CMS has developed an audit protocol and will post it to the CMS Web site each year for use by POs to prepare for their audit. The data collected for audit is detailed in this protocol and the exact fields are located in the record layout, at the end of the protocol. In addition, a questionnaire will be distributed as part of our audit. This questionnaire is also included in this package. Form Number: CMS–10630 (OMB control number: 0938—New); Frequency: Yearly; Affected Public: Private sector (Business or other for-profits and Not-for-profit institutions); Number of Respondents: 72; Total Annual Responses: 72; Total Annual Hours: 12,960. (For policy questions regarding this collection contact Caroline Zeman at 410–786–0116.)

Dated: November 29, 2016.
William N. Parham, III, Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public docket, see 80 FR 56469, September 18, 2015, or access the information at: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 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, Silver Spring, MD 20993, and 10903 New Hampshire Ave., Bldg. 51, Room 6250, Silver Spring, MD 20993, 10903 New Hampshire Ave., Bldg. 51, Room 1061, Rockville, MD 20852.

SUPPLEMENTARY INFORMATION:
I. Background

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 biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological 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 biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO 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 biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product TRUMENBA (Meningococcal Group B Vaccine). TRUMENBA is indicated for active immunization to prevent invasive disease caused by Neisseria meningitidis serogroup B. Meningococcal Group B Vaccine is approved for use in individuals 10 through 25 years of age. Subsequent to this approval, the USPTO received patent term restoration applications for TRUMENBA (U.S. Patent Nos. 8,101,194 and 8,563,007) from Wyeth Holdings LLC, and the USPTO requested FDA’s assistance in determining the patents’ eligibility for patent term restoration. In a letter dated October 19, 2015, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of TRUMENBA represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product’s regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for TRUMENBA is 2,079 days. Of this time, 1,943 days occurred during the testing phase of the regulatory review period, while 136 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 (21 U.S.C. 355(i)) became effective: February 20, 2009. FDA has verified the applicant’s claim that the date the investigational new drug application became effective was on February 20, 2009.

2. The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262): June 16, 2014. FDA has verified the applicant’s claim that the biologics license application (BLA) for TRUMENBA (BLA 125549/0) was initially submitted on June 16, 2014.

3. The date the application was approved: October 29, 2014. FDA has verified the applicant’s claim that BLA 125549/0 was approved on October 29, 2014.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 255 days or 573 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and ask for a redetermination (see DATES). 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. To meet its burden, the petition must be timely (see DATES) and 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.

Submit petitions electronically to https://www.regulations.gov at Docket No. FDA–2013–S–0610. Submit written petitions [two copies are required] to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.


Leslie Kux,
Associate Commissioner for Policy.

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