

have had an inadequate response to or cannot be treated with surgery and/or radiotherapy. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for SOMATULINE DEPOT (U.S. Patent No. 5,595,760) from Soci  t   De Conseils De Recherches Et D'Applications Scientifiques, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 22, 2008, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of SOMATULINE DEPOT represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for SOMATULINE DEPOT is 3,629 days. Of this time, 3,324 days occurred during the testing phase of the regulatory review period, while 305 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective:* September 24, 1997. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on September 24, 1997.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act:* October 30, 2006. FDA has verified the applicant's claim that the new drug application (NDA) for SOMATULINE DEPOT (NDA 22-074) was initially submitted on October 30, 2006.

3. *The date the application was approved:* August 30, 2007. FDA has verified the applicant's claim that NDA 22-074 was approved on August 30, 2007.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 5 years of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a

redetermination by January 16, 2009. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by May 18, 2009. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

Dated: October 20, 2008.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E8-27179 Filed 11-14-08; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA-1795-DR]

Indiana; Amendment No. 7 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 Indiana (FEMA-1795-DR), dated September 23, 2008, and related determinations.

DATES: *Effective Date:* November 7, 2008.

FOR FURTHER INFORMATION CONTACT:

Peggy Miller, Disaster Assistance 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 Indiana 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 September 23, 2008.

LaPorte County for Public Assistance (already designated for Individual Assistance).

Daviess County 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.)

R. David Paulison,

Administrator, Federal Emergency Management Agency.

[FR Doc. E8-27164 Filed 11-14-08; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA-1804-DR]

Arkansas; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Arkansas (FEMA-1804-DR), dated October 22, 2008, and related determinations.

DATES: *Effective Date:* October 22, 2008.

FOR FURTHER INFORMATION CONTACT:

Peggy Miller, Disaster Assistance Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-3886.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated October 22, 2008, the President declared a major disaster under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42

U.S.C. 5121–5207 (the Stafford Act), as follows:

I have determined that the damage in certain areas of the State of Arkansas resulting from Tropical Storm Ike during the period of September 13–23, 2008, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5207 (the Stafford Act). Therefore, I declare that such a major disaster exists in the State of Arkansas.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas, Hazard Mitigation throughout the State, and any other forms of assistance under the Stafford Act that you deem appropriate. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation will be limited to 75 percent of the total eligible costs. Federal funds provided under the Stafford Act for Public Assistance also will be limited to 75 percent of the total eligible costs, except for any particular projects that are eligible for a higher Federal cost-sharing percentage under the FEMA Public Assistance Pilot Program instituted pursuant to 6 U.S.C. 777. If Other Needs Assistance under Section 408 of the Stafford Act is later requested and warranted, Federal funding under that program also will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Kenneth M. Riley, of FEMA is appointed to act as the Federal Coordinating Officer for this declared disaster.

The following areas of the State of Arkansas have been designated as adversely affected by this declared major disaster:

Carroll, Clay, Craighead, Greene, Hempstead, Howard, Izard, Lafayette, Lawrence, Little River, Madison, Miller, Newton, Randolph, Sharp, and Van Buren Counties for Public Assistance.

All counties within the State of Arkansas are eligible to apply for assistance under the Hazard Mitigation Grant Program.

(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.)

R. David Paulison,

Administrator, Federal Emergency Management Agency.

[FR Doc. E8–27142 Filed 11–14–08; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

RIN 1018–AU27

Policy on Wilderness Stewardship

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability.

SUMMARY: We establish policy for implementing the National Wildlife Refuge System Administration Act of 1966, as amended, and the Wilderness Act of 1964 as Part 610 Chapters 1–5 of the Fish and Wildlife Service Manual. In the Wilderness Act, Congress called for the establishment of a National Wilderness Preservation System to secure an “enduring resource of wilderness” for the American public. This policy updates guidance on administrative and public activities on wilderness within the National Wildlife Refuge System (Refuge System).

ADDRESSES: You may download a copy of this policy at: <http://www.fws.gov/refuges/policyMakers/NWRpolicies.html> or request a copy from: National Wildlife Refuge System, U.S. Fish and Wildlife Service, Attn: Nancy Roeper, National Wilderness Coordinator, 4401 North Fairfax Drive, Room 657, Arlington, VA 22203; fax (703) 358–1929.

FOR FURTHER INFORMATION CONTACT:

Nancy Roeper, National Wilderness Coordinator, National Wildlife Refuge System, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, Room 657, Arlington, Virginia 22203 (telephone: 703–358–2389, fax: 703–358–1929).

SUPPLEMENTARY INFORMATION:

We published a draft Wilderness Stewardship policy in the **Federal Register** on January 16, 2001 (66 FR 3708) and invited the public to provide comments on the draft policy by March 19, 2001. During this comment period, we received several requests to extend the comment period. In response to

these requests and in order to ensure that the public had an adequate opportunity to review and comment on the draft policy, we extended the comment period until April 19, 2001 (66 FR 15136). We reopened the comment period from May 15 to June 14, 2001 (66 FR 26879). On June 21, 2001, we again reopened the comment period until June 30, 2001 (66 FR 33268), and corrected the May 15, 2001, notice to reflect that comments received between April 19 and May 15, 2001, would be considered, and need not be resubmitted.

During the 8 years since publication, we made numerous revisions to the draft Wilderness Stewardship policy based on public comments and on internal reviews and discussions by Service managers and staff. We also developed Intergovernmental Personnel Agreements (IPAs) with representatives from five States to facilitate an effective means of involving the State fish and wildlife agencies in the development and implementation of Refuge System policies and guidance, including the Wilderness Stewardship policy. The National Wildlife Refuge System Administration Act of 1966, as amended in 1997 by the Improvement Act (16 U.S.C. 668dd–668ee, as amended) (Administration Act), requires that, in administering the Refuge System, the Fish and Wildlife Service ensure effective coordination, interaction, and cooperation with State fish and wildlife agencies. (State employees under these agreements are on assignment to the Service, serve as Service staff, and are subject to the provisions of law governing the ethical and other conduct of Federal employees.)

This policy is intended to improve the internal management of the Service, and it is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, its Departments, agencies, instrumentalities or entities, its officers or employees, or any other person.

Purpose of This Policy and Authorities

The purpose of this policy is to implement the Administration Act and the Wilderness Act of 1964, within the Refuge System. This policy replaces existing policy found in the Refuge Manual at 6 RM 8.

The Administration Act provides a mission and goals for the Refuge System. As specially designated areas encompassed within the Refuge System, wilderness directly contributes to the fulfillment of the mission and goals by, for example, protecting a diversity of fish, wildlife, plants, and their habitats and providing opportunities for