and 4 p.m., Monday through Friday. You can view comments FDA has received on the Internet at *http://www.fda.gov/ohrms/dockets/*.

For General Information Contact: George Graber, Center for Veterinary Medicine (HFV–220), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6651; FAX 301–827–1484 or e-mail: *ggraber@cvm.fda.gov*.

For Information About Registration Contact: Linda Grassie, Center for Veterinary Medicine (HFV–12), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–3796; FAX 301–827–4065 or e-mail: *Linda.Grassie@fda.gov*.

Registration: There is no registration fee for the meeting, but registration is required. Limited space is available (maximum of 200), so early registration is encouraged. You may register by phone, Fax or e-mail (see *For Information About Registration Contact*). Registration forms are also available on the Division of Dockets Management Web site at *http://www.accessdata.fda.gov/scripts/oc/dockets/meetings/meetingdocket.cfm*.

If you need special accommodations due to a disability, please contact Linda Grassie (see *For Information About Registration Contact*) at least 7 days in advance.

Transcripts: You may request a transcript of the meeting's general session in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857. The transcript will not include the individual breakout sessions, although their summaries will be included in the general session transcript. The transcript of the public meeting will be available after the meeting, at a cost of 10 cents per page. You may also examine the transcript of the meeting at the Division of Dockets Management (see *Comments and Electronic Access*) between 9 a.m. and 4 p.m., Monday through Friday and on the Center for Veterinary Medicine Web site at *http://www.fda.gov/cvm.*

SUPPLEMENTARY INFORMATION:

I. Background

The regulation of animal feed by FDA has focused on areas recognized as having an important impact on human health. Medicated feed good manufacturing practice regulations (GMPs) help prevent potentially unsafe drug residues in edible animal tissue. The regulation that prohibits the feeding of mammalian proteins to ruminant animals is intended to help prevent bovine spongiform encephalopathy in our cattle herd and the potential for variant Creutzfeldt-Jakob disease in humans. FDA believes it may be of value to develop a comprehensive preventive program for the manufacture and distribution of animal feed.

While emphasis for fostering safety has been placed on end product sampling, only a limited number of samples are tested for potential contaminants. More and more, industry is considering preventative, risk-based system controls to augment end product testing. We are exploring risk-based, preventative measures as an approach designed to help prevent feed-related hazards from occurring and to detect problems prior to distribution and sale of feed products. Control systems vary, but generally they have a number of common basic elements. These include the following elements: (1) A thorough analysis of manufacturing and distribution for each product, (2) identification of risks associated with the process and product, (3) identification and implementation of controls to effectively prevent identified risks, (4) employee training programs, (5) controls focused on critical steps, (6) assurances such steps are accurately and consistently performed, and (7) recordkeeping and validation of the system.

Although the purpose of an AFSS would be to reduce the risks associated with animal feeds, the design of a final program would consider costs, technological limitations, and other resource limitations. Some available approaches include hazard analysis and critical control points and GMPs, International Organization for Standardization procedures, statistical process controls, and standard sanitary operating procedures. These have been used by regulatory agencies and industry to help ensure the production and distribution of safe human foods.

II. Meeting

We are holding the meeting in an effort to gather information from you, our stakeholders, on the design of an effective, comprehensive, preventive, risk-based program to help minimize risks associated with animal feeds. Resources and costs are important considerations in any such undertaking, and we are receptive to suggestions about how these can be controlled or used most effectively (such as use of State inspections and self-inspections) while focusing preventive efforts on important known and emerging health risks associated with animal feeds.

The meeting will feature stakeholder and government speakers discussing safety measures currently in use and others which could be adapted to the feed industry. We plan several facilitated break-out discussion groups to explore topics such as the following:

1. What are the strengths of the current Federal and State regulatory programs for feed safety?
2. What are the weaknesses of the current Federal and State regulatory programs for feed safety?
3. What are the strengths and weaknesses of current industry feed safety programs?
4. What are the potential benefits of a comprehensive, risk-based Federal feed safety program?
5. What components should be included in an AFSS?
6. What is the potential burden (increased cost and manpower) of a comprehensive, risk-based Federal feed safety program, and what options are available to minimize the burden?

Dated: July 19, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–19030 Filed 7–25?–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0317]

Draft Guidance for Reviewers and Industry on Good Review Management Principles for Prescription Drug User Fee Act Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for reviewers and industry entitled ''Good Review Management Principles for PDUFA Products.'' This is one in a series of guidance documents that FDA agreed to draft and implement in conjunction with the June 2002 reauthorization of the Prescription Drug User Fee Act of 1992 (PDUFA). The good review management principles (GRMPs) are intended to promote efficient and consistent management of application reviews. The GRMPs focus on the role of both reviewers and industry, emphasizing effective communication to enhance the drug development and review processes.

DATES: Submit written or electronic comments on the draft guidance by September 11, 2003. General comments on agency guidance documents are welcome at any time.

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