manufacture, preparation, propagation, compounding, or processing of licensed biologic devices. CBER will send invoices for payment of the establishment registration fee to such establishments.

Dated: July 28, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–18907 Filed 7–31–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Heritable Disorders in Newborns and Children; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, codified at 5 U.S.C. App.), notice is hereby given of the following meeting:

Name: Advisory Committee on Heritable Disorders in Newborns and Children

Dates and Times: August 27, 2015, 9 a.m. to 5 p.m.

August 28, 2015, 10 a.m. to 1 p.m.

Place: Webinar and In-Person, National Institutes of Health, 5635 Fishers Lane, Rockville, Maryland 20857

Status: The meeting will be open to the public with attendance limited to space availability. Participants also have the option of viewing the meeting via webinar. Whether attending in-person or via webinar, all participants must register for the meeting. Please register at *https://www.blsmeetings.net/ACHDNCAugust2015.* The registration deadline is Friday, August 14, 2015, 11:59 p.m. Eastern Time.

Purpose: The Advisory Committee on Heritable Disorders in Newborns and Children (Committee), as authorized by Public Health Service Act, Title XI, § 1111 (42 U.S.C. 300b-10), as amended by the Newborn Screening Saves Lives Reauthorization Act of 2014 (Pub. L. 113–240), was established to advise the Secretary of the Department of Health and Human Services about the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. In addition, the Committee's recommendations regarding additional conditions/heritable disorders for screening that have been adopted by the Secretary are included in the Recommended Uniform Screening Panel (RUSP) and constitute part of the comprehensive guidelines supported by the Health Resources and Services Administration. Pursuant to section 2713 of the Public Health Service Act, codified at 42 U.S.C. 300gg–13, non-grandfathered health plans and group and individual health insurance issuers are required to cover evidence-informed care and screenings included in the HRSA-supported comprehensive guidelines without charging a co-payment, co-insurance, or deductible for plan years (in the individual market, policy years) beginning on or after the date that is one year from the Secretary's adoption of the condition for screening.

Agenda: The meeting will include: (1) A final evidence review report on the Adrenoleukodystrophy (ALD) condition nomination for inclusion in the RUSP; (2) a presentation by the Newborn Screening Technical Assistance and Evaluation Program (NewSTEPs) on their activities and the NewSTEPs data repository, a centralized and secure database designed for state newborn screening programs to explore data to meet program needs; (3) updates on the implementation of screening for Severe Combined Immunodeficiency, Critical Congenital Heart Disease, and Pompe Disease; and (4) updates from workgroups focused on cost analysis in newborn screening, newborn screening timeliness, and pilot studies for evidence-based reviews of conditions. Following the final evidence review report on ALD, the Committee also is expected to vote on whether or not to recommend to the Secretary the addition of ALD to the RUSP. Agenda items are subject to change as necessary or appropriate. The agenda, webinar information, Committee Roster, Charter, presentations, and other meeting materials will be located on the Advisory Committee's Web site at *http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders.*

Public Comments: Members of the public may present oral comments and/or submit written comments. Comments are part of the official Committee record. The public comment period is tentatively scheduled for both days of the meeting. Advance registration is required to present oral comments and/or submit written comments. Please register at *https://www.blsmeetings.net/ACHDNCAugust2015.* The registration deadline is Friday, August 14, 2015, 11:59 p.m. Eastern Time. Written comments must be received by the deadline in order to be included in the August meeting briefing book. Written comments should identify the individual's name, address, email, telephone number, professional or business affiliation, type of expertise (*i.e.,* parent, researcher, clinician, public health, etc.), and the topic/subject matter of comments. To ensure that all individuals who have registered to make oral comments can be accommodated, the allocated time may be limited. Individuals who are associated with groups or have similar interests may be requested to combine their comments and present them through a single representative. No audiovisual presentations are permitted. For additional information or questions on public comments, please contact Lisa Vasquez, Maternal and Child Health Bureau, Health Resources and Services Administration; email: *lvasquez@hrsa.gov.*

Contact Person: Anyone interested in obtaining other relevant information should contact Debi Sarkar, Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18W68, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; email: *dsarkar@hrsa.gov.*More information on the Advisory Committee is available at *http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders.*

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2015–18953 Filed 7–31–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel; Member Conflict: HIV Molecular Biology.

Date: August 7, 2015.