

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 Society 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**

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## 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]

**BILLING CODE 9111-23-P**

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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