Registration and Requests for Oral Presentations: Send or fax written material and requests to make oral presentations to the contact person by Monday, November 16, 1998, and registration information (including name, title, firm name, address, telephone, and fax number), by Monday, November 23, 1998. Registration at the site will be done on a space available basis on the day of the meeting beginning at 8:30 a.m. There is no registration fee for the meeting. Space is limited, therefore, interested parties are encouraged to register early.

If you need special accommodations due to a disability, please contact Kathy A. Eberhart at least 7 days in advance.

SUPPLEMENTARY INFORMATION: Under section 406(b) of the Food and Drug Administration Modernization Act of 1997, CBER held two meetings with our external stakeholders. The first meeting was held on August 14, 1998, in Washington, DC (63 FR 39877, July 24, 1998), and the second one on August 28, 1998, in Oakland, CA (63 FR 39877, July 24, 1998). In addition, the FDA Pacific Regional Office sponsored a grassroots meeting on September 15, 1998 (63 FR 42052, August 6, 1998), in Irvine, CA, with the biotechnology industry.

A recurring theme during these meetings was a dissatisfaction with the handling of the medical devices regulated by CBER. Some important concerns were related to CBER procedures and standards for products similar to products regulated by the Center for Devices and Radiological Health. To address these concerns, CBER is developing a ''Device Action Plan'' to evaluate various options to change CBER's regulatory approaches for medical devices without creating a risk to the public health.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. The meeting transcript will also be available on CBER's website at ''http://www.fda.gov/cber/minutes/workshop-min.htm''.

Dated: October 26, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–29185 Filed 10–30–98; 8:45 am]

BILLING CODE 4160–01–F

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). At least one portion of the meeting will be closed 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 17, 1998, 9 a.m. to 6 p.m.

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, 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. For up-to-date information on this meeting, please call the Information Line or access the Internet address at ''http://www.fda.gov/cdrh''.

Agenda: The committee will discuss and make recommendations on a proposal for the classification of preamendment wound dressing medical devices based on: (1) A proposed rule published in the **Federal Register** of September 19, 1989 (54 FR 38600); (2) comments received in response to the proposed rule; and (3) comments from the General and Plastic Surgery Devices Panel meeting of July 20, 1995. The committee will also discuss and make recommendations on the reclassification of preamendment class III topical oxygen devices for wound healing on extremities based on information received from a call for safety and effectiveness information under section 515(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(i)) published in the **Federal Registers** of August 14, 1995, and June 13, 1997 (60 FR 41986 and 62 FR 32355, respectively).

Procedure: On November 17, 1998, from 9:30 a.m. to 6 p.m., the meeting is open to the public. 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 3, 1998. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10 a.m., and between approximately 4 p.m. and 4:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 3, 1998, 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.

Closed Committee Deliberations: On November 17, 1998, from 9 a.m. to 9:30 a.m., the meeting will be closed to the public to permit FDA to present to the committee trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)) regarding pending issues.

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

Dated: October 27, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–29274 Filed 10–30–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Control of Pharmaceutical Production; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a series of three public meetings sponsored by the Office of Regulatory Affairs (ORA), Pacific Region, and participated in by representatives from the Center for Drug Evaluation and Research (CDER), ORA's Division of Field Science, and the Pacific Region. The topic to be discussed is out-of-specification (OOS) laboratory test results, how to evaluate them and appropriate actions to take.

DATES: The public meetings are scheduled as follows:

1. Monday, November 16, 1998, from 8:30 a.m. to 3:30 p.m., in Bellevue, WA.

2. Wednesday, November 18, 1998, from 8:30 a.m. to 3:30 p.m., in Irvine, CA.
3. Friday, November 20, 1998, from 8:30 a.m. to 3:30 p.m., in Oakland, CA.

ADDRESSES: The public meetings will be held at the following locations:

Bellevue—Rockwell Institute, 13218 NE. 20th St., Bellevue, WA 98005.

Irvine—Los Angeles District Office, 19900 MacArthur Blvd., suite 300, Irvine, CA 92715.

