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.

[FR Doc. 2010–15554 Filed 6–23–10; 11:15 am]

BILLING CODE 4160–01–S

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 (EUAs) 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 EUAs 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:

Thomas R. Frieden, MD, MPH
Director
Centers for Disease Control and Prevention
1600 Clifton Rd., MS D-14
Atlanta, GA 30333

Re: Termination of Declarations of Emergency Justifying Emergency
Use Authorization (EUA) of Certain Antiviral Drugs—Zanamivir, Oseltamivir Phosphate, and Peramivir

Dear Dr. Frieden:

This letter is to provide advance notice of the termination of:

(1) the declaration of emergency that was issued by the then Acting Secretary of the Department of Health and Human Services (HHS) Charles E. Johnson on April 26, 2009, pursuant to section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 360bbb-3, justifying the authorization of the emergency use of certain products from the neuraminidase class of antivirals Oseltamivir Phosphate and Zanamivir; and

(2) the declaration of emergency that was issued by the Secretary of HHS on October 20, 2009, pursuant to section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3, justifying the authorization of the emergency use of the antiviral peramivir.

Both of the declarations described above will terminate when the Public Health Emergency determination for 2009 H1N1 influenza expires on June 23, 2010. Therefore, after June 23, 2010, the EUA authorizing the unapproved uses of zanamivir and oseltamivir phosphate and the use of the unapproved drug peramivir will no longer be in effect. For any patient who began a treatment course of peramivir prior to June 23, 2010, the authorization shall continue to be effective after June 23, 2010, to allow completion of that treatment course, to the extent the patient's attending physician finds continued treatment necessary. 21 U.S.C. § 360bbb-3(f)(2).

The advance notice of termination will be published in the Federal Register, pursuant to section 564(b)(4) of the Act, 21 U.S.C. § 360bbb-3(b)(4).

Sincerely,

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

Thomas R. Frieden, MD, MPH
Director
Centers for Disease Control and Prevention
1600 Clifton Rd., MS D-14
Atlanta, GA 30333

Re: Termination of Declaration of Emergency Justifying the Authorization of Emergency
Use of Certain Personal Respiratory Protection Devices

Dear Dr. Frieden:

This letter is to provide advance notice of the termination of the declaration of emergency that was issued by the then Acting Secretary of the Department of Health and Human Services Charles E. Johnson on April 27, 2009, pursuant to section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 360bbb-3, justifying the authorization of emergency use of certain Personal Respiratory Protection Devices. This declaration of emergency will terminate when the Public Health Emergency determination for 2009 H1N1 influenza expires on June 23, 2010.

Advance notice of termination will be published in the Federal Register, pursuant to section 564(b)(4) of the Act.

Sincerely,

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

With regard to in vitro diagnostic devices, the following letter was sent to each of the listed EUA requestors with respect to the identified devices:

TABLE 1.

EUA Requestor Name and Address	In Vitro Diagnostic Device
Centers for Disease Control and Prevention 1600 Clifton Rd., MS D–14 Atlanta, GA 30333	Swine Influenza Virus Real-time RT-PCR Detection Panel

TABLE 1.—Continued

EUA Requestor Name and Address	In Vitro Diagnostic Device
Centers for Disease Control and Prevention 1600 Clifton Rd., MS D–14 Atlanta, GA 30333	CDC Human Influenza Virus Real-time RT-PCR Detection and Characterization Panel for Respiratory Specimens (NPS, NS, TS, NPS/TS, NA2) and Viral Culture
Cepheid 904 Caribbean Drive Sunnyvale, CA 94089	Cepheid Xpert Flu A Panel
Diagnostic Hybrids, Inc. 1055 East State St., Suite 100 Athens, OH 45701	Diagnostic Hybrids, Inc. D3 Ultra 2009 H1N1 Influenza A Virus ID Kit
DIATHERIX Laboratories, Inc. 601 Genome Way, Suite 4208 Huntsville, AL 35806	Diatherix H1N1-09 Influenza Test
DxNA, LLC 3879 S. River Road, Bldg. A St. George, UT 84790	GeneSTAT 2009 A/H1N1 Influenza Test
Epoch BioSciences 21720 23rd Drive S.E., Suite 150 Bothell, WA 98021	ELITech Molecular Diagnostics 2009-H1N1 Influenza A Virus Real RT-PCR test
Focus Diagnostics, Inc. 11331 Valley View Street Cypress, CA 90630	Focus Diagnostics Influenza A H1N1 (2009) Real-Time RT-PCR IVD device
Focus Diagnostics, Inc. 11331 Valley View Street Cypress, CA 90630	Focus Diagnostics Simplexa Influenza A H1N1 (2009)device
IntelligentMDx 19 Blackstone Street Cambridge, MA 02139	IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay
IQuum, Inc. 700 Nickerson Road Marlborough, MA 01752	Liat Influenza A/2009 H1N1 Assay
Longhorn Vaccines and Diagnostics 3 Bethesda Metro Center, Suite 375 Bethesda, MD 20814	Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay
Prodesse Products Gen-Probe W229 N1870 Westwood Drive Waukesha, WI 53186	Prodesse ProFlu-ST Influenza A Subtyping Assay
QIAGEN 1201 Clopper Road Gaithersburg, MD 20878	*artus*® Inf. A H1N1 2009 LC RT-PCR Kit
Roche Diagnostics GmbH Roche Applied Science Nonnenwald 2 82377 Penzberg / Germany	Roche RealTime ready InfluenzaA/H1N1 Detection Set
TessArae, LLC 46090 Lake Center Plaza, Suite 304 Sterling, VA 20165	TessArray Resequencing Influenza A Microarray Detection Panel
United States Army Medical Material Development Activity 1430 Veterans Drive Ft. Detrick, MD 21702–9232	CDC Swine Influenza Virus Real-time rRT-PCR Detection Panel on JBAIDS
ViraCor Laboratories 1001 NW Technology Drive Lee's Summit, MO 64086	ViraCor 2009 H1N1 Influenza A Real-time RT-PCR Test

