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[1]
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)

[1]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*.)

[2]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*.)

[3]The NRC's ''Guide for the Care and Use of Laboratory Animals'' (1996).

Dated: October 16, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–26739 Filed 10–22–03; 8:45 am]

BILLING CODE 4160–01–S

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

various training and development programs to promote high performance of its regulatory project management staff. CDER seeks to significantly enhance review efficiency and review quality by providing the staff with a better understanding of the pharmaceutical industry and its operations. To this end, CDER is continuing this training program to give regulatory project managers the opportunity to tour pharmaceutical facilities. The goals are to provide: (1) First hand exposure to industry's drug development processes, and (2) a venue for sharing information about project management procedures (but not drug-specific information) with industry representatives.

II. Regulatory Project Management Site Tours and Regulatory Interaction Program

In this program, over a 2- to 3-day period, small groups (five or less) of regulatory project managers, accompanied by a senior level regulatory project manager, may observe operations of pharmaceutical manufacturing, packaging facilities, pathology/toxicology laboratories, and regulatory affairs operations. Neither this tour nor any part of the program is intended as a mechanism to inspect, assess, judge, or perform a regulatory function, but is meant rather to improve mutual understanding and to provide an avenue for open dialogue. During the Site Tours Program, regulatory project managers will also participate in daily workshops with their industry counterparts, focusing on selective regulatory issues important to both CDER staff and industry. The primary objective of the daily workshops is to learn about the team approach to drug development, including drug discovery, preclinical evaluation, project tracking mechanisms, and regulatory submission operations.

The overall benefit to regulatory project managers will be exposure to project management team techniques and processes employed by the pharmaceutical industry. By participating in this program, the regulatory project manager will grow professionally by gaining a better understanding of industry processes and procedures.

III. Site Selection

All travel expenses associated with the site tours will be the responsibility of CDER, therefore, selection will be based on the availability of funds and resources for each fiscal year.

If your firm is interested in offering a site tour or learning more about this training opportunity, please respond within 60 days of this notice by submitting a proposed agenda to Patricia A. Stewart (see **FOR FURTHER INFORMATION CONTACT**).

Dated: October 14, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–26695 Filed 10–22–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

General and Plastic Surgery 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: General and Plastic Surgery 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 21, 2003, from 8 a.m. to 5 p.m.

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

Contact Person: David Krause, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090, ext. 141, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12519. Please call the Information Line or access the Internet address of *http://www.fda.gov/cdrh/panelmtg.html* for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on two premarket approval applications (PMAs) for injectable devices intended to restore soft tissue facial contours such as nasolabial folds. Background information for each PMA, including the agenda and questions for the committee, will be available to the public 1-business day before the meeting on the Internet at *http://www.fda.gov/cdrh/panelmtg.html*. The material for this meeting will be posted on November 20, 2003.

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 7, 2003. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 8:30 a.m., 11:30 a.m. and 11:45 a.m., 1:15 p.m. and 1:30 p.m., and 4 p.m. and 4:15 p.m. Time allotted for oral public presentations may be limited. Those desiring to make formal oral presentations should notify the contact person before November 7, 2003, 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.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, at 301–594–1283, ext. 113, at least 7 days in advance of the meeting.

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

Dated: October 16, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–26696 Filed 10–22–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0478]

Draft Guidance on Marketed Unapproved Drugs; Compliance Policy Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Marketed Unapproved Drugs; Compliance Policy Guide.'' This draft guidance describes how FDA intends to exercise its enforcement discretion with