(h) Paying carriers for provided transportation services through use of a Government charge card.

Dated: December 14, 1998.

Allan J. Zaic,

Assistant Commissioner, Office of Transportation and Property Management.

[FR Doc. 98–33687 Filed 12–18–98; 8:45 am]

BILLING CODE 6820–24–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0478]

Determination of Regulatory Review Period for Purposes of Patent Extension; Requip

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Requip 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 human drug product.

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 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 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 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 Requip (ropinirole). Requip is indicated for the treatment of the signs and symptoms of idiopathic Parkinson's disease. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Requip (U.S. Patent No. 4,452,808) from SmithKline Beecham Corp., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated September 9, 1998, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Requip 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 Requip is 3,356 days. Of this time, 2,729 days occurred during the testing phase of the regulatory review period, while 627 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective*: July 14, 1988. The applicant claims July 10, 1988, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 14, 1988, 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 of the act*: January 2, 1996. FDA has verified the applicant's claim that the new drug application (NDA) for Requip (NDA 20–658) was initially submitted on January 2, 1996.

3. *The date the application was approved*: September 19, 1997. FDA has verified the applicant's claim that NDA 20–658 was approved on September 19, 1997.

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 1,826 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. 98–33639 Filed 12–18–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0788]

Determination of Regulatory Review Period for Purposes of Patent Extension; Sucralose

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined

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,