programs (TBI State Partnership Grant program and the TBI Protection and Advocacy program) and reconsider which operating division should lead them. With avid support from TBI stakeholders, the Secretary found that the goals of the federal TBI programs closely align with ACL's mission to advance policy and implement programs that support the rights of older Americans and people with disabilities to live in their communities. As a result, on Oct. 1, 2015, the federal TBI programs moved from the Health Resources and Services Administration to ACL. These programs were reauthorized again by the Traumatic Brain Injury Reauthorization Act of 2018 (Pub. L. 115–377).

The proposed performance progress reporting (PPR) tool is consistent with both the TBI State Partnership Program's purpose and also ACL's mission. The 2010 Government Performance Results Modernization Act requires federal agencies to develop annual and long-term performance outcome measures and to report on these measures annually. ACL sees the GPRA Modernization Act as an opportunity to document annually the results that are produced through the programs it administers under the authority for the TBI State Partnership Program.

It is the intent and commitment of ACL, in concert with grantees, to use the performance progress reporting tool of GPRAMA to continuously improve its programs and services.

The TBI State Partnership Program grantees have been submitting data using a PRA approved tool since 2000; that tool was revised to create the current proposed PPR tool. Revisions were made to eliminate questions that the majority of grantees could not respond to or created undue burden, make questions clearer, and add questions that were seen valuable to collect.

Comments in Response to the 60-Day Federal Register Notice

ACL published a 60-day **Federal Register** Notice from 9/30/2022–11/29/2022 (87 FR 59439–59441). ACL received no comments.

The PPR is an extension of a currently approved data collection. Changes were done during the Summer of 2022. Revisions were made to eliminate questions that the majority of grantees could not respond to or created undue burden, make questions clearer, and add questions that were seen valuable to collect.

In August 2022, ACL received feedback through an online meeting with a majority of the TBI State Partnership Program grantees regarding the proposed PPR. Some grantees also provided written feedback. Additional revisions were made to the PPR tool to incorporate feedback received from the grantees.

The questions that were eliminated because grantees could not respond to or created undue burden were regarding: estimated number of people in the states who have experienced a TBI and are getting some kind of Medicaid Home and Community Based services or supports; the types of settings the people were living in when they were screened for a TBI or receiving resource facilitation; how many people were in competitive, integrated employment and/or in school at the time of screening or receiving resource facilitation; and how many people who received resource facilitation were supported through a transition from an institution setting (*e.g.,* criminal justice system, nursing facility) into the community.

The following questions were removed because comparable information is available from other sources: program funds spent on activities; whether grantees are involved in mentoring and workgroup activities; and use of and satisfaction with the services of the technical assistance resource center.

Questions were added to collect more information regarding the advisory boards/councils that are an important component of the TBI SPP grants. The questions added are: characteristics of the advisory board/how structured within a state, regarding what supports are provided to people with TBI that are involved in the advisory boards/councils; how the advisory boards/councils are involved with the grant program; and what it means and the efforts or actions being taken to ensure that the advisory boards/councils are representative (*e.g.,* of the state's demographics, types of brain injury, severity of brain injury, etc.).

Estimated Program Burden

The annual burden estimates are shown below.

Instrument	Number of respondents	Number of responses (per respondent)	Average burden hours (per response)	Total burden hours
Semiannual Performance Progress Reporting	29	2	8	464
Estimated Total Annual Burden Hours:				464

Dated: February 3, 2023.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

[FR Doc. 2023–02672 Filed 2–7–23; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–E–5846]

Determination of Regulatory Review Period for Purposes of Patent Extension; REMEDE SYSTEM

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 REMEDE SYSTEM 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 must submit either electronic or written comments and ask for a redetermination by April 10, 2023.

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 7, 2023. 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 April 10, 2023. 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–2019–E–5846 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; REMEDE SYSTEM.'' 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 REMEDE SYSTEM. REMEDE SYSTEM is indicated for the treatment of moderate to severe central sleep apnea in adult patients. Subsequent to this approval, the USPTO received a patent term restoration application for REMEDE SYSTEM (U.S. Patent No. 8,233,987) from Respicardia, 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 REMEDE SYSTEM 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 REMEDE SYSTEM is 3,685 days. Of this time, 3,289 days occurred during the

testing phase of the regulatory review period, while 396 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:* September 6, 2007. The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the FD&C Act for human tests to begin became effective on April 30, 2010. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on September 6, 2007, which represents the IDE effective date.

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):* September 6, 2016. FDA has verified the applicant's claim that the premarket approval application (PMA) for REMEDE SYSTEM (PMA 160039) was initially submitted September 6, 2016.

3. *The date the application was approved:* October 6, 2017. FDA has verified the applicant's claim that PMA 160039 was approved on October 6, 2017.

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 301 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 3, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–02669 Filed 2–7–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2019–E–5391 and FDA–2019–E–5421]

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

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 SKYRIZI 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 biological 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 April 10, 2023. 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 7, 2023. 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 April 10, 2023. 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 Nos. FDA–2019–E–5391 and FDA–2019–E–5421 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; SKYRIZI.'' 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