LETTER SENT TO EUA IN VITRO DIAGNOSTIC TEST RECIPIENTS:

Re: Termination of Declaration of Emergency Justifying Emergency Use Authorization (EUA) of Certain In Vitro Diagnostic Tests

Dear [Recipient]:

This letter is to provide advance notice of the termination of the above-referenced declaration of emergency that was issued by the then Acting Secretary of the Department of Health and Human Services Charles E. Johnson on April 26, 2009, pursuant to section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 360bbb-3, justifying the EUAs for in vitro diagnostics for detection of 2009 H1N1 influenza virus. The declaration will terminate when the Public Health Emergency determination for 2009 H1N1 influenza expires on June 23, 2010. Therefore, after June 23, 2010, the in vitro diagnostic tests that were authorized by FDA for use by clinical laboratories to detect the 2009 H1N1 virus will no longer be authorized by FDA.

FDA recognizes that there remain a significant number of clinical laboratories that have purchased and are using authorized tests for detection of 2009 H1N1 virus and that these devices will remain in laboratory inventories, within their expiration dates, after the June 23, 2010 EUA termination date. After June 23, 2010, FDA intends to exercise enforcement discretion regarding such devices if they are already within clinical laboratory inventories on or before that date. FDA encourages manufacturers of the authorized 2009 H1N1 virus detection devices to work with FDA to submit the additional information that may be necessary to obtain FDA clearance or approval for their device. FDA is fully prepared and welcomes the opportunity to work with the manufacturer of each of the authorized in vitro diagnostic devices for detection of 2009 H1N1 virus to help facilitate the rapid efficient review of such tests.

Advance notice of termination will be published in the Federal Register, pursuant to section 564(b)(4) of the Act.

Sincerely,

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

Dated: June 22, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–15448 Filed 6–22–10; 4:15 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5375–N–24]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

DATES: *Effective Date:* June 25, 2010.

FOR FURTHER INFORMATION CONTACT: Kathy Ezzell, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7262, Washington, DC 20410; telephone (202) 708–1234; TTY number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with the December 12, 1988, court order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C.), HUD publishes a Notice, on a weekly basis, identifying unutilized, underutilized, excess and surplus Federal buildings and real property that HUD has reviewed for suitability for use to assist the homeless. Today's Notice is for the purpose of announcing that no additional properties have been determined suitable or unsuitable this week.

Dated: June 17, 2010.

Mark R. Johnston,

Deputy Assistant Secretary for Special Needs.

[FR Doc. 2010–15090 Filed 6–24–10; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNVW00000 L16100000.DP0000 LXSS015F0000 241A; 10–08807; MO#4500012011; TAS:14X1109]

Notice of Availability of the Draft Winnemucca District Resource Management Plan and Environmental Impact Statement, Nevada

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969, as amended, and the Federal Land Policy and Management Act of 1976, as amended, the Bureau of Land Management (BLM) has prepared a Draft Resource Management Plan (RMP) and Draft Environmental Impact Statement (EIS) for the Winnemucca District and by this notice is announcing the opening of the comment period.

DATES: To ensure that comments will be considered, the BLM must receive written comments on the Draft RMP/Draft EIS within 90 days following the date the Environmental Protection Agency publishes its notice of the Draft RMP/Draft EIS in the **Federal Register**. The BLM will announce future meetings or hearings and any other public participation activities at least 15 days in advance through public notices, media releases, and/or mailings.

ADDRESSES: You may submit comments related to the Winnemucca District Draft RMP/Draft EIS by any of the following methods:

- *Web site: http://www.blm.gov/nv/st/en/fo/wfo/blm_information/rmp*
- *E-mail: wdrmp@blm.gov.*
- *Fax:* (775) 623–1503
- *Mail:* Bureau of Land Management, Winnemucca District Draft RMP/EIS, 5100 East Winnemucca Boulevard, Winnemucca, Nevada 89445.

Copies of the Winnemucca District Draft RMP/Draft EIS are available in the Winnemucca District Office at the above address or on the following website: *http://www.blm.gov/nv/st/en/fo/wfo/blm_information/rmp*

FOR FURTHER INFORMATION CONTACT: For further information contact Bob Edwards, RMP Team Lead, telephone (775) 623–1597; address 5100 E. Winnemucca Boulevard, Winnemucca, Nevada 89445, e-mail: *Robert_Edwards@nv.blm.gov.*