review by an advisory committee. Section 562 of the act further provides that such review of the controversy shall take place in a timely manner. In the **Federal Register** of November 18, 1998 (63 FR 63978), FDA amended 21 CFR 10.75 to explicitly state that a sponsor, applicant, or manufacturer of a drug or device may request review of a scientific controversy by an appropriate advisory committee. In the preamble to the final rule, FDA stated that implementation of this provision would be undertaken by the individual FDA centers and would be described in guidance documents.

The Prescription Drug User Fee Act of 1992 (Public Law 102–571) (PDUFA) was reauthorized in November 1997 (PDUFA 2) as part of the Modernization Act. In conjunction with PDUFA 2, FDA agreed to specific performance goals (PDUFA goals) for activities associated with the development and review of products in human drug applications as defined in section 735(1) of the act (21 U.S.C. 379g(1)) (PDUFA products). The PDUFA goals are summarized in ''PDUFA Reauthorization Performance Goals and Procedures,'' an enclosure to a letter dated November 12, 1997, from the Secretary of Health and Human Services, Donna E. Shalala, to Senator James M. Jeffords. The PDUFA goals for major dispute resolution describe specific timeframes for CDER and CBER response to formally appealed decisions regarding scientific or procedural matters concerning PDUFA products.

The policies and procedures described in this guidance document will implement agency regulations, section 562 of the act, and the PDUFA goals for dispute resolution. Unless stated otherwise in the guidance, the document applies to PDUFA products and non-PDUFA products (e.g., generic drugs).

In the notice announcing the availability of the draft version of this guidance, FDA published notice of the proposed collection of information related to the guidance. The **Federal Register** notice also requested comments on the burden estimates for the guidance document. In the **Federal Register** of August 15, 1999 (64 FR 46397), the agency announced that it was submitting the collection of information to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995. The information collection provisions related to this guidance document have been approved under OMB control number 0910–0430. This approval expires December 31, 2002. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

This Level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The guidance represents the agency's current thinking on formal dispute resolution in CDER and CBER. 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, regulations, or both.

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 29, 2000.

**Margaret M. Dotzel,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 00–5465 Filed 3–6–00; 8:45 am]

**BILLING CODE 4160–01–F**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 99D–0296]**

### Guidance for Industry on Formal Meetings With Sponsors and Applicants for PDUFA Products; 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 ''Formal Meetings with Sponsors and Applicants for PDUFA Products.'' This guidance is intended to provide guidance to industry on procedures that will be adopted by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) for formal meetings between the agency and sponsors or applicants concerning certain drug products.

**DATES:** Submit written comments on agency guidances at any time.

**ADDRESSES:** Copies of the guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/cber/guidelines.htm. Submit written requests for single copies of this guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3844, FAX 888–CBERFAX. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

Murray M. Lumpkin, Center for Drug Evaluation and Research (HFD–2), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5400, or

Robert A. Yetter, Center for Biologics Evaluation and Research (HFM–10), 1401 Rockville Pike, Rockville, MD 20852–448, 301–827–0373.

**SUPPLEMENTARY INFORMATION:** FDA is announcing the availability of a guidance for industry entitled ''Formal Meetings with Sponsors and Applicants for PDUFA Products.''This guidance is intended to provide guidance to industry on procedures that will be adopted by CDER and CBER for formal meetings between the agency and sponsors or applicants concerning certain drug products.

In the **Federal Register** of March 19, 1999 (64 FR 13591), FDA announced the availability of a draft version of this guidance. The agency has finalized that draft guidance after considering comments received on the draft version. Few comments were received, and only minor changes were made to the draft version in response to the comments in an effort to make the document clearer.

CDER and CBER participate in many meetings each year with sponsors of investigations and applicants for marketing who seek guidance relating to the development and review (including the initial launch) of products in human drug applications as defined in section 735(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379g(1)) (PDUFA products). These meetings often represent critical points in the regulatory process. It is essential that FDA maintain procedures for the

timely and effective conduct of such meetings.

