

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.*

[FR Doc. 2010-21894 Filed 9-1-10; 8:45 am]

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#### 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