary’s Advisory Committee on Xenotransplantation, and in conducting xenotransplantation clinical trials. The guideline announced in this document finalizes the “Draft Public Health Service (PHS) Guideline on Infectious Disease Issues in Xenotransplantation” announced in the **Federal Register** of September 23, 1996, as revised in response to comments.

**DATES:** Submit written comments at any time.

**ADDRESSES:** Submit written requests for single copies of the “PHS Guideline on Infectious Disease Issues in Xenotransplantation” dated January 19, 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 guideline.

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

**FOR FURTHER INFORMATION CONTACT:** Stephen M. 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**

On behalf of the PHS, FDA is announcing the availability of a document entitled "PHS Guideline on Infectious Disease Issues in Xenotransplantation" dated January 19, 2001. This guideline was jointly developed by agencies within the PHS of the Department of Health and Human Services (DHHS), including FDA, the Centers for Disease Control and Prevention, the Health Resources and Services Administration, the National Institutes of Health, as well as the DHHS Office of the Assistant Secretary for Planning and Evaluation. This guideline is intended to identify general principles for the prevention and control of infectious diseases associated with xenotransplantation that may pose a hazard to public health. It is intended to provide general guidance to local review bodies evaluating proposed xenotransplantation protocols and to sponsors in developing xenotransplantation protocols, in preparing submissions to FDA and the Secretary's Advisory Committee on Xenotransplantation, and in conducting xenotransplantation clinical trials. Such clinical trials conducted within the United States are subject to regulation by FDA under the Public Health Service Act (42 U.S.C. 262, 264), and the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.*).

The finalized guideline announced in this document was revised based on public comments received in response to the "Draft Public Health Service (PHS) Guideline on Infectious Disease Issues in Xenotransplantation" announced in the **Federal Register** of September 23, 1996 (61

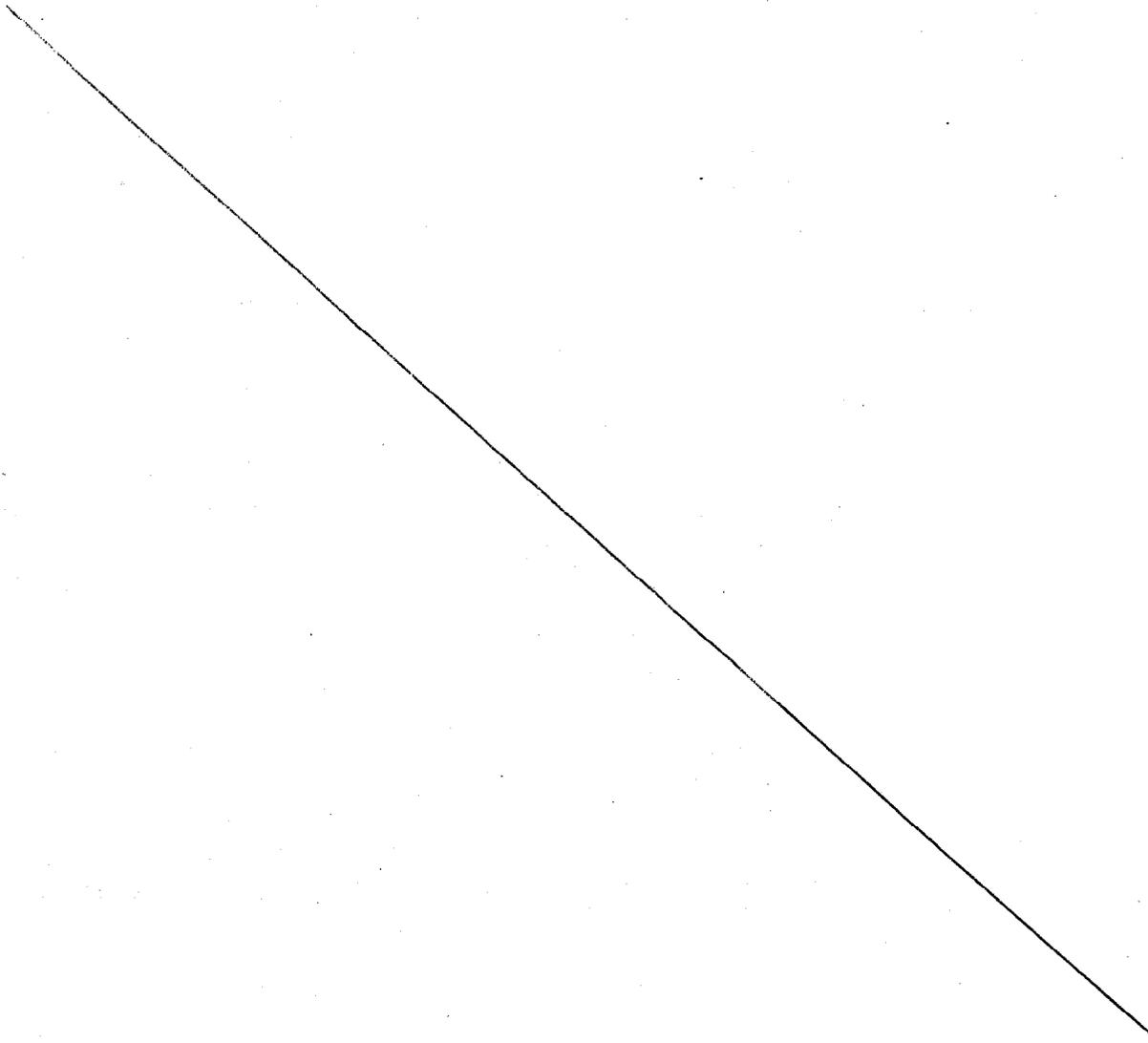
FR49920), as well as on input from national and international conferences and workshops. The preamble to the final guideline provides a summary of the major revisions and clarifications made to the draft guideline.

