DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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 March 30 and 31, 2010, from 8:30 a.m. to 5 p.m.

Location: National Transportation Safety Board (NTSB) Conference Center, 429 L’Enfant Plaza SW., Washington, DC 20594 (at Metro’s L’Enfant Plaza station; parking is limited and public transportation is recommended.)

Contact Person: Cristi Stark, Office of Science, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3992, e-mail: Cristi.Stark@fda.hhs.gov or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 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 March 30, 2010, the Tobacco Products Scientific Advisory Committee will cover the following two topics: (Topic 1) Receive presentations on the background and overview of the FDA Center for Tobacco Products, the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act), and the Tobacco Products Scientific Advisory Committee; and (Topic 2) receive presentations on and discuss the published literature on menthol as it relates to the demographics of users, preferential use by persons initiating tobacco use, the health effects of menthol in cigarettes, the effects of menthol on addiction and cessation, marketing and consumer perceptions about menthol cigarettes, the sensory qualities of menthol cigarettes, and the effects of menthol on how cigarettes are smoked. On March 31, 2010, the Committee will continue the presentations and discussions of topic 2; and also receive preliminary information about topics planned for discussion at future meetings, including an action plan designed to ensure the enforcement of restrictions required by the Tobacco Control Act on the advertising and promotion of menthol and other cigarettes to youth, and the establishment of a list of harmful and potentially harmful tobacco product constituents, including smoke constituents. These discussions are preliminary to the preparation of the Tobacco Products Scientific Advisory Committee’s required report to the Secretary of Health and Human Services regarding the impact of use of menthol in cigarettes on the public’s health. A second meeting of the Tobacco Products Scientific Advisory Committee, focusing on tobacco industry research and documents related to menthol and cigarettes, is planned for summer 2010. 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 March 22, 2010. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10:30 a.m. on March 31, 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 March 12, 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 March 15, 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 Cristi Stark 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).


Joanne Less, Acting Associate Commissioner for Special Medical Programs.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Orthopaedic and Rehabilitation Devices Panel of the Medical Devices 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
VERNON S. WILLIAMS, at 301–796–5966, at least 7 days in advance of 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 views, orally or in writing, on
issues pending before the committee. These views may be submitted in
writing to the contact person on or before March 16, 2010. Oral
presentations from the public will be scheduled at approximately 1 p.m.,
immediately following lunch. Those
inspiring to make formal oral
presentations should notify the contact
person and submit a brief statement of the
general nature of the 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 8, 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 March 9, 2010.

Persons attending FDA’s advisory
committee meetings are advised that the
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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 AnnMarie
Williams, at 301–796–5966, 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/Advisory
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).


Joanne Less,
Acting Associate Commissioner for Special
Medical Programs.
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