response to a safety labeling change notification should be available on the application holder's Web site within 10 calendar days of approval. FDA estimates that approximately 407 application holders will post new labeling one time each year in response to a safety labeling change notification and that the posting of the labeling will take approximately 4 hours to prepare.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Rebuttal statement	42	1	42	6	252

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Type of submission	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Posting approved labeling on application holder's Web site	407	1	407	4	1,628

[1] There are no capital costs or operating and maintenance costs associated with this collect of information.

Dated: August 27, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–21645 Filed 9–1–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Food and Drug Administration/Drug Information Association Oligonucleotide-Based Therapeutics Conference 2015

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration's (FDA's) Center for Drug Evaluation and Research, in cosponsorship with the Drug Information Association (DIA), is announcing a meeting entitled ''FDA/DIA Oligonucleotide-Based Therapeutics Conference 2015'' (FDA/DIA 2015 conference). The purpose of the meeting is to discuss advances, safety, and challenges in the field of oligonucleotide-based therapeutics.

DATES: The meeting will be held on September 9 to September 10, 2015, from 7 a.m. to 5 p.m. and September 11, 2015, from 7 a.m. to 12 noon.

ADDRESSES: The meeting will be held at the Grand Hyatt Washington, 1000 H St. NW., Washington, DC 20001.

FOR FURTHER INFORMATION CONTACT: Meredith Kaganovskiy, Drug Information Association (DIA), 800 Enterprise Rd., Horsham, PA 19044, 215–442–6117, FAX: 215–293–5923, email: *Meredith.kaganovskiy@diaglobal.org;* or Robert T. Dorsam, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), 10903 New Hampshire Ave., Silver Spring, MD 20993–0002; 301–796–1623, email: *robert.dorsam@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Oligonucleotide therapeutics constitute a diverse and evolving class of drug products that are being developed for a wide variety of indications. The FDA/DIA 2015 conference is a forum where regulators, academics, and members of industry will discuss the advances, challenges, and opportunities in the field of oligonucleotide therapeutics. This is the sixth meeting in approximately eight years where attendees will discuss oligonucleotide therapeutics in clinical, nonclinical, and chemistry tracks. The meeting will provide updates on advancements in this field, and will also present time for stakeholders to discuss challenges in the development and regulation of oligonucleotide therapeutics. Topics will be addressed using presentations, panel discussions, case studies, and a poster session to facilitate discipline-specific and multidisciplinary discussions. The goal of the meeting is to provide a current view of oligonucleotide therapeutics and foster advancement in the field through discussions among regulators, academics, and industry members.

II. Registration and Accommodations

A. Registration

There is a registration fee to attend this meeting. The registration fee is charged to help defray the costs of facilities, meeting materials, and food. Seats are limited, and registration will be on a first-come, first-served basis.

To register, please complete registration online at *http://www.diaglobal.org/.* (FDA has verified the Web address, but FDA is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.) The costs of registration for the different categories of attendees are as follows:

Category	Cost
Industry Representatives	$1,350
Charitable Nonprofit/Academic	675
Government	405

B. Accommodations

Attendees are responsible for their own hotel accommodations. Attendees making reservations at the Grand Hyatt Washington are eligible for a reduced rate of $209, not including applicable taxes. This rate is available for a limited number of rooms. To receive the reduced rate, hotel reservations must be made with onPeak and not directly with the hotel. Contact information for onPeak is as follows: Toll free in the United States 1–855–355–0302 or 1–212–532–1660. When calling, please select option 1 for ''Hotel Reservations,'' and inform the phone agent that you are making a reservation for Event #15011.

If you need special accommodations due to a disability, please contact Meredith Kaganovskiy (DIA) or Robert.

T. Dorsam (FDA) (see **FOR FURTHER INFORMATION CONTACT**).

Dated: August 27, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–21639 Filed 9–1–15; 8:45 am]

BILLING CODE 4164–01–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: Healthcare Delivery and Methodologies Integrated Review Group; Health Services Organization and Delivery Study Section.

Date: September 28–29, 2015.

Time: 9:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Wyndham Grand Chicago Riverfront; 71 East Wacker Drive; Chicago, IL 60601.

Contact Person: Jacinta Bronte-Tinkew, Ph.D.; Scientific Review Officer; Center for Scientific Review; National Institutes of Health; 6701 Rockledge Drive, Room 3164, MSC 7770; Bethesda, MD 20892; (301) 806–0009; *brontetinkewjm@csr.nih.gov.*

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Clinical Molecular Imaging and Probe Development.

Date: October 5–6, 2015.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Alexandria Mark Center; 5000 Seminary Road; Alexandria, VA 22311.

Contact Person: David L Williams, Ph.D.; Scientific Review Officer; Center for Scientific Review; National Institutes of Health; 6701 Rockledge Drive, Room 5110, MSC 7854; Bethesda, MD 20892; (301)435–1174; *williamsdl2@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Development and Application of PET and SPECT Imaging Ligands as Biomarkers for Drug Discovery and for Pathophysiological Studies of CNS Disorders (R21/R33).

Date: October 6, 2015.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Alexandria Mark Center; 5000 Seminary Road; Alexandria, VA 22311.

Contact Person: David L Williams, Ph.D.; Scientific Review Officer; Center for Scientific Review; National Institutes of Health; 6701 Rockledge Drive, Room 5110, MSC 7854; Bethesda, MD 20892; (301)435–1174; *williamsdl2@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 27, 2015.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–21705 Filed 9–1–15; 8:45 am]

BILLING CODE 4140–01–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; NIAID Investigator Initiated Program Project Applications (P01).

Date: September 28, 2015.

Time: 10:00 a.m. to 5:00 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: Zhuqing (Charlie) Li, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room # 3G41B, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC9823, Bethesda, MD 20892–9823, (240) 669–5068, *zhuqing.li@nih.gov.*

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Investigator Initiated Program Project Applications (P01).

Date: September 29, 2015.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Room 8F100, 5601 Fishers Lane, Rockville, MD 20892, (Telephone Conference Call).

Contact Person: Thomas F. Conway, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3G51, National Institutes of Health, NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892–9823, 240–507–9685, *thomas.conway@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: August 27, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–21704 Filed 9–1–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Co-Exclusive License: Biomarkers for Acute Ischemic Stroke

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of a co-exclusive patent license to practice the inventions embodied in U.S. Patent Application No. 13/580,571 filed 22 August, 2012 and entitled ''Biomarkers for Acute Ischemic Stroke'' [HHS Ref. No. E–023–2010/0–US–03] to CereDx, Inc., which is located in West Virginia. The patent rights in this invention have been assigned to the United States of America.

The prospective co-exclusive license territory may be worldwide and the field of use may be limited to the use of the diagnostics of ischemic stroke.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before October 2, 2015 will be considered. This notice updates the **Federal Register** Notice published in 80 FR 28633, Tuesday May 19, 2015.