

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.

[FR Doc. 2010-21994 Filed 9-1-10; 8:45 am]

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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

Administrator, under Executive Order 12148, as amended, Terry L. Quarles, of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of Douglas G. Mayne as Federal Coordinating Officer for this disaster.

(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.

[FR Doc. 2010–21900 Filed 9–1–10; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–1925–DR; Docket ID FEMA–2010–0002]

Kentucky; Amendment No. 5 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–1925–DR), dated July 23, 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 Administrator, under Executive Order 12148, as amended, Terry L. Quarles, of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of Douglas G. Mayne as

Federal Coordinating Officer for this disaster.

(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.

[FR Doc. 2010–21901 Filed 9–1–10; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R1–ES–2010–N133;10120–1113–0000–C4]

Endangered and Threatened Wildlife and Plants; 5-Year Status Reviews for *Lomatium cookii* (Cook's Lomatium) and *Limnanthes floccosa* ssp. *grandiflora* (Large-flowered Woolly Meadowfoam)

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of initiation of reviews; request for information.

SUMMARY: We, the U.S. Fish and Wildlife Service, are initiating 5-year reviews for two plant species in Oregon under the Endangered Species Act of 1973, as amended (Act). We request any new information on these species that may have a bearing on their classification as endangered. Based on the results of our 5-year reviews we will determine whether these species are properly classified under the Act.

DATES: To ensure consideration in our reviews, we are requesting submission of new information no later than November 1, 2010. However, we will continue to accept new information about any listed species at any time.

ADDRESSES: Submit information to: Field Supervisor, Attention: 5-Year Review, U.S. Fish and Wildlife Service, Oregon Fish and Wildlife Office, 2600 SE 98th Avenue, Suite 100, Portland, OR 97266. Information can also be

submitted by e-mail to: fw1or5yearreview@fws.gov.

FOR FURTHER INFORMATION CONTACT: Jeff Dillon, U.S. Fish and Wildlife Service, Oregon Fish and Wildlife Office (*see ADDRESSES*), 503–231–6179. Individuals who are hearing impaired or speech impaired may call the Federal Relay Service at (800) 877–8337 for TTY assistance.

SUPPLEMENTARY INFORMATION:

I. Why do we conduct 5-year reviews?

Under the Act (16 U.S.C. 1531 *et seq.*), we maintain Lists of Endangered and Threatened Wildlife and Plants (which we collectively refer to as the List) in the Code of Federal Regulations (CFR) at 50 CFR 17.11 (for animals) and 17.12 (for plants). Section 4(c)(2)(A) of the Act requires us to review each listed species' status at least once every 5 years. Then, under section 4(c)(2)(B), we determine whether to remove any species from the List (delist), to reclassify it from endangered to threatened, to reclassify it from threatened to endangered, or to conclude that the current listing is appropriate. Any change in Federal classification requires a separate rulemaking process.

We use the following definitions, from 50 CFR 424.02, in our analysis of classification status:

(A) *Species* includes any species or subspecies of fish, wildlife, or plant, and any distinct population segment of any species of vertebrate, that interbreeds when mature;

(B) *Endangered species* means any species that is in danger of extinction throughout all or a significant portion of its range; and

(C) *Threatened species* means any species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.

Our regulations at 50 CFR 424.21 require that we publish a notice in the **Federal Register** announcing the species we are reviewing.

II. What species are under review?

This notice announces our active review of *Lomatium cookii* (Cook's lomatium) and *Limnanthes floccosa* ssp. *grandiflora* (large-flowered woolly meadowfoam). These two plant species occur only in Oregon and were originally listed as endangered on November 7, 2002 (67 FR 68004).

III. What information do we consider in the review?

A 5-year review considers all new information available at the time of the