Kroll Scientific Testing Laboratories, Inc.)
Baptist Medical Center-Toxicology Laboratory, 9601 I–630, Exit 7, Little Rock, AR 72205–7299. 501–202–2783. (Formerly: Forensic Toxicology Laboratory Baptist Medical Center.)
Clinical Reference Lab, 8433 Quivira Road, Lenexa, KS 66215–2802. 800–445–6917.
Doctors Laboratory, Inc., 2906 Julia Drive, Valdosta, GA 31602. 229–671–2281.
DrugScan, Inc., P.O. Box 2969, 1119 Mearns Road, Warminster, PA 18974. 215–674–9310.
DynaLIFE Dx,* 10150–102 St., Suite 200, Edmonton, Alberta, Canada T5J 5E2. 780–451–3702/800–661–9876. (Formerly: Dynacare Kasper Medical Laboratories.)
ElSohly Laboratories, Inc., 5 Industrial Park Drive, Oxford, MS 38655. 662–236–2609.
Gamma-Dynacare Medical Laboratories,* A Division of the Gamma-Dynacare Laboratory Partnership, 245 Pall Mall Street, London, ONT, Canada N6A 1P4. 519–679–1630.
Laboratory Corporation of America Holdings, 7207 N. Gessner Road, Houston, TX 77040. 713–856–8288/800–800–2387.
Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869. 908–526–2400/800–437–4986. (Formerly: Roche Biomedical Laboratories, Inc.)
Laboratory Corporation of America Holdings, 1904 Alexander Drive, Research Triangle Park, NC 27709. 919–572–6900/800–833–3984. (Formerly: LabCorp Occupational Testing Services, Inc., CompuChem Laboratories, Inc.; CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., A Member of the Roche Group.)
Laboratory Corporation of America Holdings, 1120 Main Street, Southaven, MS 38671. 866–827–8042/800–233–6339. (Formerly: LabCorp Occupational Testing Services, Inc.; MedExpress/National Laboratory Center.)
LabOne, Inc. d/b/a Quest Diagnostics, 10101 Renner Blvd., Lenexa, KS 66219. 913–888–3927/800–873–8845. (Formerly: Quest Diagnostics Incorporated; LabOne, Inc.; Center for Laboratory Services, a Division of LabOne, Inc.)
Maxxam Analytics,* 6740 Campobello Road, Mississauga, ON, Canada L5N 2L8. 905–817–5700. (Formerly: Maxxam Analytics Inc., NOVAMANN (Ontario), Inc.)
MedTox Laboratories, Inc., 402 W. County Road D, St. Paul, MN 55112. 651–636–7466/800–832–3244.
MetroLab-Legacy Laboratory Services, 1225 NE. 2nd Ave., Portland, OR 97232. 503–413–5295/800–950–5295.
Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, MN 55417. 612–725–2088.
National Toxicology Laboratories, Inc., 1100 California Ave., Bakersfield, CA 93304. 661–322–4250/800–350–3515.
One Source Toxicology Laboratory, Inc., 1213 Genoa-Red Bluff, Pasadena, TX 77504. 888–747–3774. (Formerly: University of Texas Medical Branch, Clinical Chemistry Division; UTMB Pathology-Toxicology Laboratory.)
Pacific Toxicology Laboratories, 9348 DeSoto Ave., Chatsworth, CA 91311. 800–328–6942. (Formerly: Centinela Hospital Airport Toxicology Laboratory.)
Pathology Associates Medical Laboratories, 110 West Cliff Dr., Spokane, WA 99204. 509–755–8991/800–541–7891x7.
Phamatech, Inc., 10151 Barnes Canyon Road, San Diego, CA 92121. 858–643–5555.
Quest Diagnostics Incorporated, 1777 Montreal Circle, Tucker, GA 30084. 800–729–6432. (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories.)
Quest Diagnostics Incorporated, 400 Egypt Road, Norristown, PA 19403. 610–631–4600/877–642–2216. (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories.)
Quest Diagnostics Incorporated, 8401 Fallbrook Ave., West Hills, CA 91304. 800–877–2520. (Formerly: SmithKline Beecham Clinical Laboratories.)
S.E.D. Medical Laboratories, 5601 Office Blvd., Albuquerque, NM 87109. 505–727–6300/800–999–5227.
South Bend Medical Foundation, Inc., 530 N. Lafayette Blvd., South Bend, IN 46601. 574–234–4176 x1276.
Southwest Laboratories, 4625 E. Cotton Center Boulevard, Suite 177, Phoenix, AZ 85040. 602–438–8507/800–279–0027.
St. Anthony Hospital Toxicology Laboratory, 1000 N. Lee St., Oklahoma City, OK 73101. 405–272–7052.
STERLING Reference Laboratories, 2617 East L Street, Tacoma, Washington 98421. 800–442–0438.
Toxicology & Drug Monitoring Laboratory, University of Missouri Hospital & Clinics, 301 Business Loop 70 West, Suite 208, Columbia, MO 65203. 573–882–1273.
Toxicology Testing Service, Inc., 5426 NW. 79th Ave., Miami, FL 33166. 305–593–2260.
U.S. Army Forensic Toxicology Drug Testing Laboratory, 2490 Wilson St., Fort George G. Meade, MD 20755–5235. 301–677–7085.

