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.

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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:
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.

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

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.