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regulatory reinvention initiative, which directed departments and agencies to eliminate or modify regulations that are outdated or otherwise in need of reform, FDA recently published a final rule in the **Federal Register** (62 FR 34166, June 25, 1997) that revokes the postmarketing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

eligible organizations either on a reasonable cost or a risk basis for services provided under the Medicare program. *Frequency:* one time; *Affected Public:* Business or other for-profit, Not-for-profit institutions, and State, Local or Tribal Government; *Number of Respondents:* 65; *Total Annual Responses:* 65; *Total Annual Hours:* 6,500.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: August 21, 1997.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.

[FR Doc. 97–22744 Filed 8–26–97; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Council on Graduate Medical Education Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of September 1997:

Name: Council on Graduate Medical Education.

Date and Time: September 24, 1997, 1:00 p.m.–5:00 p.m. September 25, 1997, 8:30 a.m.–1:00 p.m.

Place: The Bethesda Ramada Inn, 8400 Wisconsin Avenue, Bethesda, Maryland 20814.

This meeting is open to the Public.

Agenda: The agenda will include Geographic Distribution ''1'' Report final review and action. Discussions of Draft Minorities in Medicine Report and public comments. Congressional staff presentations. Pew Commission Physician Workforce task force activities. Work plan and activities for the year.

Anyone requiring information regarding the subject should contact F. Lawrence Clare, M.D., M.P.H., Deputy Executive Secretary, telephone (301) 443–6326, Council on Graduate Medical Education, Division of Medicine, Bureau of Health Professions, Room 9A–27, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

Agenda items are subject to change as priorities dictate.

Date: August 21, 1997.

Jane M. Harrison,

Acting Director, Division of Policy Review and Coordination and Information Coordination.

[FR Doc. 97–22784 Filed 8–26–97; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Advisory Council on Drug Abuse, National Institute on Drug Abuse (NIDA) on September 16–17, 1997, at the National Institutes of Health, Building 31, 9000 Rockville Pike, Bethesda, MD 20892, which was published in the **Federal Register** on August 13, 1997, Volume 62 FR 43337.

This committee was to have convened from 9 a.m. to 4 p.m. on September 16, and from 9 a.m. to 5 p.m. on September 17. On September 17 the time has been changed to 9 a.m. to 12 p.m.

Dated: August 21, 1997.

LaVeen M. Ponds,

Policy Analyst, National Institutes of Health Committee Management Officer.

[FR Doc. 97–22822 Filed 8–26–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Meeting; National Arthritis and Musculoskeletal and Skin Diseases Advisory Council

Pursuant to Public Law 92–463, notice is hereby given of a meeting of the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council to provide advice to the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) on September 4, 1997, in Conference Room 6, Building 31, National Institutes of Health, Bethesda, Maryland.

The meeting will be open to the public September 4 from 8:30 a.m. to 12:00 p.m. to discuss administrative details relating to Council business and special reports. Attendance by the public will be limited to space available.

The meeting of the Advisory Council will be closed to the public on September 4 from 1:00 p.m. to adjournment in accordance with provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C. and section 10(d) of Public Law 92–463, for the review, discussion and evaluation of individual grant applications. These deliberations could reveal confidential trade secrets or commercial property, such as patentable material, and personal information concerning individuals associated with the applications, disclosure of which would constitute a clearly unwarranted invasion of personal property.

This notice is being published less than 15 days prior to the above meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Dr. Steven Hausman, Executive Secretary, National Arthritis and Musculoskeletal and Skin Diseases Advisory Council, NIAMS, Natcher Building, Room 5AS–13, Bethesda, Maryland 20892; (301) 594–2463.

A summary of the meeting and roster of the members may be obtained from the Extramural Programs Office, NIAMS, Natcher Building, Room 5AS–13, National Institutes of Health, Bethesda, Maryland 20892; (301) 594–2463.

(Catalog of Federal Domestic Assistance Program No. 93.846, Arthritis, Bone and Skin Diseases, National Institutes of Health.)

Dated: August 21, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–22826 Filed 8–26–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Division of Research Grants; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following