

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. 02E-0019]

Determination of Regulatory Review Period for Purposes of Patent Extension; Axert**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Axert and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Claudia Grillo, Office of Regulatory Policy (HFD-007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3460.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the

actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Axert (almotriptan malate). Axert is indicated for acute treatment of migraine with or without aura in adults. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Axert (U.S. Patent No. 5,565,447) from Almirall Prodesfarma S.A., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 14, 2002, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Axert 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 Axert is 1,348 days. Of this time, 843 days occurred during the testing phase of the regulatory review period, while 505 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(i)) became effective:* August 30, 1997. The applicant claims August 29, 1997, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 30, 1997, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act:* December 20, 1999. FDA has verified the applicant's claim that the new drug application (NDA) for Axert (NDA 20-001) was initially submitted on December 20, 1999.

3. *The date the application was approved:* May 7, 2001. FDA has verified the applicant's claim that NDA 20-001 was approved on May 7, 2001.

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 569 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments and ask for a redetermination by September 16, 2002. 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 January 13, 2003. 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 Dockets Management Branch. Three copies of any 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 22, 2002.

Jane A. Axelrad,

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

[FR Doc. 02-17782 Filed 7-15-02; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF THE INTERIOR**Fish and Wildlife Service****Notice of Intent To Prepare a Comprehensive Conservation Plan and Associated Environmental Impact Statement for Lake Umbagog National Wildlife Refuge****AGENCY:** Fish and Wildlife Service, Department of the Interior.**ACTION:** Notice of Intent.

SUMMARY: This notice advises the public that the U.S. Fish and Wildlife Service (Service) intends to prepare a Comprehensive Conservation Plan (CCP) and associated Environmental Impact Statement (EIS) for Lake Umbagog National Wildlife Refuge (NWR) pursuant to the National Environmental Policy Act and its implementing regulations. Lake Umbagog NWR is located in Coos County, New Hampshire and Oxford

County, Maine. The planning process will also include a Wilderness Review of existing refuge lands, in accordance with the Wilderness Act of 1964, as amended, and Refuge Planning Policy 602 FW Chapters 1, 2, and 3. The Service is furnishing this notice in compliance with the National Wildlife Refuge System Administration Act of 1966, as amended (16 U.S.C. 668dd *et seq.*):

- (1) To advise other agencies and the public of our intentions, and
- (2) to obtain suggestions and information on the scope of issues to include in the environmental documents.

DATES: The Service will hold a series of public scoping meetings early in the planning process to help identify issues of concern and gather comments from the public:

- Tuesday, July 30, 6:30 p.m., Errol Town Hall, Errol, New Hampshire;
- Thursday, Aug. 1, 6:30 p.m., New Hampshire Community Technical College, Berlin, New Hampshire;
- Friday, Aug. 2, 6:30 p.m., Bethel Inn, Bethel, Maine.

Remaining to be scheduled this summer are meetings in Augusta, Maine and Concord, New Hampshire.

Inquire at the address below for dates and locations of future planning activities, or to be added to our mailing list. Further notice announcing times and locations of public meetings, public hearings, and release of a draft CCP and EIS will be published in local news media.

ADDRESSES: Address comments, questions and requests for more information to the following: Refuge Manager, Lake Umbagog National Wildlife Refuge, P.O. Box 240, Errol, New Hampshire 03579, (603) 482-3415, e-mail: fw5rw_lunwr@fws.gov.

SUPPLEMENTARY INFORMATION: By Federal law, all lands within the National Wildlife Refuge System are to be managed in accordance with an approved CCP. The CCP guides management decisions and identifies refuge goals, long-range objectives, and strategies for achieving refuge purposes. It will provide other agencies and the public with a clear understanding of the desired conditions for the refuge and how the Service will implement management strategies. The planning process will evaluate many elements, including habitat and wildlife management, additional land protection and refuge expansion, public use, and cultural resource protection. Public input into this planning process is essential.

