

**ADDRESSES:** The Fairfax at Embassy Row, 2100 Massachusetts Ave., NW., Washington, DC 20008.

**FOR FURTHER INFORMATION CONTACT:** Lillian A. Sparks, Commissioner, Administration for Native Americans, at 202-401-5590, by e-mail at [Lillian.sparks@acf.hhs.gov](mailto:Lillian.sparks@acf.hhs.gov) or by mail at 370 L'Enfant Promenade, SW., 2 West, Washington, DC 20447.

**SUPPLEMENTARY INFORMATION:** On November 5, 2009, President Obama signed the "Memorandum for the Heads of Executive Departments and Agencies on Tribal Consultation." The President stated that his Administration is committed to regular and meaningful consultation and collaboration with tribal officials in policy decisions that have tribal implications, including, as an initial step, through complete and consistent implementation of Executive Order 13175.

The United States has a unique legal and political relationship with Indian tribal governments, established through and confirmed by the Constitution of the United States, treaties, statutes, executive orders, and judicial decisions. In recognition of that special relationship, pursuant to Executive Order 13175 of November 6, 2000, executive departments and agencies are charged with engaging in regular and meaningful consultation and collaboration with tribal officials in the development of Federal policies that have tribal implications, and are responsible for strengthening the government-to-government relationship between the United States and Indian tribes.

HHS has taken its responsibility to comply with Executive Order 13175 very seriously over the past decade; including the initial implementation of a Department-wide policy on tribal consultation and coordination in 1997, and through multiple evaluations and revisions of that policy, most recently in 2008. Many HHS agencies have already developed their own agency-specific consultation policies that complement the Department-wide efforts.

Since 2005, ACF has been working under the guidance of the HHS policy issued in 2005 and updated in 2008. Due to the various programs administered by ACF and the many requests from tribes for consultation for specific programs, as well as specific program mandates for tribal consultation, ACF has decided to create an ACF tribal consultation policy to help ACF program and regional offices better engage Federally Recognized Indian Tribes in the development or revision of policies, regulations and

proposed legislation that impact American Indians. ACF firmly believes that to create a good policy, ACF needs input from tribes to ensure that ACF is meeting tribal needs and to establish a partnership that can carry into the future.

Testimonies may be submitted no later than September 21, 2010, to: Lillian Sparks, Commissioner, Administration for Native Americans, 370 L'Enfant Promenade, SW., Washington, DC 20447, [anacommissioner@acf.hhs.gov](mailto:anacommissioner@acf.hhs.gov).

ACF assembled a Tribal/Federal Workgroup to develop a draft policy and is asking Tribal Leaders to read the draft policy that will be sent to them in a letter prior to the scheduled consultation date. At the consultation session planned for September 29, 2010, ACF is interested in receiving tribal feedback on the policy and in working with tribal representatives to further refine a policy that meets both ACF and tribal needs, and works towards solidifying the partnership between ACF and tribes.

In addition to the tribal consultation session, ACF will be hosting a tribal resources day to provide information about ACF programs, funding opportunities and tools on how to use ACF funding to create comprehensive community programs. The resources day will take place on September 28, 2010, at the same above address. ACF is encouraging tribes to send their tribal planning officers or comparable employee to attend the tribal resources day.

Dated: August 26, 2010.

**David A. Hansell,**

*Acting Assistant Secretary for Children and Families.*

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**BILLING CODE 4184-34-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0449]

#### Risks and Benefits of Long-Term Use of Nicotine Replacement Therapy Products; Public Workshop; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER) is announcing a scientific workshop to

solicit feedback on the risks and benefits associated with the long-term use of nicotine replacement therapy (NRT) products. NRT products facilitate smoking cessation by ameliorating the symptoms of nicotine withdrawal and are available as approved nonprescription and prescription drugs. No currently-approved NRT product is intended for use beyond 12 weeks to relieve the acute withdrawal symptoms experienced when quitting smoking.

**Date and Time:** The public workshop will be held on October 26 and 27, 2010, from 8:30 a.m. to 5 p.m.

**Location:** The workshop will be held at the Radisson Hotel, Reagan National Airport, 2020 Jefferson Davis Highway, Arlington, VA 22202, 703-920-8600, FAX: 703-920-2840.

**Contacts:** Mary C. Gross, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6178, Silver Spring, MD 20993-0002, 301-796-3519, email: [mary.gross@fda.hhs.gov](mailto:mary.gross@fda.hhs.gov); or Dominic Chiapperino, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 3134, Silver Spring, MD 20993-0002, 301-796-1183, email: [dominic.chiapperino@fda.hhs.gov](mailto:dominic.chiapperino@fda.hhs.gov).

