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: Ruth Barratt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 4540, Silver Spring, MD 20993–0002, 301–796–2600.

SUPPLEMENTARY INFORMATION:

I. Background

Since publication of the 2011 ''Identifying CDER's Science and Research Needs'' report, FDA has been engaged in efforts to further assess and prioritize the needs articulated therein. As part of these efforts, CDER's Safety Research Interest Group (SRIG), a subcommittee of the Science Prioritization and Review Committee, assessed CDER's overall drug safety-related regulatory science needs in view of FDA's ongoing research efforts and highlighted areas that would benefit from additional resources and collaboration.

The SRIG identified the following seven overall needs for drug safety-related regulatory science:

1. Improve access to postmarket data sources and explore the feasibility of their use in safety signal analyses
2. Improve risk assessment and management strategies to reinforce the safe use of drugs
3. Evaluate the effectiveness of risk communications of drug safety information to health care providers and the public
4. Improve product quality and design, manufacturing processes, and product performance relating to safety
5. Develop and improve predictive models of safety in humans, including nonclinical biomarkers
6. Improve clinical trial statistical analyses for safety, including benefit-risk assessment
7. Investigate clinical biomarkers of safety, including standards for qualification.

Particular priorities within the seven overall needs requiring further resources and outside participation were also identified. FDA seeks to stimulate collaborations with external partners and stakeholders to address these needs by asking them to: (1) Submit descriptions of their ongoing research and initiatives related to the seven overall needs, especially the identified priorities, and (2) indicate their interest in working with FDA to address these needs. Outside parties are being asked to submit comments to the docket and email address *CDER_Science_Needs@fda.hhs.gov.*

II. Comments

Interested persons may submit either electronic comments regarding the report to *http://www.regulations.gov* and email address *CDER_Science_Needs@fda.hhs.gov,* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of 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, and will be posted to the docket at *http://www.regulations.gov.*

III. Electronic Access

Persons with access to the Internet may obtain the report at *http://www.regulations.gov.*

Dated: March 13, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–06288 Filed 3–18–15; 8:45 am]

BILLING CODE 4164–01–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; NIDDK Ancillary R01 Telephone Review SEP.

Date: April 3, 2015

Time: 2:30 p.m. to 3:30 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: Xiaodu Guo, MD, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes Of Health, Room 761, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–4719, *guox@extra.niddk.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Collaborative Interdisciplinary Team Science in Diabetes and Obesity (R24).

Date: April 6, 2015.

Time: 2:30 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: Ann A. Jerkins, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 759, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, 301–594–2242, *jerkinsa@niddk.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: March 13, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–06266 Filed 3–18–15; 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; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, March 31, 2015, 04:00 p.m. to April 01, 2015, 05:00 p.m., Churchill Hotel, 1914 Connecticut Avenue NW., Washington, DC, 20009 which was published in the **Federal Register** on March 09, 2015, 80 FR 12494.

The meeting is being amended to reflect location change. The new meeting location is the Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814. The meeting is closed to the public.