Boulevard, Bethesda, MD 20892. (Telephone Conference Call)

Contact Person: Robert Wellner, PhD, Scientific Review Officer, Review Branch, Dea, Niddk, National Institutes of Health, Room 706, 6707 Democracy Boulevard, Bethesda, MD 20892–5452. 301–594–4721. *Rw175w@Nih.Gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: November 3, 2010.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–28295 Filed 11–9–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Pediatric Ancillary Study to ASSESS–AKI.

Date: December 7, 2010.

Time: 2:15 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892. (Telephone Conference Call)

Contact Person: Lakshmanan Sankaran, PhD Scientific Review Officer, Review Branch, Dea, NIDDK, National Institutes Of Health, Room 755, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7799, *Ls38z@Nih.Gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Bone Morphogenesis Program Project Review.

Date: December 8, 2010.

Time: 2 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health. Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892. (Telephone Conference Call)

Contact Person: Lakshmanan Sankaran, PhD Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 755, 6707 Democracy Boulevard, Bethesda, Md 20892–5452. (301) 594–7799. *Ls38z@Nih.Gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: November 3, 2010.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–28293 Filed 11–9–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0128]

Prescription Drug User Fee Act; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until October 31, 2011, the comment period for the notice of public meeting that published in the **Federal Register** of March 16, 2010 (75 FR 12555). In the notice, FDA announced a public meeting to solicit input on the reauthorization of the Prescription Drug User Fee Act (PDUFA) program. The Federal Food, Drug, and Cosmetic Act (the FD&C Act) requires public review of the recommendations for the human drug review program after negotiations with the regulated industry conclude. FDA expects that this additional public process will be complete by October 2011. FDA is reopening the comment period for the expected duration of the public part of the reauthorization process to ensure that all interested stakeholders have the opportunity to share their views on the matter.

DATES: Submit either electronic or written comments by October 31, 2011.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Patrick Frey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1174, Silver Spring, MD 20993–0002, 301–796–3844, FAX: 301–847–8443, e-mail: *PDUFAReauthorization@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 16, 2010 (75 FR 12555), FDA published a notice of a public meeting on PDUFA reauthorization and invited comments. In the notice, the Agency stated that 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.

The public meeting was held on April 12, 2010, and interested persons were given until May 12, 2010, to submit comments. The written comments submitted during that period are now published on the FDA Web site at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm215804.htm.* To ensure that all interested persons have sufficient opportunity to share their views on PDUFA throughout the reauthorization process, FDA is reopening the comment period until October 31, 2011. The FD&C Act requires public review of the recommendations for the human drug review program after negotiations with the regulated industry conclude. FDA expects that the public component of the reauthorization process will be complete by October 2011. Therefore, the Agency is reopening the comment period for this anticipated duration to ensure that all interested stakeholders have the opportunity to share their views on the matter.

II. Additional Information on PDUFA

There are several sources of information on FDA's Web site that may be useful for interested stakeholders to better understand the history and evolution of the PDUFA program and its current status:

- Information on the April 2010 public meeting on PDUFA Reauthorization, the **Federal Register** notice announcing the meeting, and the transcript of the meeting are available at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm117890.htm.* The slide presentations from the meeting can be found at *http://www.regulations.gov* using Docket No. FDA–2010–N–0128.
- FDA created a webinar on the PDUFA program, drug development, and FDA's drug review in PDUFA IV. These presentations are available at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm207597.htm.*
- Key **Federal Register** documents, PDUFA-related guidances, legislation, performance reports, and financial reports and plans are posted at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/default.htm.*
- Specific information on the FDA Amendments Act of 2007 is available at: *http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FoodandDrugAdministrationAmendmentsActof2007/default.htm.*

III. How To Submit Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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.

Dated: November 3, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–28357 Filed 11–9–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Solicitation for Nominations for Members of the U.S. Preventive Services Task Force (USPSTF)

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Solicits nominations for new members of USPSTF.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) invites nominations of individuals qualified to serve as members of the U.S. Preventive Services Task Force (USPSTF).

The USPSTF, a standing, independent panel of non-Federal experts that makes evidence-based recommendations to the health care community and the public regarding the provision of clinical preventive services, *see* 42 U.S.C. 299b–4(a), is composed of members appointed to serve for four-year terms with an option for a one-year or two-year extension. New members are selected each year to replace those members who are completing their appointments. Individuals nominated but not appointed in previous years, as well as those newly nominated, are considered in the annual selection process.

USPSTF members meet three times a year for two days in the Washington, DC area. Between meetings, member duties include reviewing and preparing comments (off site) on systematic evidence reviews prior to discussing and making recommendations on preventive services, drafting final recommendation documents, and participating in workgroups on specific topics or methods.

A diversity of perspectives is valuable to the work of the USPSTF. To help obtain a diversity of perspectives among nominees, AHRQ particularly encourages nominations of women, members of minority populations, and persons with disabilities. Interested individuals can self nominate. Organizations and individuals may nominate one or more persons qualified for membership on the USPSTF.

Qualification Requirements: The mission of the USPSTF is to review the scientific evidence related to the effectiveness and appropriateness of clinical preventive services for the purpose of developing recommendations for the health care community. Therefore, in order to qualify for the USPSTF, an applicant or nominee MUST demonstrate the following:

1. Knowledge and experience in the critical evaluation of research published in peer reviewed literature and in the methods of evidence review;
2. Understanding and experience in the application of synthesized evidence to clinical decisionmaking and/or policy;
3. Expertise in disease prevention and health promotion;
4. Ability to work collaboratively with peers; and,
5. Clinical expertise in the primary health care of children and/or adults, and/or expertise in counseling and behavioral interventions for primary care patients.

Some USPSTF members without primary health care clinical experience may be selected based on their expertise in methodological issues such as medical decisionmaking, clinical epidemiology, behavioral medicine, health equity, and health economics. For individuals with clinical expertise in primary health care, additional qualifications in one or more of these areas would enhance their candidacy.

Consideration will be given to individuals who are recognized nationally for scientific leadership within their field of expertise. Applicants must have no substantial conflicts of interest, whether financial, professional, or other conflicts, that would impair the scientific integrity of the work of the USPSTF.

DATES: Nominations are welcome at any time. To be considered for appointment in 2011, complete nominations must be received by November 29, 2010.

Nominated individuals will be selected for the USPSTF on the basis of their qualifications (in particular, those that address the required qualifications, outlined above) and the current expertise needs of the USPSTF. All individuals with complete nominations will be considered. AHRQ will retain and consider for future vacancies the nominations of those not selected during this cycle.

ADDRESSES: Submit your responses either in writing or electronically to: Gloria Washington, *ATTN:* USPSTF Nominations, Center for Primary Care, Prevention, and Clinical Partnerships, Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, Maryland 20850, *USPSTFnominations@AHRQ.hhs.gov.*

Nomination Submissions

Nominations may be submitted in writing or electronically, but must include:

(1) The applicant's current curriculum vitae and contact information, including