DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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: Biological Response Modifiers Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on September 17, 1997, 5 p.m. to 7 p.m. by teleconference.

Location: Food and Drug Administration, Bldg. 29, conference room 121, 8800 Rockville Pike, Rockville, MD. This meeting will be held by a telephone conference call. A speaker telephone will be provided in the conference room to allow public participation in the meeting.

Contact Person: Gail M. Dapolito or Rosanna L. Harvey, Center for Biologics Evaluation and Research (HFM–21), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12388. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss the intramural scientific programs of the Laboratory of Molecular and Developmental Immunology and an individual in the Molecular Immunology Laboratory.

Procedure: On September 17, 1997, from 5 p.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 September 10, 1997. Oral presentations from the public will be scheduled between approximately 5 p.m. and 6 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 10, 1997, 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 September 17, 1997, from 6 p.m. to 7 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The meeting will be closed to discuss personal information concerning individuals associated with the research programs.

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

Dated: August 19, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–22705 Filed 8–26–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food Safety—Everybody's Business; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing the following public workshop: Food Safety—Everybody's Business. The topics to be discussed are: An overview of FDA's food safety initiatives; the problems of Federal, State, and city agencies in dealing with food safety; and why food safety is everybody's business. Education of food handlers and consumers about the causes of foodborne illnesses and how to prevent them should result in safer foods and less illness among the consuming public.

Date and Time: The public workshop will be held on Thursday, September 18, 1997, 8 a.m. to 4 p.m.

Location: The public workshop will be held at St. Josephs's University, Professional Conference Center, 5600 City Line Ave., Philadelphia, PA 19131.

Contact Person: Theresa A. Holmes, Philadelphia District Office (HFR–MA 145), Food and Drug Administration, 900 U.S. Customhouse, Second and Chestnut Sts., Philadelphia, PA 19106, 215–597–4390, ext. 4202, FAX 215–597–6649.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number), to the contact person by Wednesday, September 10, 1997. There is no registration fee for this public workshop. Space is limited, therefore interested parties are encouraged to register early.

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

SUPPLEMENTARY INFORMATION: This public workshop will be held jointly by the FDA Philadelphia District Office; United States Department of Agriculture (USDA) Food Safety and Inspection Service; Philadelphia Department of Health; St. Joseph's University; Drexel University; and Penn State Cooperative Extension Service. Of special interest will be a video on the Ten Causes of Foodborne Illness and discussion of a ''sample menu'': From appetizer to dessert. There will be four breakout sessions in the afternoon as follows: (1) Food Allergens—''Hidden Ingredients;'' (2) Raw Food: ''Market to Plate;'' (3) Foodborne Illness—''More Than a Bellyache;'' and (4) Prepared Foods: ''Too Hot to Handle.''

Dated: August 21, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–22789 Filed 8-26-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Quality System GMP Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration's (FDA's) Office of Regulatory Affairs (ORA), Southeast Region is announcing a public workshop entitled ''Quality System GMP Workshop''. FDA is cosponsoring this public workshop with the Association of Food and Drug Officials (AFDO). This public workshop will focus on the new medical device quality system regulation, medical device reporting, premarket notification and other related good manufacturing practice (GMP) topics.

DATES: The public workshop will be held on Wednesday, September 17, 1997, from 8:30 a.m. until 4 p.m., and on Thursday, September 18, 1997, from 8 a.m. until 4 p.m. The deadline for registration is September 5, 1997.

ADDRESSES: The public workshop will be held at the Four Points Sheraton, 1850 Cotillion Dr., Atlanta, GA.

Attendees requiring overnight accommodations may contact the hotel at 770–394–5000.

FOR FURTHER INFORMATION CONTACT:

For information regarding this notice: JoAnn Pittman, Food and Drug Administration, Atlanta District Office, 60 Eighth St. NE., Atlanta, GA 30309, 404–347–7355.

For information regarding registration and the workshop: Denise Rooney, AFDO, P.O. Box 3425, York, PA 17402, 717–757–2888, FAX 717–755–8089.

SUPPLEMENTARY INFORMATION: This workshop is cosponsored with AFDO. AFDO will be assisting with the agenda and administrative functions for the meeting. Representatives from FDA's Center for Devices and Radiological Health and ORA Southeast Region and other FDA representatives will be participating.

AFDO is charging a registration fee of $200 for the public workshop that includes training materials, breaks, and lunch for 2 days. Those persons interested in attending this public workshop should send their registration fee including name(s), firm name, address, telephone number, and FAX number to Denise Rooney (address above) by September 5, 1997. Make checks payable to AFDO. Space is limited and all interested parties are encouraged to register early.

Dated: August 21, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–22791 Filed 8–26–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Regulatory Partnership Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing the following public workshop: Regulatory Partnership Workshop. The topic to be discussed is medical device reporting for user facilities. FDA is holding this public workshop to promote the President's initiative for a partnership approach between front-line regulators and the people affected by the work of this agency, and specifically to develop a device reporting partnership among the Federal, manufacturing, and medical communities.

Date and Time: The public workshop will be held on Thursday, September 11, 1997, 9 a.m. to 12 m.

Location: The public workshop will be held at Cavanaugh's Inn at the Park, 303 West North River Dr., Spokane, WA 99201, 509–326–8000.

Contact:

In Seattle: Sue J. Hutchcroft, Food and Drug Administration (HFR–PA 300), P.O. Box 3012, Bothell, WA 98041–3012, 425–483–4953, FAX 425–483–4996.

In Spokane: Dolores E. Price, Food and Drug Administration (HFR–PA 3520), 1000 North Argonne, suite 105, Spokane, WA 99212, 509–353–2470, FAX 509–353–2746.

In Oakland: Mark S. Roh, Food and Drug Administration, 1301 Clay St., suite 1180N, Oakland, CA 94612–5217, 510–637–3980, FAX 510–637–3977.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) to one of the contact persons by Thursday, September 4, 1997. There is no registration fee for this public workshop. Space is limited, therefore interested parties are encouraged to register early.

If you need special accommodations due to a disability, please contact one of the listed contact persons at least 7 days in advance.

Dated: August 21, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–22792 Filed 8–26–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee Meeting; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that published in the **Federal Register** of August 22, 1997 (62 FR 44700). The notice announced a meeting of the General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee, which is scheduled for September 15 and 16, 1997. The notice published with an error. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: LaJuana D. Caldwell, Office of Policy (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–2994.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 22, 1997 (62 FR 44700), in FR Doc. 97–22556, FDA announced that a meeting of the General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee would be held on September 15 and 16, 1997. The notice incorrectly published the dates for submissions to the contact person as August 9, 1997. The correct date should be August 29, 1997.

Beginning on page 44700, in column 3, under the ''*Procedure*:'' portion of the meeting, the date ''August 9, 1997'' should be corrected to read ''August 29, 1997'' both places that it appears.

Dated: August 22, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–22858 Filed 8-22-97; 4:20 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0345]

Guidance for Industry on Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biological Products: Clarification of What to Report; 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 ''Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biological Products: Clarification of What to Report.'' The purpose of this guidance document is to clarify requirements for postmarketing safety reporting. This guidance document is intended to improve the quality of safety reports submitted to FDA while streamlining the postmarketing surveillance of human drug and licensed biological products.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the guidance for industry ''Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biological Products: Clarification of What to Report'' to the