

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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FDA is announcing the availability of a draft guidance for reviewers and industry entitled "Good Review Management Principles for PDUFA Products."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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on GRMPs for PDUFA products.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.*

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**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*

the substance abuse treatment provided in institutional and publicly funded settings, in order to more completely describe the full range and nature of substance abuse problems affecting the nation.

The CSAT Practitioner Services Network initiative will provide support to four of the largest behavioral health associations in the nation to design and implement surveys using representative samples of their members and the clients they serve. The membership of the selected Associations collectively represent a significant proportion of the behavioral health professionals in the country. Two additional associations, the American Psychiatric Association and the American Psychological Association, have separately functioning Internet-based PSN infrastructures; from these two groups CSAT will be able to purchase reports based on the data they have already collected.

For the American Association for Marriage and Family Therapy; the

American Counseling Association; NAADAC, The Association for Addiction Professionals; and the National Association of Social Workers, CSAT will sponsor new data collection efforts to provide a core set of data elements to be collected in their upcoming membership surveys. The four Associations conduct periodic sample surveys of their memberships through their individual Practitioner Services Network infrastructures and will incorporate a common set of specific substance-abuse questions that are of importance to CSAT into these studies. CSAT will sponsor data collection and purchase, from each Association, a report that addresses the characteristics of practitioners who may be expected to encounter clients with substance abuse disorders, the characteristics of clients with behavioral and/or substance abuse disorders, and the nature of services rendered to these clients.

The reports to be purchased by CSAT will be based on the Associations' surveys of a representative sample of 500 of their members. Practitioners in the sample will abstract demographic and encounter-specific data from two of their current patients' records. No client identifying information will be collected as part of this study. Data collection methods will include mailed surveys with mailed reminders and follow-up phone calls in order to achieve a target response rate of 80 percent. This information will complement CSAT's and SAMHSA's existing data collection efforts and provide a more comprehensive view of the populations in need of services, the prevalence of substance abuse and mental health comorbidities, and the qualifications and training of private practitioners who serve these clients. The burden estimates are summarized in the following table.

Estimated number of respondents	Responses per respondent	Estimated completion time (hours)	Total burden hours
2,000 .....	1	.33	660

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Allison Herron Eydt, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: (202) 395-6974.

Dated: July 21, 2003.

**Anna Marsh,**

*Acting Executive Officer, SAMHSA.*

[FR Doc. 03-19058 Filed 7-25-03; 8:45 am]

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**DEPARTMENT OF HOMELAND SECURITY**

**Bureau of Citizenship and Immigration Services**

**Agency Information Collection Activities: Comment Request**

**ACTION:** 60-Day Notice of Information Collection Under Review; Employment Eligibility Verification; Form I-9.

The Department of Homeland Security, Bureau of Citizenship and Immigration Services has submitted the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for sixty days until September 26, 2003.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the equality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated,

electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

**Overview of This Information Collection**

(1) *Type of Information Collection:* Extension of currently approved collection.

(2) *Title of the Form/Collection:* Employment Eligibility Verification.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form I-9. Bureau of Citizenship and Immigration Services, Department of Homeland Security.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or households. This form was developed to facilitate compliance with section 274A of the Immigration and Nationality Act, as amended by the Immigration Reform and Control Act of 1986, which prohibits the knowing employment of unauthorized aliens. The information collected is used by employers or by recruiters for enforcement of provisions of immigration laws that are designed to control the employment of unauthorized aliens.