

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](mailto: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.*

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## 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](mailto: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](mailto: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.*

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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; 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](mailto: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.