* The Standards Council of Canada (SCC) voted to end its Laboratory Accreditation Program for Substance Abuse (LAPSA) effective May 12, 1998. Laboratories certified through that program were accredited to conduct forensic urine drug testing as required by U.S. Department of Transportation (DOT) regulations. As of that date, the certification of those accredited Canadian laboratories will continue under DOT authority. The responsibility for conducting quarterly performance testing plus periodic on-site inspections of those LAPSA-accredited laboratories was transferred to the U.S. HHS, with the HHS' NLCP contractor continuing to have an active role in the performance testing and laboratory inspection processes. Other Canadian laboratories wishing to be considered for the NLCP may apply directly to the NLCP contractor just as U.S. laboratories do.

Upon finding a Canadian laboratory to be qualified, HHS will recommend that DOT certify the laboratory (**Federal Register**, July 16, 1996) as meeting the minimum standards of the Mandatory Guidelines published in the **Federal Register** on April 13, 2004 (69 FR 19644). After receiving DOT certification, the laboratory will be included in the monthly list of HHS-certified laboratories and participate in the NLCP certification maintenance program.

Dated: June 3, 2010.

Elaine Parry,

Director, Office of Program Services, SAMHSA.

[FR Doc. 2010–13946 Filed 6–9–10; 8:45 am]

BILLING CODE 4160–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–E–0214]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for

PROMACTA 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.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

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 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 PROMACTA (eltrombopag olamine). PROMACTA is indicated the treatment of thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenic purpura who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for PROMACTA (U.S. Patent No. 7,160,870) from SmithKline Beecham Corp. (DBA GlaxoSmithKline), 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 29, 2009, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of PROMACTA 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 PROMACTA is 1,485 days. Of this time, 1,147 days occurred during the testing phase of the regulatory review period, while 338 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*: October 29, 2004. The applicant claims October 28, 2004, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was October 29, 2004, 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(b) of the act*: December 19, 2007. FDA has verified the applicant's claim that the new drug application (NDA) 22–291 was submitted on December 19, 2007.

3. *The date the application was approved*: November 20, 2008. FDA has verified the applicant's claim that NDA 22–291 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 347 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 August 9, 2010. 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 December 7, 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: April 23, 2010.

Jane A. Axelrad,

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

[FR Doc. 2010–13905 Filed 6ndash;9–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0281]

Draft Guidance for Industry and Food and Drug Administration Staff; "'Harmful and Potentially Harmful Constituents' in Tobacco Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act"; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry and FDA staff entitled "'Harmful and Potentially Harmful Constituents' in Tobacco Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act." This draft guidance provides written guidance to industry and FDA staff on certain provisions of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act).

DATES: Although you can comment on any guidance at any time (see 21 CFR