In the **Federal Register** of May 26, 2000 (65 FR 34196), FDA, on behalf of PHS, published a notice of the proposed reporting and recordkeeping requirements associated with the implementation of the guideline and provided an opportunity for public comment on the paperwork burden estimates for the guideline. In the **Federal Register** of October 18, 2000 (65 FR 62359), FDA, on behalf of PHS, announced the submission of the reporting and recordkeeping burden estimates to the Office of Management and Budget for review and clearance under the Paperwork Reduction Act of 1995. The information collection provisions related to this guideline have been approved under OMB control number 0910-0456. This approval expires January 31, 2004. An agency may not conduct or sponsor, and a person is not obligated to respond to, a collection of information unless it displays a currently valid OMB control number.

This guideline represents PHS' current thinking on certain infectious disease issues in xenotransplantation. It does not create or confer any rights for or on any person and does not operate to bind the PHS or the public. This guideline is not intended to set forth an approach that addresses all of the potential health hazards related to infectious disease issues in xenotransplantation nor to establish the only way in which the public health hazards that are identified in this document may be addressed. The PHS acknowledges that not all of the recommendations set forth within this document may be fully relevant to all xenotransplantation products or xenotransplantation procedures. Sponsors of clinical xenotransplantation trials are advised to confer with relevant authorities (FDA, other reviewing authorities, funding sources, etc.) in assessing the relevance and appropriate adaptation of the general guidance offered here to specific clinical applications.

## II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the guideline. 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 the brackets in the heading of this document. A copy of the guideline 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.

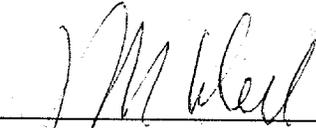


**III. Electronic Access**

Persons with access to the Internet may obtain the guideline at <http://www.fda.gov/cber/guidelines.htm>.

Dated: 2/26/00

December 26, 2000



Margaret M. Dotzel  
Associate Commissioner for Policy

**CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL**



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JK

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