The Service will solicit public input via public meetings, workshops, and written comments. Special mailings, newspaper articles, webpages, and announcements will inform people of the time and place of such opportunities for public input to the CCP. Lake Umbagog NWR includes 16,300 acres of fresh water marsh and forest surrounding the 8,500-acre Umbagog Lake on the New Hampshire and Maine border. A draft CCP and EIS is planned for public review in the fall of 2003. You can view the project's Web page at <http://northeast.fws.gov/planning/umbagog.htm>.

Review of these projects will be conducted in accordance with the requirements of the National Environmental Policy Act (NEPA) of 1969, as amended (42 U.S.C. 4321 *et seq.*), NEPA Regulations (40 CFR parts 1500-1508), other appropriate Federal laws and regulations, and Service policies and procedures for compliance with those regulations.

Dated: June 21, 2002.

Richard O. Bennett,

Deputy Regional Director, U.S. Fish and Wildlife Service, Hadley, Massachusetts.

[FR Doc. 02-17758 Filed 7-15-02; 8:45 am]

BILLING CODE 4310-55-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Receipt of Application for Endangered Species Permit

AGENCY: U.S. Fish and Wildlife Service, Interior.

ACTION: Notice of Receipt.

The following applicant has applied for a permit to conduct certain activities with an endangered species. This notice is provided pursuant to section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*):

PRT-TE058917-0

Applicant: U.S. Fish and Wildlife Service, Virginia Field Office

The applicant requests authorization to take (collect and kill) glochidia of two Federally listed endangered freshwater mussels, dwarf wedge mussel (*Alasmidonta heterodon*) from Sullivan County, New Hampshire, and oyster mussel (*Epioblasma capsaeformis*), from Scott County, Virginia and Hancock County, Tennessee. Acute and chronic toxicity tests will be conducted to determine effect levels on imperiled mussels.

Written data or comments should be submitted to the Regional Permits

Coordinator, U.S. Fish and Wildlife Service, 300 Westgate Center Drive, Hadley, Massachusetts 01035 and must be received within 30 days of the date of this publication.

Documents and other information submitted with this application are available for review by any party who submits a written request for a copy of such documents to the following office within 30 days of the date of publication of this notice: U.S. Fish and Wildlife Service, 300 Westgate Center Drive, Hadley, Massachusetts 01035. Attention: Diane Lynch, Regional Permits Coordinator. Telephone: 413-253-8628; Fax: 413-253-8482.

Dated: July 3, 2002.

Richard O. Bennett,

Acting Regional Director.

[FR Doc. 02-17788 Filed 7-15-02; 8:45 am]

BILLING CODE 4310-55-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Public Workshops for the Draft Conservation Strategy for the Tahoe Yellow Cress (*Rorippa subumbellata* Roll.)

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of public workshops.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce that public workshops will be held to introduce the Draft Conservation Strategy for the Tahoe Yellow Cress (*Rorippa subumbellata* Roll.), a candidate species for listing.

DATES: Four public workshops will be held. Two workshops will take place on July 23, 2002, from 2 to 4 p.m. and 5 to 7 p.m.; and two on July 25, 2002, from 2 to 4 p.m. and 5 to 7 p.m.

ADDRESSES: The public workshops on July 23, 2002, will be held at the El Dorado Public Library in the City of South Lake Tahoe, California, and the workshops on July 25, 2002, will be held at the North Tahoe Conference Center in Kings Beach, California. The Draft Conservation Strategy is available for review on the Tahoe Regional Planning Agency's Web site at http://www.trpa.org/tyc/Draft_strategy.html, or hard copies may be requested by writing to the Field Supervisor, U.S. Fish and Wildlife Service, Nevada Fish and Wildlife Office, 1340 Financial Boulevard, Suite 234, Reno, Nevada, 89502. Written comments will be accepted at the workshops or may be