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, OJJAARA (momelotinib). OJJAARA is indicated for the treatment of intermediate or high-risk myelofibrosis (MF), including primary MF or secondary MF [post-polycythemia vera and post-essential thrombocythemia], in adults with anemia. Subsequent to this approval, the USPTO received patent term restoration applications for OJJAARA (U.S. Patent Nos. 8,486,941 and RE48,285) from GlaxoSmithKline LLC, and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated January 30, 2024, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of OJJAARA 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 OJJAARA is 5,127 days. Of this time, 4,670 days occurred during the testing phase of the regulatory review period, while 457 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:* September 3, 2009. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on September 3, 2009.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* June 16, 2022. FDA has verified the applicant's claim that the new drug application (NDA) for OJJAARA (NDA 216873) was initially submitted on June 16, 2022.

3. *The date the application was approved:* September 15, 2023. FDA has verified the applicant's claim that NDA 216873 was approved on September 15, 2023.

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 828 days or 5 years 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: September 18, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–21844 Filed 9–23–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–E–2584]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for QUVIVIQ 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 (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by November 25, 2024. 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 March 24, 2025. 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. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 25, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–2023–E–2584 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; QUVIVIQ.'' 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, 240–402–7500.

• 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.govinfo.gov/content/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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6200, 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 or biological 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, QUVIVIQ (daridorexant hydrochloride) indicated for the treatment of adult patients with insomnia characterized by difficulties with sleep onset and/or sleep maintenance. Subsequent to this approval, the USPTO received a patent term restoration application for QUVIVIQ (U.S. Patent No. 9,732,075) from Idorsia Pharmaceuticals Ltd. and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated September 28, 2023, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of QUVIVIQ 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 QUVIVIQ is 2,115 days. Of this time, 1,660 days occurred during the testing phase of the regulatory review period, while 455 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: June 24, 2016. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on June 24, 2016.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act: January 8, 2021. FDA has verified the applicant's claim that the new drug application (NDA) for QUVIVIQ (NDA 214985) was initially submitted on January 8, 2021.

3. The date the application was approved or the date of issuance of the interim final rule controlling the drug under section 201(j) of the Controlled Substances Act: April 7, 2022. FDA has verified the applicant's claim that NDA 214985 was approved by FDA on January 7, 2022. However, the Drug Enforcement Agency issued an interim final rule controlling the product under section 201(j) of the Controlled Substances Act on April 7, 2022.

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 1,030 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: September 19, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–21836 Filed 9–23–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Building Interdisciplinary Research Careers in Women's Health (BIRCWH)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The Building Interdisciplinary Research Careers in Women's Health (BIRCWH) is an institutional mentored career-development program designed to connect junior faculty, known as BIRCWH Scholars, to senior faculty mentors with shared interest in women's health and sex differences research. The BIRCWH Annual Meeting is a gathering of senior and junior faculty that provides an opportunity to network and share scientific advances.

DATES: The meeting will be held on October 1, 2024, from 8 a.m. to 5 p.m. EDT.

ADDRESSES: The meeting will be in person; registration is at *https://www.eventbrite.com/e/2024-bircwh-annual-meeting-tickets-893884130497.* The meeting is viewable at *https://videocast.nih.gov/watch=55110.*

FOR FURTHER INFORMATION CONTACT: For information concerning this meeting, visit *https://orwh.od.nih.gov/about/newsroom/events/2024-building-interdisciplinary-research-careers-in-womens-health-bircwh-annual-meeting,* or contact Dr. Marquitta White, Senior Research Program Officer, Careers Section, in the Office of Research on Women's Health (ORWH), 6707 Democracy Boulevard, Suite 400, Bethesda, MD 20817, telephone: 301–402–1770; email: *marquitta.white@nih.gov.*

SUPPLEMENTARY INFORMATION: This notice is in accordance with 42 U.S.C. 287d of the Public Health Service Act, as amended. Created by the ORWH in partnership with NIH Institutes, Centers, and Offices.

This year, the BIRCWH abstracts have been grouped into nine categories with the following number of abstracts, from highest to lowest: Public Health (12), Reproductive Health (10), Sex and Gender Differences (9), Health Disparities (9), Cancer (9), Neuroscience (8), Clinical Research (7), Basic Research (6), and Bioengineering/Bioinformatics (3). The number and quality of abstracts centered on Public Health and Basic Research has increased this year, indicating a growing focus on women's health and the influence of biological sex on health and disease in these important areas. Specifically, several abstracts in these categories focus on maternal morbidity, perinatal health, and how biological sex and gender transition impact health and disease. The meeting will include the 2024 Ruth L. Kirschstein Memorial Lecture by Abbey B. Berenson M.D., MMS, Ph.D., and the 2024 Legacy of Leadership Lecture by Nina F. Schor, M.D., Ph.D.

Individuals interested in in-person attendance can register online at *https://www.eventbrite.com/e/2024-bircwh-annual-meeting-tickets-893884130497.*

More information about the speakers and agenda can be found at *https://orwh.od.nih.gov/about/newsroom/events/2024-building-interdisciplinary-research-careers-in-womens-health-bircwh-annual-meeting.*

This event is free.

Dated: September 16, 2024.

Lawrence A. Tabak,

Principal Deputy Director, National Institutes of Health.

[FR Doc. 2024–21717 Filed 9–23–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; Public Health Service (PHS) Applications and Pre-Award Reporting Requirements (Office of the Director)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Ms. Mikia P. Currie, Program Analyst, Office of Policy for Extramural Research Administration, 6705 Rockledge Drive, Suite 350, Bethesda, Maryland 20892, or call a non-toll-free number 301–435–0941 or email your request, including your address to *ProjectClearanceBranch@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on May 22, 2024, pages 45001–45003 (89 FR 45001) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

The Office of the Director (OD), Office of Extramural Research (OER), National Institutes of Health (NIH), may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid Office of Management and Budget (OMB) control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, NIH has submitted to OMB a request for review and approval of the information collection listed below.

Proposed Collection Title: Public Health Service (PHS) Applications and