



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0001]

The Tobacco Products Scientific 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: The Tobacco Products Scientific Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 16, 2014, from 8:30 a.m. to 5 p.m.; on April 17, 2014, from 8:30 a.m. to 5 p.m.; and on April 18, 2014, from 8:30 a.m. to 3 p.m.

Location: Center for Tobacco Products, 9200 Corporate Blvd., Rockville, MD 20850, 1-877-287-1373.

Contact Person Caryn Cohen, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1-877-287-1373 (choose option 5), email: TPSAC@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: On April 16, 2014, the committee will consider scientific issues pertaining to dependence and addiction, including the development of addiction, measurement of dependence and addiction, and concepts concerning the assessment of addiction in the review of product submissions.

On April 17, 2014, the committee will receive information on population modeling in the assessment of tobacco product applications and discuss the ways modeling can inform decisions critical to population health.

On April 18, 2014, the committee will discuss possible approaches for evaluating information on the risks and potential benefits of a proposed modified risk tobacco product to the health of individual tobacco users and to the population as a whole.

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 April 2, 2014. Oral presentations from the public will be scheduled between approximately 1 p.m. and 1:30 p.m. on April 16; between approximately 1 p.m. and

1:30 p.m. on April 17; and between approximately 11:30 a.m. and 12 p.m. on April 18. 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 March 25, 2014. 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 speak by March 24, 2014.

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 physical disabilities or special needs. If you require special accommodations due to a disability, please contact Caryn Cohen 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.

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

Dated: February 18, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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