event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview.* (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**).

Comments: FDA is holding this public workshop to obtain information on in vitro diagnostic testing for direct oral anticoagulants. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to the public workshop is November 25, 2015.

Regardless of attendance at the public workshop, interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. 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. In addition, when responding to specific questions as outlined in section II of this document, please identify the question you are addressing. 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.*

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at *http://www.fda.gov.* A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list).

SUPPLEMENTARY INFORMATION:

I. Background

Coagulation is the process of forming a clot to stop bleeding. Blood clotting is initiated by injury to a blood vessel resulting in the exposure of various proteins on the inner surface of the vessels. These proteins trigger the serial activation of coagulation factors that make up the coagulation cascade that culminates in the formation of the insoluble clot.

Although immediate clot formation is critical to prevent severe blood loss, excessive clot formation outside of wound healing obstructs blood flow and poses serious medical consequences. To prevent unwanted coagulation, a number of anticoagulant drugs have been developed. Historically, anticoagulation drug therapy was limited to the administration of non-specific anticoagulants, such as heparin or vitamin K antagonists, that act by inhibiting the coagulation cascade at several points. Although effective, these anticoagulants have numerous drawbacks, such as delayed onset and offset of action, a narrow therapeutic window, and interactions with food and drugs that necessitate frequent monitoring and dose adjustments. Several tests have been cleared for monitoring of patients undergoing vitamin K antagonist therapy.

A new class of DOACs has been developed in the last decade to overcome limitations of traditional anticoagulants. Thus far, FDA has approved four DOACs: PRAXADA (dabigatran), XARELTO (rivaroxiban), ELIQUIS (apixaban), and SAVAYSA (edoxaban). DOAC therapy creates a need for coagulation testing, which in turn poses new challenges.

Currently there are no FDA cleared devices for the characterization of DOAC effects on coagulation. Differences in individual responses to the drugs require laboratories to develop unique testing schemes to assess a patient's coagulation status while on DOAC regimens. Thus, the first aim of this workshop is to discuss the effect of DOACs on traditional coagulation test methods currently on the market and the impact these effects may have on patient management.

We will also examine clinical scenarios that would warrant DOAC testing. Instructions for coagulation monitoring as required for vitamin K antagonists are not specified in DOAC's instructions for use. However, in certain clinical settings assessment of DOAC-induced anticoagulation may be advantageous. The second aim of the workshop will focus on medical conditions that require coagulation testing of patients taking DOACs.

There are a limited number of strategies to assess coagulation in patients taking DOACs. We will review options for quantitative and qualitative determination of the drug effects and discuss problems related to interpretation of results. Also, we will consider the corresponding analytical performance criteria of DOAC testing required to provide reliable and informative test results.

Thus, the Center for Devices and Radiological Health plans to provide an overview of the scientific, clinical, and regulatory challenges that need to be addressed to ultimately support the development of in vitro testing for patients on DOAC regimens that would translate into clinically meaningful results.

II. Topics for Discussion at the Public Workshop

The public workshop seeks to involve industry and academia in addressing analytical performance requirements for the diagnostic assessment of DOACs. Furthermore, the workshop aims to focus on the clinical circumstances under which patients receiving these agents would require testing, including but not limited to, the following topic areas:

1. Overview of the effects of DOACs on traditional coagulation tests;
2. identification of clinical scenarios that necessitate DOAC testing;
3. interpretation of coagulation testing results for patients on DOACs; and
4. considerations for regulatory review of devices assessing the effect of DOACs on coagulation.

Dated: August 20, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–21095 Filed 8–25–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Meeting on American Indian/Alaska Native Lesbian, Gay, Bisexual, and Transgender Health Issues

AGENCY: Indian Health Service.

ACTION: Notice of meeting.

SUMMARY: The Indian Health Service (IHS) is continuing to seek broad public input as it continues efforts to advance and promote the health needs of the American Indian/Alaska Native (AI/AN) Lesbian, Gay, Bisexual, and Transgender (LGBT) community.

DATES: The meeting will be held as shown below:

1. September 11, 2015 from 12:00 p.m. EST to 2:00 p.m. EST.

ADDRESSES: The meeting location is:

1. Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

Written statements may be submitted to Lisa Neel, MPH, Program Coordinator, Office of Clinical and Preventive Services, Indian Health Service, 801 Thompson Avenue, Suite 300, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lisa Neel, MPH, Program Coordinator, Office of Clinical and Preventive Services, Indian Health Service, 801 Thompson Avenue, Suite 300, Rockville, MD 20852, Telephone 301–443–4305. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: The meeting will be open to the public. To facilitate the building security process, those who plan to attend should RSVP to Lisa Neel at *lisa.neel@ihs.gov* or by telephone at 301–443–4305 no later than 5:00 p.m. EST on August 31, 2015. (This is not a toll-free number.) Public attendance will be limited to the space available. Members of the public may make statements during the meeting to the extent time permits and file written statements with the Agency for its consideration. Written statements should be submitted to the address listed above.

Dated: August 19, 2015.

Robert G. McSwain,

Deputy Director, Indian Health Service.

[FR Doc. 2015–21068 Filed 8–25–15; 8:45 am]

BILLING CODE 4165–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; 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 on Deafness and Other Communication Disorders Special Emphasis Panel; Clinical Trial Review.

Date: September 22, 2015.

Time: 11:30 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Shiguang Yang, DVM, Ph.D., Scientific Review Officer, Division of Extramural Activities, NIDCD, NIH, 6001 Executive Blvd., Room 8349, Bethesda, MD 20892, 301–496–8683, *yangshi@nidcd.nih.gov.*

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel—Fellowships—Chemical Senses.

Date: October 1, 2015.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Shiguang Yang, DVM, Ph.D., Scientific Review Officer, Division of Extramural Activities, NIDCD, NIH, 6001 Executive Blvd., Room 8349, Bethesda, MD 20892, 301–496–8683, *yangshi@nidcd.nih.gov.*

Name of Committee: Communication Disorders Review Committee.

Date: October 15–16, 2015.

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

Agenda: To review and evaluate grant applications.

Place: Crowne Plaza Chicago Metro Downtown, 733 West Madison, Chicago, IL 60661.

Contact Person: Eliane Lazar-Wesley, Scientific Review Officer, Division of Extramural Activities, National Institute on Deafness and Other Communication Disorders/NIH, 6001 Executive Blvd., MSC 9670, Bethesda, MD 20892–8401, 301–496–8683, *el6r@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: August 21, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–21142 Filed 8–25–15; 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, Shared Mass Spectrometers.

Date: September 17–18, 2015.

Time: 8:00 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: David R Jollie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4150, MSC 7806, Bethesda, MD 20892, (301) 435–1722, *jollieda@csr.nih.gov.*

Name of Committee: Immunology Integrated Review Group, Transplantation, Tolerance, and Tumor Immunology Study Section.

Date: October 1–2, 2015.

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

Agenda: To review and evaluate grant applications.

Place: Washington Plaza Hotel, 10 Thomas Circle NW., Washington, DC 20005.

Contact Person: Jin Huang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4199, MSC 7812, Bethesda, MD 20892, 301–435–1230, *jh377p@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 21, 2015.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–21152 Filed 8–25–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Frederick National Laboratory Advisory Committee to the National Cancer Institute.