Dated: February 12, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–2794 Filed 2–15–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006E–0236]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (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: Beverly Friedman, Office of Regulatory Policy (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

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 human drug product 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 TYGACIL (tigecycline). TYGACIL is indicated for the treatment of infections caused by susceptible strains of the designated microorganisms in the conditions listed in this paragraph for patients 18 years of age and older: (1) Complicated skin and skin structure infections caused by *Escherichia coli* (*E. coli*), *Enterococcus* (*Entero.*) *faecalis* (vancomycin-susceptible isolates only), *Staphlococcus* (*Staph.*) *aureus* (methicillin-susceptible and -resistant isolates), *Streptococcus* (*Strept.*) *agalactiae*, *Strept. anginosus* group (includes *S. anginosus*, *S. intermedius*, and *S. constellatus*), *Strept. pyogenes* and *Bacteroides* (*B.*) *fragilis*; and (2) complicated intra-abdominal infections caused by *Citrobacter freundii*, *Enterobacter cloacae*, *E. coli*, *Klebsiella* (*K.*) *oxytoca*, *K. pneumoniae*, *Entero. faecaliss* (vancomycin-suspectible isolates only), *Staph. aureus* (methicillin-susceptible isolates only), *Strept. anginosus* group (includes *S. anginosus*, *S. intermedius*, and *S. constellatus*), *B. fragilis*, *B. thetaiotaomicron*, *B. uniformis*, *B. vulgatus*, *Clostridium perfringens*, and *Peptostreptococcus micros*. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for TYGACIL (U.S. Patent No. 5,494,903) from Wyeth Holdings 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 June 14, 2006, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of TYGACIL 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 TYGACIL is 2,487 days. Of this time, 2,304 days occurred during the testing phase of the regulatory review period, while 183 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 26, 1998. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on August 26, 1998.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: December 15, 2004. FDA has verified the applicant's claim that the new drug application (NDA) for TYGACIL (NDA 21–821) was initially submitted on December 15, 2004.

3. *The date the application was approved*: June 15, 2005. FDA has verified the applicant's claim that NDA 21–821 was approved on June 15, 2005.

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 1,335 days 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 April 17, 2007. 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 August 15, 2007. 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.

Dated: February 3, 2007.

Jane A. Axelrad,

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

[FR Doc. E7–2805 Filed 2–15–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[CGD17–07–001]

Prince William Sound Regional Citizens' Advisory Council (PWSRCAC) Charter Renewal

AGENCY: Coast Guard, DHS.

ACTION: Notice of Recertification.

SUMMARY: Under the Oil Terminal and Tanker Environmental Oversight Act of 1990, the Coast Guard may certify on an annual basis, an alternative voluntary advisory group in lieu of a regional citizens' advisory council for Prince William Sound, Alaska. This certification allows the PWSRCAC to monitor the activities of terminal facilities and crude oil tankers under the Prince William Sound Program established by the statute. The purpose of this notice is to inform the public that the Coast Guard has recertified the alternative voluntary advisory group for Prince William Sound, Alaska.

DATES: This recertification is effective for the period from March 1, 2007 through February 28, 2008.

FOR FURTHER INFORMATION CONTACT: You may request a copy of the recertification letter by writing to Commander, Seventeenth Coast Guard District (dpi), by phone at (907)463–2809, or by mail at P.O. Box 25517, Juneau, Alaska 99802.

SUPPLEMENTARY INFORMATION:

Background and Purpose

As part of the Oil Pollution Act of 1990, Congress passed the Oil Terminal and Oil Tanker Environmental Oversight and Monitoring Act of 1990 (the Act), 33 U.S.C. 2732, to foster a long-term partnership among industry, government, and local communities in overseeing compliance with environmental concerns in the operation of crude oil terminals and oil tankers.

On October 18, 1991, the President delegated his authority under 33 U.S.C 2732 (o) to the Secretary of Transportation in Executive Order 12777, section 8(g) (see 56 FR 54757; October 22, 1991) for purposes of certifying advisory councils, or groups, subject to the Act. On March 3, 1992, the Secretary redelegated that authority to the Commandant of the USCG (see 57 FR 8582; March 11, 1992). The Commandant redelegated that authority to the Chief, Office of Marine Safety, Security and Environmental Protection (G–M) on March 19, 1992 (letter #5402).

On July 7, 1993, the USCG published a policy statement, 58 FR 36504, to clarify the factors that shall be considered in making the determination as to whether advisory councils, or groups, should be certified in accordance with the Act.

The Assistant Commandant for Marine Safety and Environmental Protection (G–M), redelegated recertification authority for advisory councils, or groups, to the Commander, Seventeenth Coast Guard District on February 26, 1999 (letter #16450).

On September 16, 2002, the USCG published a policy statement, 67 FR 58440, that changed the recertification procedures such that applicants are required to provide the USCG with comprehensive information every three years (triennially). For each of the two years between the triennial application procedure, applicants submit a letter requesting recertification that includes a description of any substantive changes to the information provided at the previous triennial recertification. Further, public comment is not solicited prior to recertification during streamlined years, only during the triennial comprehensive review.

Recertification

By letter dated January 30, 2007, the Commander, Seventeenth Coast Guard certified that the PWSRCAC qualifies as an alternative voluntary advisory group under 33 U.S.C. 2732(o). This recertification terminates on February 28, 2008.

Dated: January 30, 2007.

Arthur E. Brooks,

Rear Admiral, U.S. Coast Guard, Commander, Seventeenth Coast Guard District.

[FR Doc. E7–2824 Filed 2–15–07; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–48787–N–05]

Final Guidance on Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons: Announcement of Rescheduled Meeting

AGENCY: Office of the Assistant Secretary for Fair Housing and Equal Opportunity, HUD.

ACTION: Notice; Announcement of Rescheduled Meeting.

SUMMARY: On January 25, 2007, HUD announced through **Federal Register** notice a February 13, 2007, meeting to discuss HUD's final guidance on ''Federal Financial Assistance Regarding Title VI Prohibition against National Origin Discrimination Affecting Limited English Proficient Persons'' (LEP Final Guidance). This meeting has been rescheduled for February 28, 2007, and the meeting will run from 3 p.m. to 5 p.m. (which is also a change from the February 13, 2007, meeting time of 2 p.m. to 4 p.m.).

Additionally, HUD's LEP Final Guidance was scheduled to become effective on February 21, 2007. By notice published elsewhere in today's **Federal Register**, the effective date of the guidance is now March 7, 2007.

DATES: HUD will conduct the meeting on LEP Final Guidance on February 28, 2007.

ADDRESS: The LEP Guidance meeting will be held from 3 p.m. to 5 p.m. (Eastern time) on February 28, 2007, at HUD Headquarters for which the address is the Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC. HUD is no longer soliciting participation in the meeting.

FOR FURTHER INFORMATION CONTACT: Pamela D. Walsh, Director, Program Standards and Compliance Division, Office of Fair Housing and Equal Opportunity, Department of Housing and Urban Development 451 Seventh Street, SW., Room 5226, Washington, DC 20410–0500; telephone (202) 402–2288 (this is not a toll-free number). Persons with hearing or speech disabilities may access this number through TTY by calling the toll-free Federal Information Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION