available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before January 14, 2013. Oral presentations from the public will be scheduled between approximately 12:30 p.m. to 1:30 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before January 4, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by January 7, 2013.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Cindy Hong at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 15, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–28201 Filed 11–19–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0974]

Development of Prioritized Therapeutic Area Data Standards; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the intent to prioritize and develop therapeutic area data standards to facilitate the conduct of clinical research and the regulatory review of medical products. Therapeutic area disease and domain specific data standards should enable and enhance the ability to integrate, analyze, report, and share regulatory information. FDA has developed a roadmap that provides its current thinking on therapeutic area priorities and has posted it on the FDA Web site. FDA is actively participating with regulated industry, the Clinical Data Interchange Standards Consortium (CDISC), the Critical Path Institute, Health Level 7's (HL7) Clinical Interoperability Council, and other stakeholders to support the development of these therapeutic area standards. The therapeutic area standards will be developed collaboratively based on open, consensus-based data standards development methodology.

DATES: To ensure that the Agency considers your comments, submit either electronic or written comments by January 22, 2013.

ADDRESSES: Submit written requests for a copy of the roadmap to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit electronic comments on FDA's objective to develop prioritized therapeutic area data standards or on the roadmap 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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the roadmap.

FOR FURTHER INFORMATION CONTACT:

Ron Fitzmartin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1160, Silver Spring, MD 20993–0002, *CDERDataStandards@fda.hhs.gov;* or

Amy Malla, Center for Biologics Evaluation and Research (HFM–25), 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–6085.

SUPPLEMENTARY INFORMATION:

I. Background

Traditionally, clinical study data submitted to FDA is in a format that is unique to each individual sponsor; furthermore the data quality varies. This has created inefficiencies in the review process and impeded efforts to analyze the data across applications when such analyses could be beneficial to detect trends in safety or efficacy or for other reasons. Sponsor adoption of available clinical trial data standards (CDISC/SDTM) for the submission of product applications have helped to improve the quality and standardization of submitted data. However, such a voluntary approach has proved insufficient to support both the current business requirements as well as efforts to modernize the review environment.

In 2011, the Center for Drug Evaluation and Research (CDER) identified a set of disease and therapeutic areas that could benefit from further standardization. These content area standards are primarily intended to support the efficient evaluation of medical products as noted previously in this document. Several factors were considered in the identification of these areas: (1) Areas of particular need, (2) areas with existing data standardization projects underway, and (3) areas with greater drug development pipeline activity. The initial prioritization was based on the number of active investigational new drug applications (or INDs) and input from review divisions, as well as from industry. The three tiers of priority were assembled into a roadmap and posted on the FDA Web site at *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm287408.htm.* The roadmap sets out a sequence of standardization efforts to achieve significant results by December 2017. CDER established a small grants program to fund projects that develop

disease and domain-specific therapeutic area data standards.

On July 9, 2012, President Obama signed into law the Food and Drug Administration Safety and Innovation Act of 2012, which includes the reauthorization of the Prescription Drug User Fee Act (PDUFA V). Under section XII of the PDUFA V performance goals, FDA agreed to create a plan for distinct therapeutic area data standards and to prioritize and develop the data standards in collaboration with CDISC and other open standards organizations. FDA is seeking public comment on the roadmap and will consider the comments as the Agency develops its proposed project plan which is due to be issued for review and comment by June 30, 2013. In addition, FDA will publish notices soliciting input on, and engagement in, standards development activities, and will periodically issue guidances specifying the completed data standards, formats, and terminologies that sponsors should use to submit data in applications.

II. Comments

Interested persons may submit either written comments regarding the roadmap, as well as recommendations on how the therapeutic area data standards development effort could be accomplished more rapidly, to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov.* 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 roadmap at *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm287408.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *http://www.regulations.gov.*

Dated: November 15, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–28197 Filed 11–19–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

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 meeting.

The meeting 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 General Medical Sciences Special Emphasis Panel, Review of Minority Biomedical Research Support Behavioral Applications.

Date: November 28, 2012.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Room 3An.18, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Rebecca H. Johnson, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An18C, Bethesda, MD 20892, 301–594–2771, *johnsonrh@nigms.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.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: November 14, 2012.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–28157 Filed 11–19–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

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 meeting.

The meeting 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 Child Health and Human Development Special Emphasis Panel; ''NIH Summer Research Experience Programs (R25)''.

Date: December 7, 2012.

Time: 1:30 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852, (Telephone Conference).

Contact Person: Anne Krey, Ph.D., Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01, Bethesda, MD 20892, 301–435–6908, *ak41o@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: November 13, 2012.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–28160 Filed 11–19–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as