

**Federal Register** of August 28, 2009, requesting comments on this draft PIN.

Sixteen parties, including both individuals and groups, submitted a total of 31 comments regarding the draft PIN. After review and careful consideration of all comments received, HRSA has amended the PIN to incorporate certain recommendations from the public. The final PIN reflects these changes.

In addition to making the final PIN available on HRSA's Web site, HRSA is also posting the Agency's "Response to Public Comments." The purpose of that document is to summarize the major comments received and describe the Agency's response, including any corresponding changes made to the PIN. Where comments did not result in a revision to the PIN, explanations are provided.

**FOR FURTHER INFORMATION CONTACT:** For questions regarding this notice, please contact the Office of Policy and Program Development, Bureau of Primary Health Care, HRSA, at [OPPDGeneral@hrsa.gov](mailto:OPPDGeneral@hrsa.gov).

Dated: March 8, 2010.

**Mary K. Wakefield,**  
Administrator.

[FR Doc. 2010-5671 Filed 3-15-10; 8:45 am]

**BILLING CODE 4165-15-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Clinical Laboratory Improvement Advisory Committee: Notice of Charter Renewal

This gives notice under the Federal Advisory Committee Act (Pub. L. 92-463) of October 6, 1972, that the Clinical Laboratory Improvement Advisory Committee, Centers for Disease Control and Prevention, Department of Health and Human Services, has been renewed for a 2-year period through February 19, 2012.

For information, contact Thomas Hearn, PhD, Designated Federal Officer, Clinical Laboratory Improvement Advisory Committee, Centers for Disease Control and Prevention, Department of Health and Human Services, 1600 Clifton Road, NE., Mailstop C12, Atlanta, Georgia 30333, telephone (404) 718-1048 or fax (404) 639-3039.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the CDC

and the Agency for Toxic Substances and Disease Registry.

Dated: March 9, 2010.

**Elaine L. Baker,**

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2010-5633 Filed 3-15-10; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Mine Safety and Health Research Advisory Committee, National Institute for Occupational Safety and Health (MSHRAC, NIOSH)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following meeting for the aforementioned committee:

*Time and Date:* 8:15 a.m.–5 p.m., March 30, 2010; 8 a.m.–11:30 a.m., March 31, 2010.

*Place:* Hilton Garden Inn Pittsburgh/Southpointe, 1000 Corporate Drive, Canonsburg, Pennsylvania 15317, telephone (724) 743-5000, fax (724) 743-5010.

*Status:* Open to public, limited only by the space available. The meeting room accommodates approximately 50 people.

*Purpose:* This committee is charged with providing advice to the Secretary, Department of Health and Human Services; the Director, CDC; and the Director, NIOSH, on priorities in mine safety and health research, including grants and contracts for such research, 30 U.S.C. 812(b)(2), Section 102(b)(2).

*Matters To Be Discussed:* The meeting will focus on deep cover retreat mining research, mine illumination research, mine escape and rescue, human factors research, coal dust particle size surveys, and updates on proximity detection, a mine escape vehicle, robotics research, and results of broad agency announcements for mining research.

Agenda items are subject to change as priorities dictate.

*For More Information Contact:* Jeffery L. Kohler, PhD, Designated Federal Officer, MSHRAC, NIOSH, CDC, 626 Cochran Mill Road, telephone (412) 386-5301, fax (412) 386-5300.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: March 9, 2010.

**Elaine L. Baker,**

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2010-5628 Filed 3-15-10; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### National Advisory Council on Nurse Education and Practice; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), notice is hereby given of the following meetings:

*Name:* National Advisory Council on Nurse Education and Practice (NACNEP).

*Dates and Times:* April 22, 2010, 8:30 a.m.–4:30 p.m.

April 23, 2010, 8:30 a.m.–4 p.m.  
*Place:* Doubletree Bethesda Hotel & Executive Meeting Center, 8120 Wisconsin Avenue, Bethesda, MD 20814.

*Status:* The meeting will be open to the public.

*Agenda:* Agency and Bureau administrative updates will be provided.

*Purpose:* The purpose of this meeting is to address issues relating to the role of nursing in primary care and implications for workforce. The objectives of the meeting are to: (1) Delineate the variety of roles nurses play in primary care including health promotion, screening, public education, illness prevention, primary care and management of stable chronic conditions; (2) review and evaluate the data related to education preparation and supply of primary care nurses and advanced practice registered nurses; (3) describe factors that facilitate and sustain primary care practice by qualified, competent advanced practice registered nurses; (4) identify the financial and regulatory barriers to effective, accessible primary care delivered by nurses and recommended strategies for resolution; and (5) review and recommend community-based, nurse-directed models for primary care delivery that are cost effective and produce quality outcomes. This meeting is a continuation of the meeting that was held November 2009. Experts from professional nursing, public and private organizations will make presentations on primary care delivery models. During this meeting, the NACNEP council

members will deliberate on the content presented and formulate recommendations to the Secretary of Health and Human Services and the Congress on the role of nursing in primary care. This meeting will form the basis for NACNEP's mandated Tenth Annual Report.

