the regulatory review period for Sucralose 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 Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that food additive.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6620.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 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 food additives, the testing phase begins when a major health or environmental effects test involving the food additive begins and runs until the approval phase begins. The approval phase starts with the initial submission of a petition requesting the issuance of a regulation for use of the food additive and continues until FDA grants permission to market the food additive product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner 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 food additive will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(2)(B).

FDA recently approved for marketing the food additive Sucralose (sucralose). Sucralose is used as a nonnutritive sweetener in food where standards of identity do not preclude such use. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Sucralose (U.S. Patent No. 4,435,440) from Tate & Lyle PLC, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 7, 1998, FDA advised the Patent and Trademark Office that this food additive had undergone a regulatory review period and that the approval of Sucralose 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 Sucralose is 5,332 days. Of this time, 1,260 days occurred during the testing phase of the regulatory review period, while 4,072 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date a major health or environmental effects test (''test'') involving this food additive additive product was begun*: August 30, 1983. FDA has verified the applicant's claim that the test was begun on August 30, 1983.

2. *The date the petition requesting the issuance of a regulation for use of the additive (''petition'') was initially submitted with respect to the food additive additive product under section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348)*: February 9, 1987. FDA has verified the applicant's claim that the petition was initially submitted on February 9, 1987.

3. *The date the petition became effective*: April 3, 1998. FDA has verified the applicant's claim that the regulation for the additive became effective on April 3, 1998.

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 730 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before February 19, 1999, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before June 21, 1999, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. 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 (address above) in three copies (except that individuals may submit single copies) and 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: December 4, 1998.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 98–33638 Filed 12–18–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Endangered and Threatened Species Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of applications.

The following applicants have applied for permits to conduct certain activities with 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.*).

Permit Numbers TE006010 and TE006012

Applicant: Dr. Steven J. Taylor, Center for Biodiversity, Illinois Natural History Survey, Champaign, Illinois.

The applicant requests two permits to take (collect) endangered Illinois Cave Amphipod (*Gammarus acherondytes*) in Monroe and St. Clair Counties, Illinois. Research is proposed for scientific purposes to determine environmental threats to extant amphipod populations and to determine components of distribution of the species. Activities are proposed for the purpose of survival and enhancement of the species in the wild.

Permit Number TE006007

Applicant: Dr. Julian Lewis, Clarksville, Indiana.

The applicant requests a permit to take (collect) endangered Illinois Cave Amphipod (*Gammarus acherondytes*) in Monroe and St. Clair Counties, Illinois,

in conjunction with a survey of cave fauna. Survey data will contribute to knowledge of the distribution and abundance of the species in the wild. Activities are proposed for the survival and enhancement of the species in the wild.

Written data or comments should be submitted to the Regional Director, U.S. Fish and Wildlife Service, Ecological Services Operations, 1 Federal Drive, Fort Snelling, Minnesota 55111–4056, 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, Ecological Services Operations, 1 Federal Drive, Fort Snelling, Minnesota 55111–4056. Telephone: (612) 713–5343; FAX: (612) 713–5292.

Dated: December 14, 1998.

Lynn M. Lewis,

Acting Program Assistant Regional Director, Ecological Services, Region 3, Fort Snelling, Minnesota.

[FR Doc. 98–33681 Filed 12–18–98; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Availability of the Draft Comprehensive Conservation Plan and Environmental Assessment for the Alameda National Wildlife Refuge and Notice of Public Meeting to Seek Comments

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of Availability and Notice of Public Meeting.

SUMMARY: This notice advises agencies and the public that the draft Comprehensive Conservation Plan (Plan) and Environmental Assessment (Assessment) for the proposed Alameda National Wildlife Refuge are available for public review and comment. This notice also advises that an open house meeting will be held to solicit public comments on the draft Plan and Assessment.

