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

regard to drugs marketed in the United States that do not have required FDA approval for marketing. This document will, when finalized, supersede section 440.100 entitled ''Marketed New Drugs Without Approved NDAs or ANDAs'' (CPG 7132c.02) of the Compliance Policy Guide (CPG). It applies to any new drug required to have FDA approval for marketing, including new drugs covered by the over-the-counter (OTC) review.

DATES: Submit written or electronic comments on the draft guidance by December 22, 2003. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self addressed adhesive label to assist the office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Sakineh Walther, Center for Drug Evaluation and Research (HFD–316), Food and Drug Administration, 1451 Rockville Pike, Rockville, MD 20852, 301–827–8964.

SUPPLEMENTARY INFORMATION:

I. Background

In the United States, as many as several thousand drug products are marketed illegally without required FDA approval. The manufacturers of these drugs have neither received FDA approval to legally market their drugs, nor have the drugs been marketed in accordance with a final over-the-counter (OTC) monograph. The drug approval and OTC monograph processes play an essential role in ensuring that all drugs are both safe and effective. Manufacturers of new drugs that lack required approval, including those that are not marketed in accordance with an OTC monograph, have not provided FDA with evidence demonstrating that their products are safe and effective. Therefore, FDA has an interest in taking steps to either encourage the manufacturers of these products to obtain the required evidence and comply with the approval provisions of the Federal Food, Drug, and Cosmetic Act (the act), or to remove the products from the market. FDA recognizes that these goals need to be achieved without adversely affecting public health, imposing undue burdens on consumers, or unnecessarily disrupting the market.

In general, in recent years, FDA has employed a risk-based enforcement approach to marketed unapproved drugs that includes efforts to identify illegally marketed drugs, prioritization of those drugs according to potential public health concerns or other impacts on the public health, and subsequent regulatory followup. Some of the specific actions the agency has taken have been precipitated by evidence of safety or effectiveness problems that has either come to our attention during inspections or was brought to our attention by outside sources.

The goals of this draft guidance are to address the following issues: (1) Clarify for FDA personnel and the regulated industry how FDA intends to exercise its enforcement discretion regarding unapproved drugs and (2) emphasize that illegally marketed drugs must obtain FDA approval.

The draft guidance reflects the agency's desire to address this issue with policies that are predictable, reasonable, and supportive of the public health. The agency's approach encourages companies to comply with the drug approval process, but it also seeks to minimize disruption to the marketplace and to safeguard consumer health when there are potential safety risks. The draft guidance explains that FDA will continue to give priority to enforcement actions involving unapproved drugs: (1) with potential safety risks, (2) that lack evidence of effectiveness, and (3) that constitute health fraud. It also explains how the agency intends to address those situations in which a firm obtains FDA approval to sell a drug that other firms have long been selling without FDA approval.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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 requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet can obtain the guidance at *http://www.fda.gov/cder/guidance/index.htm*.

Dated: October 15, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–26753 Filed 10–20–03; 3:00 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0466]

International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products; Draft Guidance for Industry on ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Repeat-Dose (Chronic) Toxicity Testing;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for comments of a draft guidance document for industry (#160) entitled ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Repeat-Dose (Chronic) Toxicity Testing'' (VICH GL–37). This draft guidance has been developed for veterinary use by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft VICH guidance document establishes recommendations for internationally harmonized repeat-dose chronic toxicity testing.

DATES: Submit written or electronic comments on the draft guidance by November 24, 2003 to ensure their adequate consideration in preparation of the guidance document. General comments on agency guidance documents are welcome at any time.