In Vitro Diagnostic Testing for Direct Oral Anticoagulants; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing a public workshop entitled "In Vitro Diagnostic Testing for Direct Oral Anticoagulants". The objective of the workshop is to gain public input and to discuss analytical performance requirements for the diagnostic assessment of direct oral anticoagulants (DOACs) and the clinical circumstances under which patients receiving these agents would require testing. Specifically, this workshop aims to do the following: (1) Evaluate the impact of DOACs on traditional coagulation testing results; (2) identify clinical circumstances where testing of DOACs anticoagulant activity or concentration would be relevant; (3) discuss clinically meaningful interpretation of coagulation testing results for patients on DOACs; and (4) review the regulatory requirements for granting clearance for in vitro diagnostic devices intended for coagulation testing in patients treated with DOACs.

Date and Time: The public workshop will be held on October 26, 2015, from 9 a.m. to 5 p.m.

Location: The public workshop will be held at FDA’s White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public meeting 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/Workplace/WhiteOakCampusInformation/ucm241740.htm.

Contact Person: Claudia Dollins, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66 Rm. 5262, Silver Spring, MD 20993–0002, 301–796–4807, Claudia.Dollins@fda.hhs.gov.

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 4 p.m., October 16, 2015. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the public workshop will be provided beginning at 8 a.m.

Contact for Special Accommodations: If you need special accommodations due to a disability, please contact Susan Monahan, Center for Devices and Radiological Health, Office of Communication and Education, 301–796–5661, susan.monahan@fda.hhs.gov no later than October 9, 2015.

To register for the public workshop, please visit FDA’s Medical Devices News & Events—Workshops & Conferences calendar at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm. (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, email, and telephone number. Those without Internet access should contact Susan Monahan at susan.monahan@fda.hhs.gov.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by October 16, 2015. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after October 20, 2015. If you have never attended a Connect Pro
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.

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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: