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.