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 IBRANCE (palbociclib). IBRANCE is indicated for the treatment of hormone receptor-positive, human epidermal growth factor receptor 2-negative advanced or metastatic breast cancer in combination with:

- An aromatase inhibitor as initial endocrine based therapy in postmenopausal women; or
- fulvestrant in women with disease progression following endocrine therapy.

Subsequent to this approval, the USPTO received patent term restoration applications for IBRANCE (U.S. Patent Nos. 6,936,612 and 7,208,489) from Warner-Lambert Company, LLC, and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated July 12, 2016, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of IBRANCE 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 IBRANCE is 3,954 days. Of this time, 3,779 days occurred during the testing phase of the regulatory review period, while 175 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 (FD&C Act) (21 U.S.C. 355(i)) became effective:* April 9, 2004. FDA has verified the Warner-Lambert Company, LLC, claim that April 9, 2004, is the date the investigational new drug application (IND) became effective.

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 13, 2014. FDA has verified the applicant's claim that the new drug application (NDA) for IBRANCE (NDA 207103) was initially submitted on August 13, 2014.

3. *The date the application was approved:* February 3, 2015. FDA has verified the applicant's claim that NDA 207103 was approved on February 3, 2015.

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 applications for patent extension, this applicant seeks 1,810 days or 1,509 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. 2018–03029 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–2018–N–0001]

Utilizing Innovative Statistical Methods and Trial Designs in Rare Disease Settings; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following 1-day public workshop entitled ''Utilizing Innovative Statistical Methods and Trial Designs in Rare Disease Settings.'' This workshop is convened by the Duke-Robert J. Margolis, MD, Center for Health Policy at Duke University and supported by a cooperative agreement with FDA. The purpose of the public workshop is to bring rare disease stakeholders together to discuss the challenges associated with the development and regulatory decision-making for rare disease treatments and to also discuss promising study designs and analytical methods that can help overcome these challenges.

DATES: The public workshop will be held on March 19, 2018, from 9 a.m. to 5 p.m. Eastern Daylight Time (EDT). See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at the DoubleTree by Hilton Hotel Washington DC-Silver Spring, 8727 Colesville Rd., Silver Spring, MD 20910. For additional travel and hotel information, please refer to the Duke Margolis Center for Health Policy website at: *https://healthpolicy.duke.edu/events/innovative-tools-and-statistical-methods-treatment-development-rare-disease-settings.*

FOR FURTHER INFORMATION CONTACT: Robyn Bent, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–402–2572, *Robyn.Bent@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Rare disease settings pose several significant challenges for clinical

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'').