**Registration to Attend the Workshop and Requests to Participate in Open Public Hearing:** If you wish to attend or testify for the open public hearing, please email your registration to [NRTPublicMeeting@fda.hhs.gov](mailto:NRTPublicMeeting@fda.hhs.gov) by October 5, 2010. Those without email access may register by contacting one of the persons listed in the *Contacts* section of the document. Please provide complete contact information for each attendee, including name, title, affiliation, address, email address, and telephone number. Registration is free and will be on a first-come, first-served basis. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization as well as the total number of participants based on space limitations. Registrants will receive confirmation once they have been accepted for the workshop. Onsite registration on the day of the meeting will be based on space availability. If registration reaches maximum capacity, FDA will post a notice closing meeting registration for the workshop at: <http://www.fda.gov/Drugs/NewsEvents/ucm221185.htm>.

An open public hearing will be held between 1:30 p.m. to 2:30 p.m. on October 27, 2010, during which speaker testimony will be accepted. We will try to accommodate all persons who wish to testify, however, the duration of each

speaker's testimony during this open public hearing may be limited by time constraints.

**Comments:** Submit either electronic or written comments by December 27, 2010. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

If you need special accommodations due to a disability, contact Mary Gross or Dominic Chiapperino (see *Contacts*) at least 7 days in advance.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Introduction**

Nicotine is the primary addictive substance in tobacco. NRT products are designed to help people stop smoking by supplying controlled amounts of purified nicotine to replace the nicotine derived from smoking. People who use NRT products instead of cigarettes during an attempt to quit smoking obtain nicotine to ease the symptoms associated with quitting, but significantly reduce their exposure to harmful chemicals present in tobacco products and tobacco smoke. NRT products are available over-the-counter (OTC) and by prescription. The labeling for all NRT products recommends that they be used for a short time only (up to 12 weeks) to relieve the acute withdrawal symptoms experienced when quitting smoking. Prescription NRT products are marketed under the brand name Nicotrol and are available as a nasal spray and oral inhaler. OTC NRT products include skin patches (transdermal nicotine patches, various brand names and generics), chewing gum (Nicorette and generics) and lozenges (Commit, Nicorette, and generics).

FDA will explore the following topics during this public workshop:

- What is known about the long-term safety of nicotine from animal studies?
- What is known about the long-term safety of nicotine from human studies?
- What evidence is there that long-term NRT helps people to sustain abstinence from smoking?
- What evidence is there that long-term NRT helps people to sustain reduced smoking levels?

- What evidence is there that using NRT to maintain reduced levels of smoking, rather than complete abstinence, yields clinical benefits?
- What is known about dependence/addiction to NRT products?
- Does the route of administration/speed of onset influence the addiction potential?
- What factors mitigate against abuse/addiction to NRT products and against initiation of NRT products by people who have never used tobacco products previously?

FDA will post the agenda and additional workshop background material approximately 5 days before the workshop at: <http://www.fda.gov/Drugs/NewsEvents/ucm221185.htm>.

##### **II. Transcripts**

Please be advised that approximately 30 days after the public workshop, a transcript will be available. It will be accessible at <http://www.regulations.gov>, and may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857.

Dated: August 27, 2010.

**David Dorsey,**

*Acting Deputy Commissioner for Policy, Planning and Budget.*

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**BILLING CODE 4160-01-S**

#### **DEPARTMENT OF HOMELAND SECURITY**

##### **Federal Emergency Management Agency**

[Internal Agency Docket No. FEMA-1934-DR; Docket ID FEMA-2010-0002]

##### **Missouri; Amendment No. 1 to Notice of a Major Disaster Declaration**

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of a major disaster declaration for the State of Missouri (FEMA-1934-DR), dated August 17, 2010, and related determinations.

**DATES:** *Effective Date:* August 26, 2010.

**FOR FURTHER INFORMATION CONTACT:** Peggy Miller, Recovery Directorate,

Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-3886.

**SUPPLEMENTARY INFORMATION:** The notice of a major disaster declaration for the State of Missouri is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of August 17, 2010.

Knox, Linn, Marion, Monroe, Pike, Ralls, and Shelby Counties for Public Assistance. The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

**W. Craig Fugate,**

*Administrator, Federal Emergency Management Agency.*

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#### **DEPARTMENT OF HOMELAND SECURITY**

##### **Federal Emergency Management Agency**

[Internal Agency Docket No. FEMA-1912-DR; Docket ID FEMA-2010-0002]

##### **Kentucky; Amendment No. 8 to Notice of a Major Disaster Declaration**

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of a major disaster declaration for the Commonwealth of Kentucky (FEMA-1912-DR), dated May 11, 2010, and related determinations.

**DATES:** *Effective Date:* August 19, 2010.

**FOR FURTHER INFORMATION CONTACT:** Peggy Miller, Recovery Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-3886.

**SUPPLEMENTARY INFORMATION:** The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the