[7] FDA estimates there are approximately 12 clinical centers doing xenotransplantation procedures x approximately 25 health care workers involved per center = 300 health care workers.
[8] Fifty-eight source animal records + 29 recipient records = 87 total records.

Because xenotransplantation is a relatively new area of medical science, potential problems and adverse effects are not well known. Because of the potential risk for cross-species transmission of infectious agents from source animals to patients, their close contacts, and the general public and the latency period of known human pathogenic persistent virus, the guideline recommends that health records be retained for 50 years. Since these records are medical records, they are not considered ''information'' as that term is defined under the PRA (5 CFR 1320.3(h)(5)). Also, because of the limited number of clinical studies with small patient populations, the number of records is small and, therefore, the capital and operating costs are expected to be insignificant at this time.

Many of the information collections described in this guideline are not new and can be found under existing regulations and, therefore, are not included in the hour burden estimates in tables 1 through 4 of this document. These information collections are included under the regulations and approved under the OMB control numbers as follows: (1) ''Current Good Manufacturing Practice for Finished Pharmaceuticals,'' 21 CFR 211.1 through 211.208, approved under OMB control number 0910–0139; (2) ''Investigational New Drug Application,'' 21 CFR 312.1 through 312.160, approved under OMB control number 0910–0014; and (3) information included in a license application, 21 CFR 601.2, approved under OMB control number 0910–0427. (Although it is possible that a xenotransplantation product may not be regulated as a biological product (e.g., it may be regulated as a medical device), FDA expects, based on its knowledge and experience with xenotransplantation, that any xenotransplantation product subject to FDA regulation within the next 3 years will most likely be regulated as a biological product.)

TABLE 5.—COLLECTIONS OF INFORMATION UNDER CURRENT REGULATIONS

PHS Guideline Section	Description of Collection of Information Activity	21 CFR Section (unless otherwise stated)
2.2.1	Document offsite collaborations.	312.52
2.5	Sponsor ensure counseling patient + family + contacts.	312.62(c)
3.1.1 and 3.1.6	Document well-characterized health history and lineage of source animals.	312.23(a)(7)(iv)(*a*) and 211.84
3.1.8	Registration with and import permit from the Centers for Disease Control and Prevention.	42 CFR 71.53
3.2.2	Document collaboration with accredited microbiology labs.	312.52
3.2.5, 3.4, and 3.4.1	Herd health maintenance and surveillance to be documented, available, and in accordance with documented procedures; record standard veterinary care.	211.100 and 211.122
3.3.3	Validate assay methods.	211.160(a)
3.6.1	Procurement and processing of xenografts using documented aseptic conditions.	211.100 and 211.122
3.6.2	Develop, implement, and enforce SOP's for procurement and screening processes.	211.84(d) and 211.122(c)
3.6.4	Communicate to FDA animal necropsy findings pertinent to health of recipient.	312.32(c)
3.7.1	PHS specimens to be linked to health records; provide to FDA justification for types of tissues, cells, and plasma, and quantities of plasma and leukocytes collected.	312.23(a)(6)
4.1.1	Surveillance of xenotransplant recipient; sponsor ensures documentation of surveillance program life-long (justify > 2 yrs.); investigator case histories (2 yrs. after investigation is discontinued).	312.23(a)(6)(iii)(*f*) and (*g*), and 312.62(b) and (c)
4.1.2	Sponsor to justify amount and type of reserve samples.	211.122
4.1.2.2	System for prompt retrieval of PHS specimens and linkage to medical records (recipient and source animal).	312.57(a)
4.1.2.3	Notify FDA of a clinical episode potentially representing a xenogeneic infection.	312.32
4.2.2.1	Document collaborations (transfer of obligation).	312.52
4.2.3.1	Develop educational materials (sponsor provides investigators with information needed to conduct investigation properly).	312.50
4.3	Sponsor to keep records of receipt, shipment, and disposition of investigative drug; investigator to keep records of case histories.	312.57 and 312.62(b)

Dated: October 10, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–26671 Filed 10–17–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Ophthalmic Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Ophthalmic Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 8, 2000, 8:30 a.m. to 5 p.m.

Location: Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Sara M. Thornton, Center for Devices and Radiological Health (HFZ 460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2053, e-mail: SMT@CDRH.FDA.GOV, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12396. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application (PMA) for a collagen glaucoma drainage device for the reduction of intraocular pressure in patients with open-angle glaucoma uncontrolled on maximum tolerated medical therapy. The committee will also discuss issues related to the development of guidance for the postapproval study of extended wear contact lenses used beyond 7 days. Study design topics will include the type of study, definition of endpoints, and selection of participating study sites.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 1, 2000. Oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9:15 a.m. Near the end of the committee deliberations on the PMA, an additional 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 1, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 11, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–26741 Filed 10–17–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–4114]

''Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors;'' 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 ''Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors'' dated October 2000. The guidance document applies to the manufacture of gene therapy retroviral vector products intended for in vivo or ex vivo use and to followup monitoring of patients who have received retroviral vector products. The guidance document announced in this notice finalizes the draft guidance document entitled ''Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors,'' announced in the **Federal Register** of November 3, 1999. The guidance document also supplements the guidance document entitled ''Guidance for Industry: Guidance for Human Somatic Cell Therapy and Gene Therapy,'' dated March 1998; and a letter to sponsors of an investigational new drug using retroviral vectors, dated September 20, 1993.

DATES: Submit written comments at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors,'' dated October 2000 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: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors'' dated October 2000. The guidance document applies to the manufacture of gene therapy retroviral vector products intended for in vivo or ex vivo use and to followup monitoring of patients who have received retroviral vector products. The document provides guidance for replication competent retrovirus (RCR) testing during manufacture, including timing, amount of material to be tested, and general testing methods. The document also provides guidance on monitoring patients for evidence of retroviral infection. The recommendations are based on data and analyses generated by CBER and members of the gene therapy community. The guidance document finalizes the draft document entitled ''Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors,'' announced in the **Federal Register** of November 3, 1999 (64 FR 59783). The guidance document also supplements the guidance and recommendations pertaining to RCR testing given in the following documents: (1) ''Guidance for Industry: Guidance for Human Somatic Cell