

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.*

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**BILLING CODE 4165-15-P**

## 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

the process for the review of original new human drug and biological product applications, resubmissions of original applications, and supplements to approved applications. During the first few years of PDUFA I, the additional funding enabled FDA to eliminate backlogs of original applications and supplements. Phased in over the 5 years of PDUFA I, the goals were to review and act on 90 percent of priority new drug applications (NDAs), biologics license applications (BLAs), and efficacy supplements within 6 months of submission of a complete application; to review and act on 90 percent of nonpriority original NDAs, BLAs, and efficacy supplements within 12 months; and on resubmissions and manufacturing supplements within 6 months. Over the course of PDUFA I, FDA exceeded all of these performance goals and significantly reduced median review times of both priority and standard NDAs and BLAs.

Under PDUFA II, many of these review performance goals were shortened and new procedural goals were added to improve FDA interactions with industry sponsors and help facilitate the drug development process. The procedural goals, for example, articulated timeframes for scheduling sponsor-requested meetings intended to address emerging drug development challenges, as well as timeframes for the timely response to industry submitted questions on special study protocols. FDA met or exceeded nearly all of the review and procedural goals under PDUFA II. However, concerns grew that overworked review teams often had to return applications as "approvable" as they did not have the resources and sufficient staff time to work with the sponsors to resolve issues so that applications could reach approval in the first review cycle.

A sound financial footing and support for limited postmarket risk management were key themes of PDUFA III. Base user fee resources were significantly increased and a mechanism to account for changes in human drug review workload was adopted. PDUFA III also expanded the scope of user fee activities to include postmarket surveillance of new therapies for up to 3 years after marketing approval. FDA committed to the development of guidance for industry on risk assessment, risk management, and pharmacovigilance as well as guidance to review staff and industry on Good Review Management Principles (GRMPs). Initiatives to improve application submission and agency-sponsor interactions during the drug development and application review processes were also adopted.

With PDUFA reauthorization under FDAAA Title I (PDUFA IV), FDA obtained a significant increase in base fee funding and committed to full implementation of GRMPs, which includes providing a planned review timeline for premarket review, development of new guidance for industry on innovative clinical trials, modernization of postmarket safety, and elimination of the 3-year limitation on fee support for postmarket surveillance. However, the passage of FDAAA Titles IV, V, and IX added statutory requirements that increased the pre- and postmarket review process requirements, added new deadlines, and effectively increased the review workload. For example, these provisions significantly increased the number of applications requiring advisory committee review while creating more stringent conflict-of-interest rules for advisory committee members. The provisions also provided expanded drug safety authorities such as the authority to require Risk Evaluation Mitigation Strategies (REMS), order safety labeling changes, and require postmarket studies and trials. Since enactment of PDUFA IV at the start of fiscal year 2008, FDA has focused on implementation of the new statutory requirements, rapidly hiring new staff to increase FDA review capacity, and the iterative improvement of review processes. This necessary focus has affected performance on a number of PDUFA review goals and delayed work on some of the new PDUFA IV initiatives.

FDA has published a number of reports that may provide the public with useful background on PDUFA IV and FDAAA. Key **Federal Register** documents, PDUFA-related guidances, legislation, performance reports, and financial reports and plans can be found at <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/default.htm>. FDA will also post a webinar on PDUFA to give the public more background information on the program. The webinar will be available at <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm117890.htm> approximately 10 days before the public meeting. FDAAA-specific information is available at: <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCAAct/SignificantAmendments/totheFDCAAct/FoodandDrugAdministrationAmendmentsActof2007/default.htm>.

### III. What Information Should You Know About the Meeting?

#### A. When and Where Will the Meeting Occur? What Format Will FDA Use?

Through this notice, we are announcing a public meeting to hear stakeholder views on what features we should propose in the PDUFA V program. We will conduct the meeting on April 12, 2010, at the Hilton Washington DC/Rockville (see **ADDRESSES**). In general, the meeting format will include presentations by FDA and a series of panels representing different stakeholder interest groups (such as patient advocates, consumer protection, industry, health professionals, and academic researchers). We will also provide an opportunity for individuals to make presentations at the meeting and for organizations and individuals to submit written comments to the docket after the meeting. FDA policy issues are beyond the scope of these reauthorization discussions. Accordingly, the presentations should focus on process enhancements and funding issues, and not focus on policy issues.

#### B. What Questions Would FDA Like the Public to Consider?

Please consider the following questions for this meeting:

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?

