

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 TAPENTADOL HYDROCHLORIDE (tapentadol hydrochloride). TAPENTADOL HYDROCHLORIDE is indicated for the relief of moderate to severe acute pain in patients 18 years of age or older. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for TAPENTADOL HYDROCHLORIDE (U.S. Patent No. RE 39,593) from Grunenthal GmbH, 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 26, 2009, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of TAPENTADOL HYDROCHLORIDE represented the first permitted commercial marketing or use of the product. 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 TAPENTADOL HYDROCHLORIDE is 2,880 days. Of this time, 2,577 days occurred during the testing phase of the regulatory review period, while 303 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:* January 3, 2001. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on January 3, 2001.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act:* January 23, 2008. FDA has verified the applicant's claim that the new drug application (NDA) 22-304 was submitted on January 23, 2008, as the date the NDA for TAPENTADOL HYDROCHLORIDE (NDA 22-304) was initially submitted.

3. *The date the application was approved:* November 20, 2008. FDA has verified the applicant's claim that NDA 22-304 was approved on November 20, 2008.

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 1,492 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 November 2, 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 March 1, 2010. 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: June 8, 2009.

Jane A. Axelrad,

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

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DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Chemical and Petrochemical Inspections, LP, as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Chemical and Petrochemical

Inspections, LP, as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 19 CFR 151.13, Chemical and Petrochemical Inspections, LP, 5300 39th Street, Groves, TX 77619, has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquires regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344-1060. The inquiry may also be sent to cbp.labhq@dhs.gov. Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories.

http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/.

DATES: The accreditation and approval of Chemical and Petrochemical Inspections, LP, as commercial gauger and laboratory became effective on June 02, 2009. The next triennial inspection date will be scheduled for June 2012.

FOR FURTHER INFORMATION CONTACT: Anthony Malana, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202-344-1060.

Dated: August 25, 2009.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

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DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of SGS North America, Inc., as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.