

the regulatory review period for BEYAZ 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 electronic comments to <http://www.regulations.gov>. Submit written petitions along with three copies and written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6284, Silver Spring, MD 20993-0002, 301-796-3602.

**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 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 BEYAZ (drospirenone, ethinyl estradiol, and levomefolate calcium). BEYAZ is

indicated for use in women to: Prevent pregnancy; treat symptoms of premenstrual dysphoric disorder for women who choose to use an oral contraceptive for contraception; treat moderate acne for women at least 14 years old only if the patient desires an oral contraceptive for birth control; and raise folate levels in women who choose to use an oral contraceptive for contraception. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for BEYAZ (U.S. Patent No. 6,441,168) from Eprova AG, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 28, 2012, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of BEYAZ 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 BEYAZ is 1,271 days. Of this time, 874 days occurred during the testing phase of the regulatory review period, while 397 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 FD&C Act) (21 U.S.C. 355(i)) became effective:* April 4, 2007. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on April 4, 2007.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* August 24, 2009. The applicant claims August 21, 2009, as the date the new drug application (NDA) for BEYAZ (NDA 22-532) was initially submitted. However, FDA records indicate that NDA 22-532 was submitted on August 24, 2009.

3. *The date the application was approved:* September 24, 2010. FDA has verified the applicant's claim that NDA 22-532 was approved on September 24, 2010.

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 834 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**) either electronic or written comments and ask for a redetermination by April 1, 2013. 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 July 30, 2013. 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.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written petitions. It is only necessary to send one set of comments. However, if you submit a written petition, you must submit three copies of the petition. Identify comments with the docket number found in brackets in the heading of this document. Comments and petitions that have not been made publicly available on <http://www.regulations.gov> may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 24, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013-02086 Filed 1-30-13; 8:45 am]

**BILLING CODE 4160-01-P**

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## DEPARTMENT OF HOMELAND SECURITY

### Public Availability of DHS Fiscal Year 2012 Service Contract Inventory

**AGENCY:** Office of the Chief Procurement Officer, DHS.

**ACTION:** Notice of availability.

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**SUMMARY:** In accordance with Section 743 of Division C of the Consolidated Appropriations Act of 2010 (Pub. L. 111-117), the Department of Homeland Security (DHS) is publishing this notice to advise the public of the availability of the FY 2012 Service Contract inventory. This inventory provides information on service contract actions over \$25,000 that were made in FY 2012. The information is organized by function to show how contracted resources are distributed throughout the agency. The inventory has been developed in accordance with guidance issued on November 5, 2010 and

December 19, 2011 available at <http://www.whitehouse.gov/omb/procurement-service-contract-inventories> by the Office of Management and Budget's Office of Federal Procurement Policy (OFPP). The guidance for preparing and analyzing FY 2012 inventories is unchanged from OFPP's November 5, 2010 and December 19, 2011 guidance for preparing the inventories. DHS has posted its FY 2012 inventory for public review at: [http://www.dhs.gov/xopnbiz/regulations/editorial\\_0504.shtm](http://www.dhs.gov/xopnbiz/regulations/editorial_0504.shtm) under "Acquisition Reports and Notices."

**FOR FURTHER INFORMATION CONTACT:** For questions about this notice, please contact Gail Carter at [Gail.A.Carter1@dhs.gov](mailto:Gail.A.Carter1@dhs.gov), or telephone 202-447-5302.

Anne Terry,

Acting Chief Procurement Officer.

[FR Doc. 2013-01674 Filed 1-30-13; 8:45 am]

BILLING CODE 9110-9B-P

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Customs and Border Protection

#### Accreditation and Approval of AmSpec Services, LLC, as a Commercial Gauger and Laboratory

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

**ACTION:** Notice of accreditation and approval of AmSpec Services, LLC, as a commercial gauger and laboratory.

**SUMMARY:** Notice is hereby given, pursuant to CBP regulations, that AmSpec Services, LLC, has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes for the next three years as of August 20, 2012.

**DATES: Effective Dates:** The accreditation and approval of AmSpec Services, LLC, as commercial gauger and laboratory became effective on August 20, 2012. The next triennial inspection date will be scheduled for August 2015.

**FOR FURTHER INFORMATION CONTACT:** Approved Gauger and Accredited Laboratories Manager, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Suite 1500N, Washington, DC 20229, tel. 202-344-1060.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, AmSpec Services, LLC, 1950 East 220th St, Suite #304, Long Beach, CA 90745, 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](mailto: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/linkhandler/cgov/trade/basic\\_trade/labs\\_scientific\\_svcs/commercial\\_gaugers/gaulist.ctt/gaulist.pdf](http://cbp.gov/linkhandler/cgov/trade/basic_trade/labs_scientific_svcs/commercial_gaugers/gaulist.ctt/gaulist.pdf).

Dated: January 23, 2013.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. 2013-02122 Filed 1-30-13; 8:45 am]

BILLING CODE 9111-14-P

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Customs and Border Protection

#### Accreditation and Approval of King Laboratories, 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 King Laboratories, Inc., as a commercial gauger and laboratory.

**SUMMARY:** Notice is hereby given, pursuant to CBP regulation, that King Laboratories, Inc., has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes for the next three years as of June 13, 2012.

**DATES: Effective Dates:** The accreditation and approval of King Laboratories, Inc., as commercial gauger and laboratory became effective on June 13, 2012. The next triennial inspection date will be scheduled for June 2015.

**FOR FURTHER INFORMATION CONTACT:** Approved Gauger and Accredited Laboratories Manager, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania

Avenue NW., Suite 1500N, Washington, DC 20229, tel. 202-344-1060.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, King Laboratories, Inc., 1300 E. 223rd St. #401, Carson, CA 90745, 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](mailto: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/linkhandler/cgov/trade/basic\\_trade/labs\\_scientific\\_svcs/commercial\\_gaugers/gaulist.ctt/gaulist.pdf](http://cbp.gov/linkhandler/cgov/trade/basic_trade/labs_scientific_svcs/commercial_gaugers/gaulist.ctt/gaulist.pdf).

Dated: January 23, 2013.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. 2013-02130 Filed 1-30-13; 8:45 am]

BILLING CODE 9111-14-P

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Customs and Border Protection

#### Accreditation and Approval of Saybolt 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 Saybolt LP, as a commercial gauger and laboratory.

**SUMMARY:** Notice is hereby given, pursuant to CBP regulations, that Saybolt LP, has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes for the next three years as of September 12, 2012.

**DATES: Effective Dates:** The accreditation and approval of Saybolt LP, as commercial gauger and laboratory became effective on September 12, 2012.