Oakland—Roybal Auditorium, Oakland Federal Bldg., 1301 Clay St., Third Floor Conference Center, Oakland, CA 94612.

FOR FURTHER INFORMATION CONTACT:

Regarding meeting content and format: Mark S. Roh, Small Business Representative, Pacific Region, Food and Drug Administration, Oakland Federal Bldg., 1301 Clay St., suite 1180N, Oakland, CA 94612, 510–637–3980, FAX 510-637-3977.

Regarding the Bellevue, WA, meeting: Jaimee Hansen, Registration Coordinator, Organization of Regulatory and Clinical Associates (ORCA), P.O. Box 3490, Redmond, WA 98073, 425–487–7179, FAX 425–487–8666.

Regarding the Irvine, CA, meeting: Judy Keast, Food and Drug Administration, Oakland Federal Bldg., 1301 Clay St., suite 1180N, Oakland, CA 94612, 510–637–3960, FAX 510–637–3976.

Regarding the Oakland, CA, meeting: Judy Keast (address above).

Those persons interested in attending the Bellevue, WA, meeting should register by faxing their name(s), title, firm name, address, telephone, and fax number to Jaimee Hansen (fax number above). This meeting is being conducted in cooperation with a local nonprofit organization, ORCA. There is limited seating, so early registration is encouraged. A registration fee of $45.00 to cover the cost of the facilities for this meeting should be paid to ORCA. Arrangements for payment should be made directly with Ms. Hansen.

Those persons interested in attending the Irvine and/or Oakland, CA, meetings should register by faxing their name(s), title, firm name, address, telephone, and fax number; and date and location of the meeting to Judy Keast (fax number above). There is no registration fee for the Irvine and Oakland meetings. However, seating is limited, so early registration is encouraged.

If you need special accommodations due to a disability, please contact Ms. Hansen (Bellevue meeting) or Ms. Keast (Irvine and Oakland meetings) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The purpose of these meetings is to continue the dialogue, begun in 1996, with members of trade, technical, and professional organizations, and other interested persons on issues associated with pharmaceutical laboratory practices and procedures. The information presented at these meetings will also be appropriate and useful for other industries performing laboratory analysis, including private laboratories and manufacturers of in vitro products.

On November 20, 1996, FDA held a public meeting to informally address and outline ways to discuss problems associated with the development and monitoring of products. The meeting explored issues of concern to the agency and industry laboratories. As a result of the meeting, industry members asked FDA to provide guidance in two control aspects of pharmaceutical production: (1) Evaluating OOS test results, and (2) system suitability requirements in measuring performance of a chromatographic system.

Interested persons who are unable to attend these meetings may submit comments on this topic as well as suggest additional laboratory training issues of interest to FDA regulated industry for future dialogue. Submit written comments to Mark Roh (address above).

Dated: October 26, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–29187 Filed 10–30–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0549]

Guidance for Industry on Advisory Committees: Implementing Section 120 of the Food and Drug Administration Modernization Act of 1997; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Advisory Committees: Implementing Section 120 of the Food and Drug Administration Modernization Act of 1997.'' This document provides guidance for industry on changes to the policies and procedures being used by the Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) with regard to advisory committees as a result of section 120 of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act).

DATES: Written comments on the guidance may be submitted by February 1, 1999. General comments on the agency guidance documents are welcome at any time.

ADDRESSES: Copies of this guidance for industry are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm'' or ''http://www.fda.gov/cber/guidelines.htm''. Submit written requests for single copies to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments are to be identified with the docket number found in brackets in the heading of this document. After the comment period, comments may be submitted to one of the centers at the address below.

FOR FURTHER INFORMATION CONTACT:

Andrea C. Masciale, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5648, or

William Freas, Center for Biologics Evaluation and Research (HFM–21), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''Advisory Committees: Implementing Section 120 of the Food and Drug Administration Modernization Act of 1997.'' Advisory committees provide independent advice and recommendations to FDA on scientific and technical matters related to the development and evaluation of products regulated by the agency. CDER and CBER request advice from advisory committees on a variety of matters, including various aspects of clinical investigations and applications for marketing approval of drug products.