Sector, Business or other for profits, Not for profit institutions; *Number of Respondents:* 125; *Total Annual Responses:* 125; *Total Annual Hours:* 166. (For policy questions regarding this collection contact Shevi Marciano at 410–786–2874.)

William N. Parham, III

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–20527 Filed 9–10–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for Office of Management and Budget Review; Children's Bureau Regional Partnership Grants Final Report Outline (NEW)

AGENCY: Children's Bureau, Administration on Children, Youth and Families, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Children's Bureau (CB) is requesting a new collection effort for the Regional Partnership Grant (RPG) program, for the use of a Regional Partnership Grants Final Report Outline to collect cumulative project information. Information from the report will aid grant recipients in meeting grant management requirements as well as to support CB in gathering information on the projects to better monitor the project's use of funds, implementation successes and challenges and program and service effectiveness.

DATES: *Comments due October 11, 2024.* The Office of Management and Budget (OMB) must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register** Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of 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. You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: Information from the proposed collection will aid grant recipients in meeting grant management requirements as well as support CB in gathering information on the projects to monitor the project's use of funds, implementation successes and challenges, and program and service effectiveness. The Regional Partnership Grants Final Report Outline will provide a clear and consistent way for CB to gather information on the projects to better monitor the project's use of funds, implementation successes and challenges and program and service effectiveness.

The Regional Partnership Grants program is in its 7th Round of funding, providing a consistent clear template for the project's final reports will assist CB to ensure appropriate program monitoring and to build the evidence of effective programing and practice for RPG sites and other CB efforts to support families impacted by substance use.

Respondents: Regional Partnership Grants recipients. There are currently two active cohorts (Round 6 and Round 7) of RPG recipients. There are 8 grant recipients in Round 6 and 18 grant recipients in Round 7. Regional Partnership Grants recipients, include state agencies, a judicial court state agency, and community-based organizations (mental health and health care community service providers).

Total Burden Estimates

The Round 6 cohort will complete projects by September 2024, with a Final Report due in fiscal year (FY)25. The Round 7 cohort will continue work through September 2027, with a Final Report due in FY28. There are 8 grant recipients in Round 6 and 18 grant recipients in Round 7. This request includes burden estimates for both cohorts. If needed, the Administration for Children and Families will request an extension to allow for FY28 reporting in 2027. Estimated burden for Round 6 grant recipients is 480 hours in FY 2025. Estimated burden for Round 7 grant recipients is 1080 hours in FY 2028.

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours
Regional Partnership Grants Final Report Outline	RPG Round 6 (FY25 Reporting) ... RPG Round 7 (FY28 Reporting) ...	1 1	60 60	480 1,080
Estimated total burden for both cohorts (FY25–FY28):		.....	.....	1,560

Authority: Title IV, part B, subpart 2-Promoting Safe and Stable Families, Section 437(f) of the Social Security Act (42 U.S.C. 629g(f)).

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–20425 Filed 9–10–24; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–E–0218]

Determination of Regulatory Review Period for Purposes of Patent Extension; VOQUEZNA TRIPLE PAK—New Drug Application 215152

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 VOQUEZNA TRIPLE PAK—new drug application (NDA) 215152 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 12, 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 10, 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 12, 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–2024–E–0218 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; VOQUEZNA TRIPLE PAK—NDA 215152.'' 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, VOQUEZNA TRIPLE PAK—NDA 215152 (vonoprazan tablets/amoxicillin capsules/clarithromycin tablets) indicated for the treatment of *Helicobacter pylori* infection in adults. Subsequent to this approval, the USPTO received a patent term restoration application for VOQUEZNA TRIPLE PAK—NDA 215152 (U.S. Patent No. 7,977,488) from Phathom Pharmaceuticals, Inc. and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated January 24, 2024, FDA advised the USPTO that this human drug product had undergone a regulatory review

period and that the approval of VOQUEZNA TRIPLE PAK—NDA 215152 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 VOQUEZNA TRIPLE PAK—NDA 215152 is 971 days. Of this time, 727 days occurred during the testing phase of the regulatory review period, while 244 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 8, 2019. The applicant claims September 23, 2019, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was September 8, 2019, which was 30 days after FDA receipt of an earlier IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act: September 3, 2021. FDA has verified the applicant's claim that the NDA for VOQUEZNA TRIPLE PAK—NDA 215152 was initially submitted on September 3, 2021.

3. The date the application was approved: May 3, 2022 4:37 p.m. FDA has verified the applicant's claim that NDA 215152 was approved on May 3, 2022 4:37 p.m.

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 599 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 6, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–20552 Filed 9–10–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–E–0218]

Determination of Regulatory Review Period for Purposes of Patent Extension; VOQUEZNA DUAL PAK—New Drug Application 215153

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 VOQUEZNA DUAL PAK—new drug application (NDA) 215153 and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications 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 12, 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 10, 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 12, 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–2024–E–0218 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; VOQUEZNA DUAL PAK—New Drug Application 215153.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for