The purpose of the Comprehensive Management Plan is to guide Refuge management decisions and to identify strategies to meet the goals and objectives of the Alameda Refuge and National Wildlife Refuge System. The Comprehensive Conservation Plan addresses resources protection, management, and restoration; research and monitoring; education and interpretation; public involvement, use, and access; facilities development; and compatibility of uses with the purpose of the refuge.

The Environmental Assessment evaluates the alternatives and analyzes the environmental effects of establishing the Alameda Refuge and of implementing the Comprehensive Conservation Plan. The four alternatives evaluated in the Environmental Assessment provide different levels of wildlife management and public use opportunities. The Environmental Assessment will be used to determine whether the implementation of the selected alternative would have a significant impact upon the quality of the human environment.

DATES: The agency must receive written comments on the Plan and Assessment on or before February 16, 1999. The agency will hold an open house meeting on January 14, 1999, 6:30 p.m. to 9:00 p.m. in Alameda, California.

ADDRESSES: Address written comments to Charles Houghten, Division of Refuge Planning (ARW–RPL), U.S. Fish and Wildlife Service, 911 NE 11th Avenue, Portland, OR 97232–4181. The public open house will be held at the Alameda High School Cafeteria, 2200 Central Avenue between Walnut and Oak Streets in Alameda, California.

See the Supplementary Information Section for the electronic access and filing address.

SUPPLEMENTARY INFORMATION:

Availability of Documents

Individuals who want copies of the draft Comprehensive Conservation Plan for the Alameda National Wildlife Refuge and associated Environmental Assessment should immediately contact the Division of Refuge Planning at the above referenced address or call 800–662–8933. These documents are also available at www.r1.fws.gov/planning/plnhome.html/.

Background Information

The draft Comprehensive Management Plan presents an overview of the Service's proposed management approaches to wildlife and habitats, public uses and wildlife-dependent recreation activities, and facilities. This plan corresponds to Alternative C, the preferred alternative, in the draft Environmental Assessment. The proposed management actions only apply to lands and waters within the National Wildlife Refuge System.

The proposed Refuge would be managed for the conservation and management of native species of wildlife and fish and their habitats. Wildlife species identified as endangered or threatened will receive management priority, with a special emphasis on stewardship of the California least tern nesting colony. Management actions, including expanding the colony, would be taken to assure that the Alameda least tern colony continues to be one of the most successful breeding sites in California. Habitat management will emphasize keeping most of the currently unvegetated areas free of vegetation to deter predators, removing exotic species of plants, and restoring wetland habitat. Predators of least terns will be managed by an integrated program of preventative and selective humane control methods.

Four alternatives for management of wildlife and habitat are analyzed in the draft Environmental Assessment. All alternatives except the no-action alternative would establish a national wildlife refuge of the same size but would differ in the type of management. Alternative A—No Action, Alternative B—Establish a national wildlife refuge with a minimum level of management, Alternative C—Establish a national wildlife refuge and optimize Wildlife Management and Wildlife-Dependent Public Uses (Preferred Alternative), and Alternative D—Establish a national wildlife refuge and maximize public use with moderate wildlife management.

The environmental review of the Comprehensive Conservation Plan and associated Environmental Assessment will be conducted in accordance with the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 *et seq.*), NEPA regulations (40 CFR 1500–1508), National Wildlife Refuge System Administration Act of 1966 as amended by the National Wildlife Refuge System Improvement Act of 1997 (16 U.S. C. 668dd *et seq.*), other appropriate Federal laws and regulations, and Service policies and procedures for compliance with those regulations.

Electronic Access and Filing Address

You may submit comments by sending electronic mail (e-mail) to r1planning__guest@fws.gov (with ''Alameda NWR'' typed in the subject line). If comments are an attached file, submit as an ASCII file, avoiding the use of special characters and any form of encryption.

Dated: December 14, 1998.

Michael J. Spear,

Manager, California/Nevada Operations, Sacramento, California.

[FR Doc. 98–33698 Filed 12–18–98; 8:45 am]

BILLING CODE 4310–55–P