Section 119(a) of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act) (Public Law 105–115) amends section 505(b) of the act (21 U.S.C. 355(b)) and directs FDA to meet with sponsors and applicants, provided certain conditions are met, for the purpose of reaching agreement on the design and size of clinical trials intended to form the primary basis of an effectiveness claim in a new drug application submitted under section 505(b) of the act or in a biologics license application submitted under section 351 of the Public Health Service Act (21 U.S.C. 355(b)(4)(B)). Moreover, in conjunction with the reauthorization of the Prescription Drug User Fee Act of 1992 (PDUFA) in November 1997, FDA agreed to specific performance goals for the management of meetings with sponsors and applicants for PDUFA products. The performance goals are summarized in an enclosure to a letter dated November 12, 1997, from the Secretary of Health and Human Services, Donna E. Shalala, to Senator James M. Jeffords.

The procedures and policies described in this guidance are designed to promote efficient, well-managed meetings between sponsors, applicants, and CDER or CBER. These procedures will implement section 119(a) of the Modernization Act and are consistent with the timeframes described in the performance goals.

In the notice announcing the availability of the draft version of this guidance (64 FR 13591), FDA published notice of the proposed collection of information related to the draft guidance. The **Federal Register** notice also requested comments on the burden estimates for the guidance. In the **Federal Register** of August 26, 1999 (64 FR 46684), the agency announced that it was submitting the collection of information to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995. The information collection provisions related to this guidance have been approved under OMB control number 0910–0429. This approval expires December 31, 2002. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

This Level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The guidance represents the agency's current thinking on formal meetings with sponsors and applicants 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 statute, regulations, or both.

Interested persons may, at any time, submit written comments on the guidance 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 and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 20, 2000.

**Margaret M. Dotzel,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 00–5464 Filed 3–6–00; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Graduate Medical Education Advisory Council; 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 April 2000.

*Name:* Council on Graduate Medical Education (COGME).

*Date and Time:* April 5, 2000; 8:30 a.m.—5:30 p.m.; April 6, 2000; 8:30 a.m.—12 p.m.

*Place:* The Latham Hotel, Georgetown-Presidential Ballroom, 3000 M Street, N.W., Washington, D.C. 20007.

The meeting is open to the public.

*Agenda:* The agenda will include: Welcome and opening comments from the Administrator, Health Resources and Services Administration, the Associate Administrator for Health Professions, and the Acting Executive Secretary of COGME; a presentation on the Minimum Requirements for Physicians Enrolled in US Post-Graduate Training Programs; a panel of speakers discussing the Role of Labor in Graduate Medical Education; a legislative update on Graduate Medical Education; a presentation on the History of COGME's 110:50/50 Ratio; and a discussion of COGME Resource Papers. The Council will hear the reports of its work groups on GME Financing, and Physician Workforce.

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

Agenda items are subject to change as priorities dictate.

Dated: February 29, 2000.

**Jane M. Harrison,**

*Director, Division of Policy Review and Coordination.*

[FR Doc. 00–5420 Filed 3–6–00; 8:45 am]

**BILLING CODE 4160–15–U**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Statement of Organization, Functions, and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (DHHS), Health Resources and Services Administration (60) FR 56605 as amended November 6, 1995, as last amended at 65 FR 8375–6 dated February 18, 2000).

This notice reflects the organizational and functional changes in the Bureau of Health Professions (RP).

Make the following changes:

A. Delete the opening functional statement for the Bureau of Health Professions in its entirety and replace with the following:

**Bureau of Health Professions (RP)**

Provides national leadership in coordinating, evaluating, and supporting the development and utilization of the Nation's health personnel. Specifically: (1) Assess the Nation's health personnel supply and requirements and forecasts supply and requirements for future time periods under a variety of health resources utilization assumptions; (2) collects and analyzes data and disseminates information on the characteristics and capacities of the Nation's health personnel production systems; (3) proposes new or modifications of existing Departmental legislation, policies, and programs related to health personnel development and utilization; (4) develops, tests and demonstrates new and improved approaches to the development and utilization of health personnel within various patterns of health care delivery and financing systems; (5) provides financial support to institutions and individuals for health professions education programs; (6) administers Federal programs for