#### C. How Do You Register for the Meeting or Submit Comments?

If you wish to attend and/or present at the meeting, please register by e-mail to [PDUFAreauthorization@fda.hhs.gov](mailto:PDUFAreauthorization@fda.hhs.gov) by April 5, 2010. Your e-mail should contain complete contact information for each attendee, including name, title, affiliation, address, e-mail address, and phone number. Registration is free and will be on a first-come, first-served basis. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. We will try to accommodate all persons who wish to make a presentation. The time allotted for presentations may depend on the number of persons who wish to speak. If you need special accommodations because of disability, please contact

Mary Gross (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

In addition, any person may submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**). Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. To ensure consideration, all comments must be received by May 12, 2010.

*D. Will Meeting Transcripts Be Available?*

Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov> and <http://www.fda.gov>. It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A transcript will also be available in either hard copy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857.

Dated: March 11, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Office of Family Assistance; Privacy Act of 1974; System of Records

**AGENCY:** Office of Family Assistance, ACF, HHS.

**ACTION:** Notice to establish a new system of records.

**SUMMARY:** In accordance with the requirements of the Privacy Act of 1974 (5 U.S.C. 552a), as amended, the Administration for Children and Families (ACF) is publishing notice of a new system of records, entitled "Administration for Children and Families' National Responsible Fatherhood Pledge Campaign (NRFPC)."

**DATES:** The Department of Health and Human Services (HHS) invites

interested parties to submit written comments on the proposed system until April 14, 2010. As required by the Privacy Act (5 U.S.C. 552a(r)), HHS on March 9, 2010, sent a report of a new system of records to the Committee on Homeland Security and Governmental Affairs of the Senate, the Committee on Oversight and Government Reform of the House of Representatives, and the Office of Information and Regulatory Affairs of the Office of Management and Budget (OMB). The proposed action described in this notice is effective on April 26, 2010, unless HHS receives comments which result in a contrary determination.

**ADDRESSES:** Interested parties may submit written comment on this notice by writing to Robin Y. McDonald, Office of Family Assistance, Administration for Children and Families, 370 L'Enfant Promenade, SW., 5th Floor East, Washington, DC 20447. Comments received will be available for public inspection at this address from 9 a.m. to 5 p.m., Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:** Robin Y. McDonald, Office of Family Assistance, Administration for Children and Families, 370 L'Enfant Promenade, SW., 5th Floor East, Washington, DC 20447. The telephone number is (202) 401-5587.

**SUPPLEMENTARY INFORMATION:** The establishment of the proposed new system of records will enable ACF, in response to President Barack Obama's call for a national conversation on responsible fatherhood and healthy families, to assist interested parties to do all they can in providing children in their homes and communities the encouragement and support they need to fulfill their potential. In support of this objective, pledge cards will be available on the National Responsible Fatherhood Clearinghouse Web site and in print formats. The voluntarily provided data elements from these pledge cards will assist ACF and the White House Office of Faith-Based and Neighborhood Partnerships to provide supporting parties with information to promote a national discourse on responsible fatherhood and healthy families.

Dated: March 9, 2010.

**Carmen R. Nazario,**

*Assistant Secretary for Children and Families.*

**09-80-0390**

**SYSTEM NAME:**

Administration for Children and Families' National Responsible Fatherhood Pledge Campaign (NRFPC).

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Administration for Children and Families, Office of Family Assistance, 370 L'Enfant Promenade, W., 5th Floor East, Washington, DC 20447.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Parties who voluntarily complete and submit the NRFPC pledge card through the National Responsible Fatherhood Clearinghouse, part of the Administration for Children and Families (ACF).

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Name, Mobile Phone Number, E-mail address, City, State, Zip Code.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Legal authority for maintenance of the system is provided by section 403(a)(2)(C) of the Social Security Act, 42 U.S.C. 603(a)(2)(C).

**PURPOSE:**

As authorized by the Social Security Act, and in response to President Barack Obama's call for a national conversation on responsible fatherhood and healthy families, parties will pledge to renew their commitment to family and community and recognize the positive impact that responsible adults can have on our children and youth. By taking the President's Pledge on Responsible Fatherhood, parties commit to do all they can in providing children in their homes and communities the encouragement and support they need to fulfill their potential. In support of this objective, pledge cards will be available on the National Responsible Fatherhood Clearinghouse website and in print formats. The voluntarily provided data elements from these pledge cards will assist the Administration for Children and Families and the White House Office of Faith-Based and Neighborhood Partnerships to provide supporting parties with information to promote a national discourse on responsible fatherhood and healthy families.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

These routine uses specify circumstances, in addition to those provided by statute in the Privacy Act of 1974, under which ACF may release information from this system of records without the consent of the data subject. Each proposed disclosure of information under these routine uses will be evaluated to ensure that the disclosure