Tobacco Products Scientific Advisory Committee

Date: April 6, 2017

Time: The meeting will be held on April 6, 2017 from 8:30 a.m. to 5 p.m.

Location:
Tommy Douglas Conference Center
10000 New Hampshire Avenue
Silver Spring, Maryland 20903

Webcast:
Seating for this meeting may be limited, so the public is encouraged to watch the free webcast instead of traveling to the meeting. The link for the webcast will be available approximately 15 minutes prior to the beginning of the meeting each day and can be accessed at http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/default.htm.

Agenda: Under section 910(b)(2) (21 U.S.C. 387j(b)(2)) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA may refer applications for premarket review of new tobacco products (PMTA) to the Tobacco Products Scientific Advisory Committee (Committee). The FD&C Act also provides for mandatory referral of modified risk tobacco product applications (MRTPA) to the Committee under section 911(f)(1). 21 U.S.C. 387k (f)(1). On April 6, 2017, FDA will present information to the Committee on the processes used in review of tobacco product applications, including premarket tobacco, substantial equivalence, and modified risk tobacco product applications. Topics will include the statutory standards applicable to the different types of applications, the scientific basis for review decisions, with a focus on PMTA and MRTPA, and the role of the Committee in the review process.

Meeting Materials: Links to meeting materials will be added as they become available. FDA intends to make the 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 website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and will be posted on FDA's website after the meeting.

Public Participation Information: 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 **March 23, 2017**. Please send 20 paper copies, and one electronic copy, of your submission to:

  Caryn Cohen
  Office of Science
  Center for Tobacco Products
  Food and Drug Administration
  Document Control Center
  Bldg. 71, Rm. G335
  10903 New Hampshire Ave.
  Silver Spring, MD 20993–0002

  Copies must be received by 4 p.m. (Eastern) on March 23, 2017

Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 p.m. on April 6, 2017. 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 15, 2015**.

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 16, 2017.

Contact Information

- Caryn Cohen
  Office of Science
  Center for Tobacco Products
  Food and Drug Administration
  Document Control Center, Bldg. 71, rm. G335
  10903 New Hampshire Ave.
  Silver Spring, MD 20993-0002

  Phone: 1-877-287-1373 (choose Option 5)
  Email: TPSAC@fda.hhs.gov

- 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 Website and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

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/oc/advisory/default.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).