

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0001]

Tobacco Products Scientific Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Tobacco Products Scientific Advisory Committee. This meeting was announced in the *Federal Register* of May 19, 2010 (75 FR 28027). The amendment is being made to reflect a change in the *Agenda* and *Procedure* portions of the document. The *Agenda* portion is changed to cancel Topic 1 regarding dissolvable tobacco products. This portion of the meeting has been cancelled. The *Procedure* portion is changed to a 1-hour open public hearing from 10 a.m. to 11 a.m. on July 16, 2010. There are no other changes.

FOR FURTHER INFORMATION CONTACT:

Cristi Stark, 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.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of May 19, 2010 (75 FR 28027), FDA announced that a meeting of the Tobacco Products Scientific Advisory Committee would be held on July 15 and 16, 2010. On page 28027, in the first column, the *Agenda* portion of the document is changed to read as follows:

Agenda: On July 15, 2010, the committee will: (1) 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 (2) hear and discuss industry presentations on menthol in cigarettes as they relate to the following five topics: Characterization of menthol, clinical effects of menthol, biomarkers of disease risk, marketing data, and population effects.

On page 28027, in the third column, the *Agenda* portion of the document is changed to read as follows:

Agenda: On July 16, 2010, the committee will continue discussion on topic 2.

On page 28028, in the first column, the *Procedure* portion of the document is changed to read as follows:

Procedure: Oral presentations from the public (excluding the tobacco industry) will be scheduled between approximately 10 a.m. and 11 a.m. on July 16, 2010.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: June 22, 2010.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2009-N-0276, FDA-2009-N-0277, FDA-2009-N-0278, and FDA-2009-N-0521]

Termination of Declarations Justifying Emergency Use Authorizations of Certain In Vitro Diagnostic Devices, Antiviral Drugs, and Personal Respiratory Protection Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing this notice, under the Federal Food, Drug, and Cosmetic Act (the act), of the termination of the declarations of emergency justifying Emergency Use Authorizations (EUs) of certain in vitro diagnostic devices, personal respiratory protection devices, and antiviral products that were issued in response to the public health emergency involving 2009 H1N1 Influenza. Advance notice of the termination of the declarations was provided under the act.

DATES: The Authorizations are terminated as of June 23, 2010.

FOR FURTHER INFORMATION CONTACT:

RADM Boris Lushniak, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4140, Silver Spring, MD 20993, 301-796-8510.

SUPPLEMENTARY INFORMATION:

I. Background

On April 26, 2009, the then Acting Secretary of the Department of Health and Human Services (DHHS) determined, under section 564(b)(1)(C) of the act (21 U.S.C. 360bbb-3(b)(1)(C)) that a public health emergency exists involving Swine Influenza A (now known as 2009 H1N1 Influenza) that affects, or has significant potential to affect, national security. The determination was renewed four times: March 26, 2010, December 28, 2009, October 1, 2009, and July 24, 2009. On March 26, 2010, the Secretary of DHHS renewed the declarations justifying the authorization for the emergency use of certain in vitro diagnostic devices, antiviral drugs, and personal respiratory protection devices. For additional background information on the declarations, see the April 2, 2010, renewal notice (75 FR 16810).

For additional background information on the products authorized for emergency use in response to the public health emergency involving 2009 H1N1 Influenza, see the following *Federal Register* notices:

- For certain personal respiratory protection devices: 74 FR 38644, August 4, 2009;
- For certain antiviral drug products: 74 FR 38648, August 4, 2009; 75 FR 20430, April 19, 2010; 74 FR 56640, November 2, 2009; and 75 FR 20437, April 19, 2010; and
- For certain in vitro diagnostic devices: 74 FR 38636, August 4, 2009; 75 FR 20441, April 19, 2010; and 75 FR 35045, June 21, 2010.

II. Advance Notice of Termination

FDA is issuing this notice, under section 564(b)(4) of the act, of the termination of the declarations of emergency justifying EUs of certain in vitro diagnostic devices, personal respiratory protection devices, and antiviral products that were issued in response to the public health emergency involving 2009 H1N1 Influenza. Under section 564(b)(3) of the act, the Commissioner of Food and Drugs provided advance notice of the termination of the declaration of emergency to the EUA requestor for each product authorized for emergency use in response to the public health emergency involving 2009 H1N1 Influenza. The June 21, 2010, letters notifying the EUA requestors of the termination of the declaration of emergency follow: