Level I and Level II into PACE quality data. Additionally, we are establishing three PACE Quality measures adopted from the National Quality Forum (NQF) and modified for PACE use. These modified PACE quarterly measures are Falls, Falls with Injury, and Pressure Injury Prevalence/Prevention. Currently, the existing Level I and Level II elements have not been tested for reliability or feasibility. By adopting NQF defined reliable data collection process for these elements, certain existing Level I and Level II elements will then officially meet quality measures collection standards. These measures will be used to improve quality of care for participants in PACE. PACE Quality measures will be implemented via the existing HPMS. POs will be educated on data criteria, entry and will report quarterly. *Form Number:* CMS–10525 (OMB control number: 0938–1264); *Frequency:* Quarterly and occasionally; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 100; *Total Annual Responses:* 29,500; *Total Annual Hours:* 211,500. (For policy questions regarding this collection contact Tamika Gladney at 410–786–0648.)

4. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* The PACE Organization (PO) Monitoring and Audit Process in 42 CFR part 460; *Use:* Historically, the Programs of All-Inclusive Care for the Elderly (PACE) audit protocols have been included in the Medicare Advantage (MA) and Medicare Part D audit protocol's information collection request (CMS–10191, OMB 0938–1000). However, in examining previous submissions, we do not believe that including it with the MA and Part D audit protocols allowed for an accurate representation of the PACE burden. Due to PACE audits being substantially different from our MA and Part D audits, we have separated the PACE audit protocols from the MA and Part D protocols and created this information collection request which seeks OMB approval under a new control number.

POs are required to comply with all PACE program requirements. The growth of these PACE organizations forced CMS to develop an audit strategy to ensure we continue to obtain meaningful audit results. As a result, CMS' audit strategy reflected a move to a more targeted, data-driven and outcomes-based audit approach. We focused on high-risk areas that have the greatest potential for participant harm.

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 layouts, 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-profits 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.

[FR Doc. 2016–29007 Filed 12–1–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2015–E–3158; FDA–2015–E–3159]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for TRUMENBA 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 the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by January 31, 2017. 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 May 31, 2017. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket Nos. FDA–2015–E–3158 and FDA–2015–E–3159 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; TRUMENBA.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be

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 dockets, 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, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

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.

Dated: November 23, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–28916 Filed 12–1–16; 8:45 am]

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