DATES: *Dates and Time:* The scientific workshop will be held on March 20, 2015, from 8:30 a.m. to 5:30 p.m.

ADDRESSES: The scientific workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503A), Silver Spring, MD 20993–0002. Participants must enter through Building 1 and undergo security screening. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Contact Persons: Mary Gross, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3519, *mary.gross@fda.hhs.gov;* or Georgiann Ienzi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3515, *georgiann.ienzi@fda.hhs.gov.*

If you need special accommodations due to a disability, contact Mary Gross or Georgiann Ienzi at least 7 days in advance.

Registration: The scientific workshop is free and seating will be on a first-come, first-served basis. It may be necessary to limit both the number of attendees from individual organizations and the total number of attendees based on space limitations. Email registrations should be sent to *Dystrophin_Workshop@fda.hhs.gov* by March 17, 2015. If you cannot attend in person, the meeting will be Webcast live. Information about how to access the Webcast will be located at: *http://www.fda.gov/Drugs/NewsEvents/ucm432429.htm.*

Comments and Meeting Summary: Submit electronic comments to *http://www.regulations.gov* by May 20, 2015. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Please identify your comments with the docket number found in brackets in the heading of this document. It is only necessary to send one set of comments. 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.*

A summary of the scientific workshop's highlights will be made available for review at the Division of Dockets Management and at *http://www.regulations.gov.* You may submit a request to obtain a hard copy by sending a request to the Division of Freedom of Information (ELEM–1029), Office of Management Programs, Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

SUPPLEMENTARY INFORMATION: FDA and NIH are cosponsoring this scientific workshop to discuss current methodologies being used in drug development and scientific research for DMD. Recent scientific advances present an opportunity for the development and validation of robust methods for the objective, reliable, and quantitative measurement of DMD-associated proteins.

I. Background

Dystrophinopathies result from genetic mutations in the dystrophin gene that decrease dystrophin protein expression levels and result in altered dystrophin function. These changes can lead to muscle degeneration and, in many patients, downstream pathologies including inflammation and fibrosis that interfere with muscle regeneration, loss of movement, orthopedic complications, and ultimately respiratory and cardiac failure.

II. Scope of the Scientific Workshop

The workshop will include sessions which will focus on current technologies used in the detection of dystrophin. Presentations will provide overviews of the technologies (including limitations, detection sensitivities, linearity, and reproducibility). A panel discussion will help identify development challenges for each method. Muscle biopsy collection, sample handling, reference materials, and image analysis will also be discussed.

FDA will post the agenda and other background material approximately 2 days before the public scientific workshop at: *http://www.fda.gov/Drugs/NewsEvents/ucm432429.htm.*

Dated: February 24, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–04384 Filed 3–2–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Pediatric Neurocognitive Workshop; Advancing the Development of Pediatric Therapeutics Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration's (FDA) Division of Gastroenterology and Inborn Errors Products Division and Division of Pediatric and Maternal Health in the Center for Drug Evaluation and Research, and the Office of Pediatric Therapeutics in the Office of the Commissioner are announcing a 2-day public workshop. Day 1 of the workshop is entitled ''Assessment of Neurocognitive Outcomes in the Inborn Errors of Metabolism''. Day 2 of the workshop is entitled, ''Advancing the Development of Pediatric Therapeutics: Assessment of Pediatric Neurocognitive Outcomes''. The purpose of this 2-day workshop is to provide a forum to consider issues related to advancing pediatric regulatory science in the evaluation of neurocognitive outcomes in pediatric patients.

DATES: The public workshop will be held on April 16 and 17, 2015, from 8 a.m. to 5 p.m.

ADDRESSES: The public workshop will be held in the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503A), Silver Spring, MD 20993–0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

FOR FURTHER INFORMATION CONTACT: For questions regarding Day 1 of the workshop, contact Richard (Wes) Ishihara, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–0069, *richard.ishihara@fda.hhs.gov.*

For questions regarding Day 2 of the workshop, contact Denise Pica-Branco, Center for Drug Evaluation and Research, Food and Drug

Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002,Telephone: 301–796–1732, FAX: 301–796–9858, *denise.picabranco@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: The first day of the workshop will focus on approaches for assessing the efficacy of therapeutic products on neurocognitive outcomes in patients diagnosed with inborn errors of metabolism disorders. The session will address the role of natural history studies and methodological approaches for selecting appropriate assessment scales and standardizing neurocognitive assessments. The second day of the workshop will discuss identification of signals in animal studies and clinical trials that warrant further clinical investigation and testing that may be predictive of neurocognitive outcome in children. Additionally, strategies and methods to address the challenges of assessing long-term neurocognitive outcomes for products used to treat pediatric patients will be discussed.

Participation in the Public Workshop

Registration: There is no fee to attend the public workshop, but attendees should register in advance. Space is limited, and registration will be on a first-come, first-served basis. Persons interested in attending this workshop must register online at *neurocognitive_workshop@fda.hhs.gov* before March 31, 2015. For those without Internet access, please contact Denise Pica-Branco (see **FOR FURTHER INFORMATION CONTACT**) to register. Onsite registration will not be available.

If you need special accommodations due to a disability, please contact Denise Pica-Branco (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance.

Transcripts: Transcripts of the workshop will be available for review at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and at *http://www.regulations.gov* approximately 30 days after the workshop. A transcript will also be available in either hard copy or on CD–ROM, after submission of a Freedom of Information request. Send written requests to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Send faxed requests to 301–827–9267.

Dated: February 24, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–04376 Filed 3–2–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious 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 Allergy and Infectious Diseases Special Emphasis Panel; Immunobiology of Xenotransplantation (U01, U19).

Date: March 23–24, 2015.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Room 3F100, 5601 Fishers Lane, Rockville, MD 20892, (Telephone Conference Call).

Contact Person: Nancy Vazquez-Maldonado, Ph.D., Scientific Review Officer, Scientific Review Program, DEA/NIAID/NIH/DHHS, 6700B Rockledge Drive, MSC–7616, Bethesda, MD 20892–7616, 301–496–3253, *nvazquez@niaid.nih.gov*.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Mucosal Environment and HIV Prevention (MEHP II (R01)).

Date: March 23–24, 2015.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Room 3C100, 5601 Fishers Lane, Rockville, MD 20892, (Telephone Conference Call).

Contact Person: Kelly Y. Poe, Ph.D., Scientific Review Officer, Scientific Review Program, DEA/NIAID/NIH/DHHS, 5601 Fishers Lane, Rockville, MD 20892, 240–669–5036, *Kelly.poe@nih.gov*.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Innovative Assays to Quantify the Latent HIV Reservoir (R01).

Date: March 26, 2015.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Room 4F100, 5601 Fishers Lane, Rockville, MD 20892.

Contact Person: Jay R Radke, Ph.D., AIDS Review Branch, Scientific Review Program, DEA/NIAID/NIH/DHHS, Room 3G11B, 5601 Fishers Lane, Rockville, MD 20892, 240–669–5046, *jay.radke@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: February 25, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–04328 Filed 3–2–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel; Program Project: Structure/Function studies of Secondary Transporters in a Lipid Environment.

Date: March 23–25, 2015.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Albert Wang, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4146, MSC 7806, Bethesda, MD 20892, 301–435–1016, *wangca@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: AIDS and AIDS Related Research.

Date: March 24–25, 2015.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.