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.

[FR Doc. E9–21100 Filed 8–31–09; 8:45 am]

BILLING CODE 4160–01–S

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.

[FR Doc. E9–21106 Filed 8–31–09; 8:45 am]

BILLING CODE 9111–14–P

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.

ACTION: Notice of accreditation and approval of SGS North America, Inc., as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 19 CFR 151.13, SGS North America, Inc., 614 Heron Drive, Bridgeport, NJ 08014, 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 SGS North America, Inc., as commercial gauger and laboratory became effective on June 10, 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.

[FR Doc. E9–21102 Filed 8–31–09; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: Form N–600K, Extension of a Currently Approved Information Collection; Comment Request

ACTION: 30-Day Notice of Information Collection Under Review: Form N–600K, Application for Citizenship and Issuance of Certificate Under Section 322; OMB Control No. 1615–0087.

The Department of Homeland Security, U.S. Citizenship and Immigration Services (USCIS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on June 11, 2009, at 74 FR 27810, allowing for a 60-day public comment period. USCIS did not receive any comments for this information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until October 1, 2009. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Department of Homeland Security (DHS), and to the Office of Management and Budget (OMB) USCIS Desk Officer. Comments may be submitted to: USCIS, Chief, Regulatory Products Division, Clearance Office, 111 Massachusetts Avenue, Washington, DC 20529–2210. Comments may also be submitted to DHS via facsimile to 202–272–8352 or via e-mail at *rfs.regs@dhs.gov,* and OMB USCIS Desk Officer via facsimile at 202–395–5806 or via *oira_submission@omb.eop.gov.*

When submitting comments by e-mail please make sure to add OMB Control Number 1615–0087 in the subject box. Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a currently approved information collection.

(2) *Title of the Form/Collection:* Application for Citizenship and Issuance of Certificate Under section 322.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form N–600K. U.S. Citizenship and Immigration Services (USCIS).

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary: Individuals or Households.* This form provides an organized framework for establishing the authenticity of an applicant's eligibility and is essential for providing prompt, consistent and correct processing of such applications for citizenship under section 322 of the Act.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 1,500 responses at 1 hour and 35 minutes (1.583 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 2,374 annual burden hours.

If you need a copy of the information collection instrument, please visit the Web site at: *http://www.regulations.gov.*

We may also be contacted at: USCIS, Regulatory Products Division, 111 Massachusetts Avenue, NW., Washington, DC 20529–2210; Telephone 202–272–8377.

Dated: August 26, 2009.

Stephen Tarragon,

Deputy Chief, Regulatory Products Division, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. E9–20992 Filed 8–31–09; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: Form I–865, Extension of a Currently Approved Information Collection; Comment Request

AGENCY: U.S. Citizenship and Immigration Services, DHS.

ACTION: 30-Day Notice of Information Collection under Review: Form I–865,