Dated: February 10, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2016–03152 Filed 2–16–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0160]

Pilot Program for Tobacco Product Manufacturers; Center for Tobacco Products eSubmissions Portal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Center for Tobacco Products (CTP) in the Food and Drug Administration (FDA) is soliciting applications from regulated tobacco product manufacturers to participate in a voluntary pilot program to help CTP evaluate a potential new portal, the CTP eSubmissions Portal (CTP Portal), that is being designed to improve the process in connection with providing certain regulatory submissions electronically to CTP. CTP plans to accept up to six participants for the pilot program. The pilot program is intended to provide CTP regulatory review staff with an opportunity to evaluate the CTP Portal, including its capability for sending and receiving secure messages and providing information as to the documents submitted to it (for example, receipt date and tracking number).

DATES: Interested parties should submit an electronic application to participate in this pilot program by March 2, 2016. We plan to conduct user testing beginning on or about March 18, 2016. See section III of this document for information on applications for participation.

ADDRESSES: If you are interested in participating in this pilot program, please submit an electronic application to *CTPeSub@fda.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Ann Staten, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. G402, Silver Spring, MD 20993–0002, *ann.staten@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Family Smoking Prevention and Tobacco Control Act of 2009 (Tobacco Control Act) (Pub. L. 111–31) grants FDA important authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. Among its many provisions, the Tobacco Control Act created requirements for tobacco product manufacturers and importers, among others, to submit certain regulatory documents and information to FDA, including, but not limited to, new tobacco product applications, documents relating to certain research activities and research findings, and documents relating to tobacco product ingredients, including harmful and potentially harmful constituents. While certain of these documents must be submitted electronically, for others an electronic format for submission currently is not required but is strongly encouraged to facilitate efficiency and timeliness of data submission and management. Also, in June 2013, CTP announced a workshop to obtain public input on topics related to the potential electronic submission of tobacco product applications and other information and opened a docket for public comment on this topic. (For more information about this workshop, please see ''Electronic Submission of Tobacco Product Applications and Other Information; Public Workshop; Request for Comments'' (78 FR 34393, June 7, 2013).

CTP has reviewed the input received from the comments and other sources and is committed to improving the processes for providing regulatory submissions electronically to FDA. Consequently, CTP is announcing a pilot program to test the functionality of the CTP Portal, an electronic submission and communication tool that should enhance efficiency, communication, and timeliness.

II. Pilot Program Participation

The pilot program to evaluate the CTP Portal is to last approximately 3 months. During the pilot program, CTP staff will be available to answer any questions or concerns that may arise. Pilot program participants will receive training and will be asked to submit regulatory submissions using data provided to them by CTP for testing purposes. Pilot program participants also will be asked to provide written and verbal feedback during their training and after their participation in the pilot program is over. These comments and discussions will assist CTP in its development of the CTP Portal. CTP estimates that each individual participant's involvement should take about 15 hours.

CTP is soliciting applications from regulated tobacco product manufacturers and, in particular, is interested in hearing from small tobacco product manufacturers (STPMs) and tobacco product manufacturers that use an authorized agent.

III. Applications for Participation

Applications to participate in the pilot program should be sent electronically to *CTPeSub@fda.hhs.gov.* Applications should include the following information: Company and contact name; contact phone number; contact email address; and whether you are an STPM. Once applications for participation are received, FDA will contact interested applicants to discuss the pilot program. FDA is seeking a limited number of participants (no more than six) to participate in this pilot program. The pilot program is expected to last approximately 3 months.

Dated: *February 10, 2016.*

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–03145 Filed 2–16–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–4462]

Point of Care Prothrombin Time/ International Normalized Ratio Devices for Monitoring Warfarin Therapy; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Point of Care Prothrombin Time/ International Normalized Ratio Devices for Monitoring Warfarin Therapy.'' The purpose of this workshop is to discuss and receive input from stakeholders regarding approaches to the analytical and clinical validation of point of care (POC) Prothrombin Time/International Normalized Ratio (PT/INR) in vitro diagnostic devices for improved clinical management of warfarin therapy in addition to describing the FDA's process for facilitating the development of safe and effective POC and patient self-testing PT/INR devices. The goal of the workshop is to seek and identify potential solutions to address the scientific and regulatory challenges associated with POC PT/INR devices to ensure safety and effectiveness. The public workshop on ''Point of Care

Prothrombin Time/International Normalized Ratio Devices for Monitoring Warfarin Therapy'' that had been scheduled for January 25, 2016, was postponed due to unanticipated weather conditions and rescheduled for March 18, 2016.

