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