ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communications, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Food and Drug Administration, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: John Jenkins, Center for Drug Evaluation and Research (HFD–020), Food and Drug Administration, 1451 Rockville Pike, Rockville, MD 20852, 301–594–3937; or Robert A. Yetter, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for reviewers and industry entitled ''Good Review Management Principles for PDUFA Products.'' This document is intended to provide guidance to industry and the review staff in CDER and CBER on GRMPs for the conduct of the first-cycle review of a new drug application (NDA), a biologics license application (BLA), or an efficacy supplement under PDUFA. The GRMPs in this guidance are based on the collective experience of CDER and CBER with review of applications for PDUFA products and are intended to promote efficient and consistent management of application reviews. A key aspect of GRMPs is their emphasis on effective communication between the agency and applicants throughout the drug and biologic product development and review processes.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on GRMPs for PDUFA products.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 requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of mailed 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 draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: July 18, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–19026 Filed 7–25–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Council on Graduate Medical Education; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Council on Graduate Medical Education (COGME).

Dates and Times: September 17, 2003, 8 a.m.–4:45 p.m., September 18, 2003, 8 a.m.–3 p.m.

Place: Holiday Inn Select, Versailles 1, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Status: The meeting will be open to the public.

Agenda: The agenda for September 17 will include: Welcome and opening comments from the Chair of COGME and staff of the Health Resources and Services Administration. In the morning there will be a series of speakers on topics covering the physician workforce, including ''Managed Care Staffing Patterns,'' ''Small Area Variations,'' and the ''Impact of an Aging Society on Physician Workforce Requirements.'' There will also be presentations on the ''Impact of Residency Duty Hours Restrictions-Cost and Structural Adaptations.''

In the afternoon there will be a luncheon presentation on the ''University of Michigan Supreme Court Case and its Impact for Medical School Diversity Initiatives.'' Lunch will not be provided to the general public. Later that afternoon, the Council's three workgroups—Diversity, Graduate Medical Education Financing, and Physician Workforce—will convene.

The agenda for September 18 will include a presentation by the Gallup Organization regarding the results of the General Services Administration's Stakeholder Engagement Survey of the Council; discussion of the survey by the Council will follow. The Council's three workgroup chairs will give their reports. There will be a report on development of a framework for revised COGME physician workforce goals, with subsequent discussion of Council recommendations covering the physician workforce and graduate medical education.

Agenda items are subject to change as priorities dictate.

For Further Information Contact: Anyone requiring information regarding the meeting should contact Stanford M. Bastacky, D.M.D., M.H.S.A., Acting Executive Secretary, Council on Graduate Medical Education, Division of Medicine and Dentistry, Bureau of Health Professions, Room 9A–27, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–6326.

Dated: July 22, 2003.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 03–19074 Filed 7–25–03; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

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

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Practitioner Services Network Initiative—New—SAMHSA's Center for Substance Abuse Treatment (CSAT) plans to obtain information about the providers, care and characteristics of clients with substance abuse disorders and related co-morbidities that receive treatment from practitioners in private practice and organizational settings. This information is needed to complement available information about