Dated: February 10, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

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

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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