DATES: The public workshop will be held on March 18, 2016, from 8 a.m. to 5 p.m. This public workshop is being rescheduled because of a postponed meeting announced in the **Federal Register** of December 15, 2015 (80 FR 77641), originally scheduled for January 25, 2016. Submit either electronic or written comments on the public workshop by April 18, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–N–4462 for ''Point of Care Prothrombin Time/International Normalized Ratio Devices for Monitoring Warfarin Therapy.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, Rm. 1503 (the Great Room), 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/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

FOR FURTHER INFORMATION CONTACT: Rachel Goehe, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 66, Rm. 5533, Silver Spring, MD 20993, 240–402–6565, email: *Rachel.Goehe@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Warfarin, an oral vitamin K antagonist, is a commonly prescribed anticoagulant drug used to reduce the risk of thromboembolic events. Warfarin inhibits the synthesis of clotting factors II, VII, IX, and X, in addition to the naturally occurring endogenous anticoagulant proteins C and S. The response of individual patients to warfarin is highly variable because of factors such as diet, age, and interaction with other drugs. As a consequence, it is important that warfarin dosage be tailored individually to maintain clinical benefit. The PT test is used to determine a patient's clotting time, which the Clinical and Laboratory Standards Institute defines as the time in seconds required for a fibrin clot to form in a plasma sample after tissue thromboplastin and an optimal amount of calcium chloride have been added to the sample. It is well-recognized that a PT result obtained with one test system cannot be compared to a PT result obtained with another test system because of the variety of thromboplastins used in different test systems. Therefore, PT test results are converted into a standardized unit known as the INR, which was adopted by the World Health Organization with the intent to reduce intersystem variation in test results. The INR result is used to monitor patients' response to warfarin.

POC PT/INR devices offer an alternative to laboratory-based testing and venipuncture, enabling a rapid INR determination from a finger stick sample of whole blood. POC devices can be used in a variety of settings including, but not limited to, physician's office laboratory, anti-coagulation clinic, patient bedside, hospital emergency department, and prescription home use. The purpose of POC PT/INR testing is to monitor warfarin and to provide immediate information to physicians about the patient's anticoagulation

status so that this information can be integrated into appropriate treatment decisions that can improve patient outcomes. POC PT/INR testing is increasingly being viewed as a testing modality with performance expectations similar to that of traditional laboratory testing. From a regulatory standpoint, POC PT/INR devices have been reviewed and cleared for prescription use under appropriate professional supervision or prescription home use (patient self-testing), depending on the claimed intended use. For this workshop, both settings will be open for discussion.

II. Topics for Discussion at the Public Workshop

This public workshop will consist of presentations covering the topics listed in this document. Following the presentations, there will be a moderated panel discussion where participants will be asked to provide their perspectives. The workshop panel discussion will focus on identifying potential solutions to address the scientific and regulatory challenges associated with POC PT/INR devices. In advance of the meeting, FDA plans to post a discussion paper outlining FDA's current thinking on the various topics mentioned in the following list, and invite comment on this from the community.

Topics to be discussed at the public workshop include, but are not limited to, the following:

- Current regulatory process involved with the clearance of POC PT/INR devices.
- Current benefit/risk balance of POC PT/INR devices.
- Technological differences amongst marketed POC PT/INR devices, advantages and limitations of each technology, and comparability of test results obtained using different technologies.
- Challenges associated with correlating results from whole blood POC PT/INR devices to conventional plasma-based laboratory tests.
- Appropriate study design for validation and usability studies from the perspectives of the Agency, manufacturers and end users to help improve our understanding of the accuracy, reliability and safety of POC PT/INR devices.
- Types of quality control and the test system elements assessed by the controls.
- Challenges associated with different sample matrices (venous, fingerstick, arterial).

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., March 10, 2016. 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 7 a.m.

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, email: *Susan.Monahan@fda.hhs.gov* no later than March 4, 2016.

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, address, email, and telephone number. Those without Internet access should contact Susan Monahan (contact for special accommodations) to register. Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. The Webcast link will be available on the workshop Web page after March 10, 2016. 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.) 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, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

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 **ADDRESSES**). 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).

Dated: February 9, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–03153 Filed 2–16–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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 Heart, Lung, and Blood Institute Special Emphasis Panel Career Development Program in Emergency Care Research (K12).

Date: March 10, 2016.

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

Agenda: To review and evaluate grant applications.

Place: Hilton Washington, DC/Rockville 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Stephanie J. Webb, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7196, Bethesda, MD 20892, 301–435–0291, *stephanie.webb@nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel Pathophysiology and Treatment of Bicuspid Aortic Valve Disease.

Date: March 11, 2016.

Time: 9:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn Bethesda, 7301 Waverly Street, Bethesda, MD 20814.

Contact Person: Chang Sook Kim, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7188, Bethesda, MD 20892–7924, 301–435–0287, *carolko@mail.nih.gov.*