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

Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

For information concerning human drug products: Audrey A. Thomas, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5625.

For information concerning human licensed biological products: Marcel E. Salive, Center for Biologics Evaluation and Research (HFM–220), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3974.

SUPPLEMENTARY INFORMATION: 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.'' FDA has undertaken a major effort to clarify and revise its regulations regarding pre- and postmarketing safety reporting requirements for human drug and biological products. With regard to the postmarketing safety reporting regulations for human drug and licensed biological products, the agency published a proposed rule in the **Federal Register** of October 27, 1994 (59 FR 54046), to amend these requirements, as well as others, to implement international standards, and to facilitate the reporting of adverse experiences. FDA is still considering comments submitted in response to this proposed rule and will be finalizing the proposed amendments based on those comments as well as on recommendations developed by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and by the World Health Organization's Council for International Organizations of Medical Sciences (CIOMS). In addition, in response to the President's regulatory reinvention initiative, which directed departments and agencies to eliminate or modify regulations that are outdated or otherwise in need of reform, FDA recently published a final rule in the **Federal Register** (62 FR 34166, June 25, 1997) that revokes the postmarketing safety reporting requirement to submit expedited increased frequency reports for human drug and licensed biological products.

At this time, the agency is considering recommendations recently developed by ICH and plans to propose additional amendments to its postmarketing safety reporting regulations. Throughout this effort, the agency intends to develop guidances for industry to provide recommendations on how industry can best fulfill the postmarketing safety reporting requirements. FDA plans to prepare a single consolidated guidance document on this topic once the process is concluded.

This guidance document: (1) Describes the information that should be obtained before an individual case of an adverse experience should be considered for submission to FDA in an expedited or periodic report; (2) clarifies how safety information from solicited contacts with patients should be handled; and (3) informs applicants and licensed manufacturers that FDA will entertain waiver requests for periodic submission of individual case reports for adverse experiences that are determined to be nonserious and labeled. The guidance for industry should be used in conjunction with CDER's ''Guideline for Postmarketing Reporting of Adverse Drug Experiences'' (March 1992) and CBER's ''Guideline for Adverse Experience Reporting for Licensed Biological Products'' (October 1993).

This guidance document represents the agency's current thinking on reporting of certain postmarketing adverse experiences for human drug and licensed biological products. 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 requirement of the applicable statute, regulations, or both.

Interested persons may, at any time, submit written comments and requests on the guidance document to the Dockets Management Branch (address above). Two copies of any 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 guidance document and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

An electronic version of this guidance is also available on the Internet at http://www.fda.gov/cder/guidance.htm or http://www.fda.gov/cber/guidelines.htm.

Dated: August 21, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–22790 Filed 8–26–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA 901, 1–3]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Reinstatement, without change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Qualification Application for Competitive Medical Plan, Medicare Contract Application for Federally Qualified Health Maintenance Organization (HMO) and supporting regulations 42 CFR 417.143, and 417.408; *Form No.:* HCFA–901, 1–3 OMB # 0938–0470; *Use:* Prepaid health plans must meet certain regulatory requirements which are captured in these applications, before they are considered a Federally qualified HMO that is eligible for a Medicare § 1876 contract. Section 1876 of the Social Security Act authorizes compensation to