research, drug development, and regulatory review. Small population sizes, possible limited scientific understanding of the disease of interest, and a lack of market incentives often preclude more traditional clinical trial or analytical approaches from being pursued. To help collaboratively address these barriers, FDA is working with stakeholders to solicit feedback on promising designs and methodologies for use in the development of rare disease treatments that can form the basis of formal guidance documents.

II. Topics for Discussion at the Public Workshop

During the public workshop, speakers and participants will discuss a range of tools and methods that can be used in the development of treatments for rare diseases and small patient populations. The meeting will include both presentations by panelists and dedicated time for questions and comments from attendees. Topics will include: Master protocols, use of external controls in single-arm trials, analytical tools for trials with multiple or novel endpoints, and best practices for leveraging Bayesian statistics and adaptive study designs.

III. Participating in the Public Workshop

Registration: To register for the public workshop, visit the following website: *https://healthpolicy.duke.edu/events/innovative-tools-and-statistical-methods-treatment-development-rare-disease-settings.* If you are unable to attend the meeting in person, you can register to view a live webcast of the meeting. There will be no onsite registration. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by 5 p.m. EDT on Thursday, March 15, 2018. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization.

If you need special accommodations due to a disability, please contact Sarah Supsiri at the Duke-Margolis Center for Health Policy (phone: 202–791–9561, email: *sarah.supsiri@duke.edu*) no later than March 12, 2018.

Streaming webcast of the public workshop: This public workshop will also be webcast. Archived video footage will also be available at the Duke-Margolis website following the workshop (*https://healthpolicy.duke.edu/events/innovative-tools-and-statistical-methods-treatment-development-rare-disease-settings*). Persons interested in viewing the live webcast must register online before 5 p.m. EDT on March 18, 2018 (see *Registration*). Early registration is recommended because webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location whenever possible. Webcast participants will be sent technical system requirements in advance of the event. Prior to joining the streaming webcast of the public workshop, it is recommended that you review these technical system requirements.

Transcripts: Please be advised that transcripts will not be available.

Other Issues for Consideration: A 1-hour lunch break is scheduled, but food will not be provided. There are multiple restaurants within walking distance of the DoubleTree by Hilton Hotel, 8727 Colesville Rd., Silver Spring, MD 20910.

All event materials will be provided to registered attendees via email prior to the workshop and will be publicly available at the Duke-Margolis Center for Health Policy website (*https://healthpolicy.duke.edu/events/innovative-tools-and-statistical-methods-treatment-development-rare-disease-settings*).

Dated: February 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–02990 Filed 2–13–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–E–2576]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined the regulatory review period for JARDIANCE 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 drug product.

DATES: Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by April 16, 2018. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 16, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of April 16, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date. 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 August 13, 2018. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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 No. FDA–2015–E–2576 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; JARDIANCE.'' Received comments, those filed in a timely manner (see **ADDRESSES**),will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 Dockets Management Staff. 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 § 10.20 (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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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 Dockets Management Staff, 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 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 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 drug 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 drug product JARDIANCE (empagliflozin). JARDIANCE is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Subsequent to this approval, the USPTO received a patent term restoration application for JARDIANCE (U.S. Patent No. 7,579,449) from Boehringer Ingelheim International GmbH, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 15, 2015, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of JARDIANCE 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 JARDIANCE is 2,275 days. Of this time, 1,760 days occurred during the testing phase of the regulatory review period, while 515 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:* May 11, 2008. The applicant claims May 10, 2008, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was May 11, 2008, 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 FD&C Act:* March 5, 2013. FDA has verified the applicant's claim that the new drug application (NDA) for JARDIANCE (NDA 204629) was initially submitted on March 5, 2013.

3. *The date the application was approved:* August 1, 2014. FDA has verified the applicant's claim that NDA 204629 was approved on August 1, 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 1,001 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, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), 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 comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (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 Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: February 8, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–02992 Filed 2–13–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Information Collection Request Title: Health Professions Student Loan (HPSL) Program and Nursing Student Loan (NSL) Program Administrative Requirements (Regulations and Policy). OMB No. 0915-0047-Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than March 16, 2018.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Health Professions Student Loan (HPSL) Program and Nursing Student Loan (NSL) Program Administrative Requirements (Regulations and Policy). OMB No. 0915-0047-Revision.

Abstract: The HPSL Program, as authorized by Public Health Service (PHS) Act Sections 721–722 and 725–735, provides long-term, low-interest loans to students attending schools of medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, podiatric medicine, and pharmacy. The NSL Program, as authorized by PHS Act Sections 835–842, provides long-term, low-interest loans to students who attend eligible schools of nursing in programs leading to a diploma and degrees in nursing, including an associate degree, a baccalaureate degree, or graduate degree in nursing. It also contains a number of recordkeeping and reporting requirements for academic institutions and loan applicants. The applicable regulations for these programs under 42 CFR part 57 implement and detail the various statutory requirements (see chart below). In an effort to consolidate information collection requests and achieve greater programmatic efficiency, HRSA is incorporating the Deferment Form (Deferment-HRSA Form 519) and the Annual Operating Report (AOR–HRSA Form 501) both formerly incorporated under OMB No. 0915–0044, into this information collection request. As a result, the OMB No. 0915–0044 package will be discontinued.

Need and Proposed Use of the Information: Participating HPSL and NSL schools are responsible for determining eligibility of applicants, making loans, and collecting monies owed by borrowers on their outstanding loans. The Deferment Form (Deferment-HRSA Form 519), provides the schools with documentation of a borrower's deferment status, as detailed for the HPSL Program under 42 CFR part 57.210 and for NSL under 42 CFR part 57.310. The Annual Operating Report (AOR–HRSA Form 501), provides HHS with information from participating schools (including schools that are no longer disbursing loans but are required to report and maintain program records, student records, and repayment records until all student loans are repaid in full and all monies due to the Federal Government are returned) relating to HPSL and NSL Program operations and financial activities. Moreover, the HPSL and NSL Program requirements are essential for assuring that borrowers are aware of their rights and responsibilities, academic institutions have accurate records of the history and status of each loan account in order to pursue aggressive collection efforts to reduce default rates, and that academic institutions maintain adequate records for audit and assessment purposes to help HHS safeguard federal funds expended through the Federal Capital Contribution (FCC). Academic institutions are free to use improved information technology to manage the information required by the regulations.

Likely Respondents: Financial Aid Directors working at institutions participating in the HPSL and NSL Programs.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.