DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA2010N0001]

Tobacco Product Constituents Subcommittee of 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: Tobacco Product Constituents Subcommittee of 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 July 7, 2010, from 8:30 a.m. to 5 p.m. and on July 8, 2010, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, Montgomery Ballroom, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel phone number is 3019778900.

Contact Person: Karen Templeton-Somers, Office of Science, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 18772871373 (choose Option 4), e-mail: TPSAC@fda.hhs.gov or FDA Advisory Committee Information Line, 18007418138 (3014430572 in the Washington, DC area), code 8732110002. Please call the Information Line for up-to-date information on this meeting. 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 and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On July 7 and 8, 2010, the subcommittee will continue discussions, as

needed, from the June 8 and 9, 2010, meeting of this subcommittee. The subcommittee will then receive presentations and discuss the analytic methods and ancillary and normalization standards applicable to the measurement and reporting of harmful or potentially harmful constituents in tobacco products, including smoke constituents. The subcommittee will finalize its proposed list of harmful or potentially harmful constituents, the rational for inclusion of each substance, validated methods for measuring the constituents and the ancillary and normalization standards for the identified constituents for presentation at a future meeting of the Tobacco Products Scientific Advisory Committee.

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 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 June 29, 2010. Oral presentations from the public will be scheduled between approximately 2:45 p.m. and 3:45 p.m. on July 7, 2010. Those desiring to make 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 June 21, 2010. 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 June 22, 2010.

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 Karen Templeton-Somers at least 7 days in advance of the meeting.

 $\ensuremath{\mathsf{FDA}}$ is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at

http://www.fda.gov/Advisory&fxsp0;Committees/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 10, 2010.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

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