

TABLE 5.—COLLECTION OF INFORMATION REQUIRED BY CURRENT REGULATIONS AND STANDARDS—Continued

21 CFR Section	Description of Collection of Information Activity	21 CFR Section (unless otherwise stated)
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
3.2.6	Animal facility SOPs	PHS Policy <sup>1</sup>
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 SOPs 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)

<sup>1</sup>The "Public Health Service Policy on Humane Care and Use of Laboratory Animals" (<http://www.grants.nih.gov/grants/olaw/references/phspol.htm>). (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the *Federal Register*.)

<sup>2</sup>AAALAC International Rules of Accreditation (<http://www.aaalac.org>). (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the *Federal Register*.)

<sup>3</sup>The NRC's "Guide for the Care and Use of Laboratory Animals" (1996).

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**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2003N-0455]

#### Training Program for Regulatory Project Managers; Information Available to Industry

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) is announcing the continuation of the Regulatory Project Management Site Tours and Regulatory Interaction Program. This training program was initiated in 1999, and it is intended to give CDER regulatory project managers an opportunity to tour pharmaceutical facilities and to exchange regulatory experiences with their industry counterparts. The Site Tours Program is intended to enhance review efficiency and quality by providing CDER staff with a better understanding of the pharmaceutical industry and its operations. Further, this program is intended to improve communication and cooperation between CDER staff and industry. The purpose of this notice

is to invite pharmaceutical companies interested in participating in these programs to contact CDER.

**DATES:** Pharmaceutical companies may submit proposed agendas to the agency on or before December 22, 2003.

**FOR FURTHER INFORMATION CONTACT:** Patricia A. Stewart, Center for Drug Evaluation and Research (HFD-160), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7496, FAX 301-480-6036.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

An important part of CDER's commitment to make safe and effective drugs available to all Americans is optimizing the efficiency and quality of the drug review process. To support this primary goal, the center has initiated