The NACNEP will join the Council on Graduate Medical Education (COGME), the Advisory Committee on Training in Primary Care Medicine and Dentistry (ACTPCMD), and the Advisory Committee on Interdisciplinary, Community-Based Linkages (ACICBL) on April 21, 2010, for the third Bureau of Health Professions (BHPr) All Advisory Committee Meeting. Please refer to the **Federal Register** notice for the BHPr All Advisory Committee Meeting for additional details.

For further information regarding NACNEP, to obtain a roster of members, minutes of the meeting, or other relevant information, contact Lakisha Smith, Executive Secretary, National Advisory Council on Nurse Education and Practice, Parklawn Building, Room 8C-26, 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443-5688. Information can also be found at the following web site: <http://bhpr.hrsa.gov/nursing/nacnep.htm>

Dated: March 10, 2010.

**Sahira Rafiullah,**

*Director, Division of Policy and Information Coordination.*

[FR Doc. 2010-5675 Filed 3-15-10; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0128]

#### Prescription Drug User Fee Act; Public Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public meeting.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public meeting on the Prescription Drug User Fee Act (PDUFA). The legislative authority for PDUFA expires in September 2012. At that time, new legislation will be required for FDA to continue collecting user fees for the prescription drug program. The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that before FDA begins negotiations with the regulated industry on PDUFA reauthorization, we publish a notice in the **Federal Register** requesting public input on the

reauthorization, hold a public meeting at which the public may present its views on the reauthorization, provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes, and publish the comments on FDA's Web site. FDA invites public comment on the PDUFA program and suggestions regarding the features FDA should propose for the next PDUFA program.

**DATES:** The public meeting will be held on April 12, 2010, from 9 a.m. to 5 p.m. Registration to attend the meeting must be received by April 5, 2010. See Section III.C of this document for information on how to register for the meeting. Submit written or electronic comments by May 12, 2010.

**ADDRESSES:** The meeting will be held at the Hilton Washington DC/Rockville Hotel and Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852.

Submit written comments 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.regulations.gov>. All comments should be identified with the docket number found in brackets in the heading of this document.

Transcripts of the meeting will be available for review at the Division of Dockets Management and on the Internet at <http://www.regulations.gov> approximately 30 days after the meeting.

#### FOR FURTHER INFORMATION CONTACT:

Mary Gross, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 51, rm. 6178, Silver Spring, MD 20993, 301-796-3519, FAX: 301-847-8753, [Mary.Gross@fda.hhs.gov](mailto:Mary.Gross@fda.hhs.gov); or Patrick Frey, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 51, rm. 6350, Silver Spring, MD 20993, 301-796-3844, FAX: 301-847-8443, [Patrick.Frey@fda.hhs.gov](mailto:Patrick.Frey@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Introduction

FDA is announcing its intention to hold a public meeting on PDUFA. The authority for PDUFA expires in September 2012. Without new legislation, FDA will no longer be able to collect user fees to fund the human drug review process. Section 736B(d)(2) (21 U.S.C. 379h-2(d)(2)) of the FD&C Act requires that before FDA begins negotiations with the regulated industry on PDUFA reauthorization, we do the

following: (1) Publish a notice in the **Federal Register** requesting public input on the reauthorization, (2) hold a public meeting at which the public may present its views on the reauthorization, (3) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes, and (4) publish the comments on the FDA Web site. This notice, the public meeting, the 30 day comment period after the meeting, and the posting of the comments on the FDA Web site will satisfy these requirements. The purpose of the meeting is to hear stakeholder views on PDUFA as we consider the features to propose in the next PDUFA program. FDA is interested in responses to the following two general questions and welcomes any other pertinent information stakeholders would like to share:

1. What is your assessment of the overall performance of the PDUFA IV program thus far?

2. What aspects of PDUFA should be retained, changed, or discontinued to further strengthen and improve the program?

The following information is provided to help potential meeting participants better understand the history and evolution of the PDUFA program and its current status.

##### II. What is PDUFA? What Does It Do?

PDUFA is a law that authorizes FDA to collect fees from drug companies that submit marketing applications for certain human drug and biological products. The original PDUFA (PDUFA I) was enacted in 1992 (as the Prescription Drug User Fee Act, Public Law 102-571) and had a 5-year life. In 1997, as PDUFA I expired, Congress passed the FDA Modernization Act (FDAMA, Public Law 105-115) which included an extension of PDUFA (PDUFA II) for an additional 5 years. In 2002, Congress extended PDUFA again through fiscal year 2007 (PDUFA III) through the Public Health Security and Bioterrorism Preparedness and Response Act (Public Law 107-188). Most recently, Title I of the Food and Drug Administration Amendments Act of 2007 (FDAAA, Public Law 110-85) reauthorized PDUFA through fiscal year 2012 (PDUFA IV).

PDUFA's intent has been to provide additional revenues so that FDA could hire more staff, improve systems, and establish a better managed human drug review process to make important therapies available to patients sooner without compromising review quality or approval standards. In conjunction with PDUFA, FDA agrees to certain performance goals. These goals apply to