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, TAZVERIK (tazemetostat). TAZVERIK is indicated for the treatment of adults and pediatric patients aged 16 years and older with metastatic or locally advanced epithelioid sarcoma not eligible for complete resection. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. Subsequent to this approval, the USPTO received a patent term restoration application for TAZVERIK (U.S. Patent No. 8,410,088) from Epizyme, Inc., and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated March 1, 2021, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of TAZVERIK 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 TAZVERIK is 1,618 days. Of this time, 1,372 days occurred during the testing phase of the regulatory review period, while 246 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:* August 21, 2015. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on August 21, 2015.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* May 23, 2019. FDA has verified the applicant's claim that the new drug application (NDA) for TAZVERIK (NDA 211723) was initially submitted on May 23, 2019.

3. *The date the application was approved:* January 23, 2020. FDA has verified the applicant's claim that NDA 211723 was approved on January 23, 2020.

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 650 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: June 22, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–13743 Filed 6–25–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–E–5831]

Determination of Regulatory Review Period for Purposes of Patent Extension; GORE CARDIOFORM ASD OCCLUDER

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined the regulatory review period for GORE CARDIOFORM ASD OCCLUDER 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 medical device.

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 August 27, 2021. 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 December 27, 2021. 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 August 27, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 27, 2021. 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.

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–2019–E–5831 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; GORE CARDIOFORM ASD OCCLUDER.'' 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. 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 medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (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 medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device, GORE CARDIOFORM ASD OCCLUDER. GORE CARDIOFORM ASD OCCLUDER is indicated for the percutaneous, transcatheter closure of the following defects of the atrial septum: Ostium secundum atrial septal defects (ASDs), patent foramen ovale to reduce the risk of recurrent ischemic stroke in patients, predominantly between the ages of 18 and 60 years, who have had a cryptogenic stroke due to a presumed paradoxical embolism, as determined by a neurologist and cardiologist following an evaluation to exclude known causes of ischemic stroke. Subsequent to this approval, the USPTO received a patent term restoration application for GORE CARDIOFORM ASD OCCLUDER (U.S. Patent No. 9,474,517) from W.L. Gore & Associates, Inc., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated January 21, 2020, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of GORE CARDIOFORM ASD OCCLUDER 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 GORE CARDIOFORM ASD OCCLUDER is 931 days. Of this time, 751 days occurred during the testing phase of the regulatory review period, while 180

days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption for this device, under section 520(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(g)), became effective:* November 10, 2016. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) for human tests to begin, as required under section 520(g) of the FD&C Act, became effective November 10, 2016.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* November 30, 2018. FDA has verified the applicant's claim that the premarket approval application (PMA) for GORE CARDIOFORM ASD OCCLUDER (PMA 050006 S071) was initially submitted November 30, 2018.

3. *The date the application was approved:* May 28, 2019. FDA has verified the applicant's claim that PMA 050006 S071 was approved on May 28, 2019.

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 556 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: June 22, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–13687 Filed 6–25–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0281]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before August 27, 2021.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 795–7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–0281–60D and project title for reference, to Sherrette A. Funn, email: *Sherrette.Funn@hhs.gov,* or call (202) 795–7714 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Prevention Communication Formative Research.

Type of Collection: Revision.

OMB No.: 0990–0281.

Abstract: The Office of Disease Prevention and Health Promotion (ODPHP) is focused on developing and disseminating health information to the public. ODPHP faces an increasingly urgent interest in finding effective ways to communicate health information to America's diverse population. ODPHP strives to be responsive to the needs of America's diverse audiences while simultaneously serving all Americans across a range of channels, from print to new communication technologies. To carry out prevention information efforts, ODPHP is committed to conducting formative and usability research to provide guidance on the development and implementation of their communication and education efforts. The information collected will be used to improve communication, products, and services that support key office activities including: Healthy People, Dietary Guidelines for Americans, Physical Activity Guidelines for Americans, the Move Your Way Campaign and the President's Council on Sports, Fitness & Nutrition. ODPHP communicates through its website (*www.health.gov*) and through other channels including social media, print materials, interactive training modules, and reports. Data collection will be qualitative and quantitative and may include in-depth interviews, focus groups, web-based surveys, omnibus surveys, card sorting, and various forms of usability testing of materials and interactive tools to assess the public's understanding of disease prevention and health promotion content, responses to prototype materials, and barriers to effective use.

The program is requesting a 3-year extension of the clearance.

ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
In-depth interviews—Screener	1,500	1	10/60	250
In-depth interviews—Instrument	500	1	1.00	500
Focus groups—Screener	2,925	1	10/60	487.5