DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–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.

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 15, 2010, from 8:30 a.m. to 5 p.m. and on July 16, 2010, from 8 a.m. to 5 p.m.

Location: Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Blvd., Gaithersburg, MD. The hotel phone number is 301–590–0044.

Contact Person: Cristi Stark, Office of Science, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1–877–287–1373 (choose Option 4), e-mail: *TPSAC@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 affect a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice to the public. Therefore, you should always check the agency's Web site and call the advisory committee information line to learn about possible modifications of this meeting's schedule before coming to the meeting.

Agenda: On July 15, 2010, the committee will (1) hear and discuss a presentation on dissolvable tobacco products in order to prepare for the Tobacco Products Scientific Advisory Committee's required report to the Secretary of Health and Human Services regarding the impact of the use of dissolvable tobacco products on the public health; (2) receive updates on upcoming committee business related to menthol, including agency requests for information from industry on menthol cigarettes in order to prepare for 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 health; and (3) hear and discuss industry presentations on menthol in cigarettes as they relate to five topics: Characterization of menthol, clinical effects of menthol, biomarkers of disease risk, marketing data, and population effects. Specific areas of interest identified by the committee for industry presentations include the following:

Characterization of menthol

1. Trends in quantities of menthol present in the cigarette rod and smoke over time for various brands/subbrands of menthol and nonmenthol products as determined by the Cambridge Filter/ISO test method using standard parameters as well as the intense smoking conditions set forth in Canadian regulations.

2. Information regarding the manufacturing of menthol and nonmenthol cigarettes, including (a) the source and type of menthol used, (b) the presence or use of any menthol analogs, and (c) the types of manufacturing processes through which menthol is introduced into the tobacco product, as well as the considerations in selecting a particular method.

3. The threshold (menthol content) at which a product is identified and marketed as a menthol cigarette and how that threshold is established.

4. The rationale for adding menthol to cigarettes not marketed as menthol cigarettes, and the criteria for determining the quantity of menthol to be added.

5. For international brands of menthol cigarettes, the quantities of menthol in both menthol and nonmenthol cigarettes sold internationally, and the factors considered in determining the quantity of menthol to be added.

Clinical effects of menthol

6. Studies of dose-response relationships for the physiologic effects of mentholated tobacco smoke.

7. Mechanistic studies of menthol effects including (a) chemosensory effects of menthol compounds in tobacco smoke, including effects at thermal and trigeminal receptors; (b) the effect of menthol on the neurobiology of tobacco dependence; and (c) the effect of menthol on clinical and behavioral measures.

8. Studies addressing the dosing relationship and the metabolic interactions between nicotine and menthol, including resulting perceptions of nicotine strength and the interaction between menthol delivery and nicotine/tar levels, for both low-menthol and high-menthol products.

9. Information on correlations between menthol content and consumer perceptions regarding (a) taste, (b) nicotine strength, and (c) product harm.

Biomarkers

10. Analyses of laboratory and populations studies using biomarkers to assess the effect of menthol content on disease risk for cigarette smokers, based on cigarette consumption (e.g., cigarettes per day), including data related to menthol among population subgroups.

Marketing data

11. Data on consumer preferences for menthol cigarettes.

12. Consumer perception studies of advertising, packaging, and labeling of menthol cigarettes.

13. Marketing strategies for various brands/subbrands of menthol cigarettes, including strategies targeted to particular demographic groups.

14. Marketing strategies for various brands/subbrands of menthol cigarettes sold internationally.

Population effects

15. Among cigarette smokers, rates of switching from menthol to nonmenthol cigarettes and vice versa.

16. Comparative rates of initiation by youth and young adults with menthol and nonmenthol cigarettes.

17. Comparative rates of cessation for users of menthol and nonmenthol cigarettes.

Information regarding menthol derived from both natural and synthetic sources, as well as menthol analogs and functional equivalents will be important to the committee in evaluating the impact of the use of menthol in cigarettes on the public health. Furthermore, FDA asks that to the extent possible and where relevant, data prepared for the presentations be stratified by gender, race/ethnicity, and age.

On July 16, 2010, the committee will continue discussion on topic 3.

The FDA will work with representatives of the tobacco industry who wish to make presentations to ensure that adequate time, separate from the time slots for the general Open Public Hearing, is provided. Companies interested in making formal presentations to the Committee should respond by June 10, 2010, to *TPSAC@fda.hhs.gov* with the following information: (1) Confirmation of your availability to present at the July 15 and 16, 2010, TPSAC meeting, (2) specific topics for which you have relevant information and which you intend to present during the July 15 and 16, 2010, TPSAC meeting, and (3) whether you

are planning to provide background materials for the committee before the meeting. Each of the five broad categories listed in the *Agenda* portion of this notice will be allotted approximately 1 hour of presentation time during the meeting. Companies with common interest are urged to coordinate their oral presentations.

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 30, 2010. Oral presentations from the public (excluding the tobacco industry) will be scheduled between approximately 9 a.m. and 9:15 a.m. on July 15, 2010, for dissolvable tobacco products, and 12:30 p.m. and 1:30 p.m. on July 16, 2010, for menthol. 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 23, 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).

Dated: May 13, 2010.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2010–11907 Filed 5–18–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Cancer Institute Clinical Trials and Translational Research Advisory Committee.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Cancer Institute Clinical Trials and Translational Research Advisory Committee.

Date: July 14, 2010.

Time: 8 a.m. to 4 p.m.

Agenda: Update on the progress of the implementation of the Clinical Trials Working Group and the Translational Research Working Group reports.

Place: National Institutes of Health, Building 31, 6th Floor, C–Wing, Room 10, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Sheila A. Prindiville, MD, MPH, Director, Coordinating Center for Clinical Trials, Office of the Director, National Cancer Institute, National Institutes of Health, 6120 Executive Blvd., 3rd Floor Suite, Bethesda, MD 20892, 301–451–5048, *prindivs@mail.nih.gov*.

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: May 17, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–12006 Filed 5–18–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental and Craniofacial Research; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel; PAR DE–09–182.

Date: June 15, 2010.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Lynn M. King, PhD, Chief, Scientific Review Branch, National Institute of Dental and Craniofacial Research/NIH, 6701 Democracy Blvd., Bethesda, MD 20892–6402, 301–594–5006, *lynn.king@nih.gov*.