4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

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: 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 August 16, 2013, from 8:30 a.m. to 3 p.m.

Location: Sheraton Silver Spring Hotel, 8777 Georgia Ave., Silver Spring, MD 20910.

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 August 16, 2013, the Committee will discuss possible approaches for evaluating information on the risks and potential benefits of a proposed modified risk tobacco product (MRTP) to the population as a whole. MRTPs are tobacco products that are sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products. Before an MRTP can be introduced or delivered for introduction into interstate commerce, an order from FDA under section 911(g) (21 U.S.C. 387k(g)) of the Federal Food, Drug, and Cosmetic Act must be in effect with respect to the tobacco product. 21 U.S.C. 387k(a).

In reviewing MRTP applications, among other things, FDA must evaluate the effects of a proposed product on the health of individual tobacco users and the population as a whole, taking into account: (1) The relative health risks to individuals of the MRTP; (2) the increased or decreased likelihood that existing users of tobacco products who would otherwise stop using such products will switch to the MRTP; (3) the increased or decreased likelihood that persons who do not use tobacco products will start using the MRTP; (4) the risks and benefits to persons from the use of the MRTP compared to the use of smoking cessation drug or device products approved by FDA to treat nicotine dependence; and (5) comments, data, and information submitted to FDA by interested persons. 21 U.S.C. 387k(g)(4).

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 August 1, 2013. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon. 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 July 25, 2013. 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 July 26, 2013.

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: June 19, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

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