website at *https://www.fda.gov/safety/report-problem-fda* for more information. Since the inception of the MedWatch program in July 1993, the program has been promoting and facilitating voluntary reporting by both the public and healthcare professionals. FDA has further encouraged voluntary reporting by requiring inclusion of the MedWatch toll-free phone number or the MedWatch internet address on all outpatient drug prescriptions dispensed, as mandated by section 17 of the Best Pharmaceuticals for Children Act (Pub. L. 107–109).

Section 906 of the FDA Amendments Act amended section 502(n) of the FD&C Act, mandating that published direct-to-consumer advertisements for prescription drugs include the following statement printed in conspicuous text (this includes vaccine products): ''You are encouraged to report negative side effects of prescription drugs to the FDA. Visit *https://www.fda.gov/medwatch,* or call 1–800–FDA–1088.'' Most private vendors of consumer medication information, the drug product-specific instructions dispensed to consumers at outpatient pharmacies, remind patients to report ''side effects'' to FDA and provide contact information to permit MedWatch reporting.

Since 2013, FDA has made available the 3500B form. Proposed during the previous authorization in 2012, the 3500B form is a version of the 3500 form that is tailored for consumers and written in plain language in conformance with the Plain Writing Act of 2010 (*https://www.govinfo.gov/content/pkg/PLAW-111publ274/pdf/PLAW-111publ274.pdf*). The 3500B form evolved from several iterations of draft versions, with input from human factors experts, from other regulatory agencies and with extensive input from consumer advocacy groups and the public. Since 2019, the 3500B form has been available in Spanish at *https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda* and available to upload electronically since 2021 at *https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.spanish.*

Form FDA 3500B, may be used to report adverse events, product problems, product use errors and problems after switching from one product maker to another maker to the Agency. The form is provided in both paper and electronic formats. Respondents may submit reports by mail or fax paper forms to the Agency or electronically submit a report via the MedWatch Online Voluntary Reporting Form at *https://www.accessdata.fda.gov/scripts/medwatch/.* A fillable .pdf version of the form, available at *http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM349464.pdf* may be downloaded, completed, and mailed or faxed to the Agency. Reporting is supported for drugs, non-vaccine biologicals, medical devices, food products, special nutritional products, cosmetics, and non-prescription human drug products marketed without an approved application. The paper form may also be used to submit reports about dietary supplements. Electronic reports for dietary supplements may be submitted to the Agency via an online submission route called the Safety Reporting Portal at *http://www.safetyreporting.hhs.gov/.* Electronic reports for tobacco products may be submitted to the Agency via the tobacco questionnaire within the online Safety Reporting Portal at *http://www.safetyreporting.hhs.gov/.*

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA center or 21 CFR section and/or FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Center for Biologics Evaluation and Research/Center for Drug Evaluation and Research: Form 3500	14,727	1	14,727	0.66 (40 minutes)	9,720
Form 3500A(§§ 310.305, 314.80, 314.98, 600.80, and 1271.350)	599	98	58,702	1.21	71,029
Form 3500A (§ 310.305 outsourcing facilities)	50	2	100	1.21	121
Center for Devices and Radiological Health: Form 3500	5,233	1	5,233	0.66 (40 minutes)	3,454
Form 3500A (part 803)	2,277	296	673,992	1.21	815,530
Center for Food Safety and Applied Nutrition: Form 3500	1,793	1	1,793	0.66 (40 minutes)	1,183
Form 3500A	1,659	1	1,659	1.21	2,007
Center for Tobacco Products: Form 3500	39	1	39	0.66 (40 minutes)	26
All Centers: Form 3500B	13,750	1	13, 750	0.46 (28 minutes)	6,325
Written requests for temporary waiver under § 329.100(c)(2)	1	1	1	1	1
Total					909,396

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We are retaining the currently approved burden estimates for the information collection.

Dated: June 24, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–13943 Filed 6–29–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–E–1340]

Determination of Regulatory Review Period for Purposes of Patent Extension; AXONICS SACRAL NEUROMODULATION SYSTEM

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for AXONICS SACRAL NEUROMODULATION 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 may submit either electronic or written comments and ask for a redetermination by August 30, 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 30, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 30, 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–2020–E–1340 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; AXONICS SACRAL NEUROMODULATION 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 FDA grants permission to market the device. 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 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 AXONICS SACRAL NEUROMODULATION SYSTEM. AXONICS SACRAL NEUROMODULATION SYSTEM is indicated for treatment of chronic fecal incontinence in patients who have failed or are not candidates for more conservative treatments. Subsequent to this approval, the USPTO received a patent term restoration application for AXONICS SACRAL NEUROMODULATION SYSTEM (U.S. Patent No. 7,331,499) from Alfred E. Mann Foundation for Scientific

Research, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 14, 2020, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of AXONICS SACRAL NEUROMODULATION 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 AXONICS SACRAL NEUROMODULATION SYSTEM is 681 days. Of this time, 494 days occurred during the testing phase of the regulatory review period, while 187 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:* October 27, 2017. 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 October 27, 2017.

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):* March 4, 2019. The applicant claims March 1, 2019, as the date the premarket approval application (PMA) for AXONICS SACRAL NEUROMODULATION SYSTEM (PMA 190006) was initially submitted. However, FDA records indicate that PMA 190006 was submitted on March 4, 2019.

3. *The date the application was approved:* September 6, 2019. FDA has verified the applicant's claim that PMA 190006 was approved on September 6, 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 434 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 25, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–13972 Filed 6–29–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0515]

Agency Information Collection Activities; Proposed Collection; Comment Request; Postmarketing Adverse Experience Reporting and Recordkeeping for Drug and Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on postmarketing reporting and recordkeeping of adverse experiences for drug and biological products.

DATES: Submit either electronic or written comments on the collection of information by August 30, 2021.

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 30, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 30, 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:

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- 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.''