**Statutory Authority:** Section 814 of the Native American Programs Act of 1974, as amended.

**Lillian Sparks Robinson,**

*Commissioner, Administration for Native Americans.*

[FR Doc. 2016–03132 Filed 2–16–16; 8:45 am]

**BILLING CODE 4184–34–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2016–N–0001]**

### Science Board to the Food and Drug Administration Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Science Board to the Food and Drug Administration (Science Board).

*General Function of the Committee:* The Science Board provides advice to the Commissioner of Food and Drugs and other appropriate officials on specific, complex scientific and technical issues important to the FDA and its mission, including emerging issues within the scientific community. Additionally, the Science Board provides advice to the Agency on keeping pace with technical and scientific developments including in regulatory science, input into the Agency's research agenda and on upgrading its scientific and research facilities and training opportunities. It will also provide, where requested, expert review of Agency-sponsored intramural and extramural scientific research programs.

*Date and Time:* The meeting will be held on March 1, 2016, from 8:30 a.m. until 5 p.m.

*Location:* FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503, Section A), Silver Spring, MD 20993–0002. For those unable to attend in person, the meeting will also be webcast. The link for the webcast is available at *https://collaboration.fda.gov/scienceboard0316/.* Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

*Contact Person:* Rakesh Raghuwanshi, Office of the Chief Scientist, Office of the Commissioner, Food and Drug Administration, Bldg. 1 Rm. 3309, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–4769, *rakesh.raghuwanshi@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

*Agenda:* The Science Board will hear about and discuss: (1) The role of opioids in pain management; (2) scientific challenges facing FDA in supporting the development of pain medications, including opioids, that have reduced risks of being abused; (3) scientific challenges facing FDA in seeking to understand the real-world use of opioids to treat pain, including the impact of opioids with potentially less risk for abuse; (4) the role that FDA plays as a part of a larger Federal, State, and local response to the challenges of providing appropriate pain treatment while reducing opioid abuse; and (5) postmarket surveillance activities related to opioids. The Science Board will also receive a final report from the Centers of Excellence in Regulatory Science and Innovation Program Evaluation Subcommittee.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 23, 2016. Oral presentations from the public will be scheduled between approximately 3:15 and 4:15 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 23, 2016. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to February 25, 2016.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Mr. Rakesh Raghuwanshi at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

FDA regrets that it was unable to publish this notice 15 days prior to the March 1, 2016, meeting of the Science Board. Because the Agency believes there is some urgency to bring these issues to public discussion and qualified members of the Science Board were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

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]

**BILLING CODE 4164–01–P**

## 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