ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
1301.6(a)	3,020	1	0.70	2,114	2,114
1302.12(k)	1,054,720	1	.166	175,084	175,084
1302.14(c)	3,020	1	2.00	6,040	6,040
1302.16(b)	3,020	1	5.00	15,100	15,100
1302.33(a)–(b)	1,054,720	1	1.00	1,054,720	1,054,720
1302.33(c)(2)	294,632	1	2.00	589,264	589,264
1302.42(a)–(b)	1,054,720	1	0.66	696,115	696,115
1302.42(e)	3,020	1	0.50	1,510	1,510
1302.47(b)(7)(iv)	3,020	1	0.50	1,510	1,510
1302.53(b)–(d)	3,020	1	0.166	501	501
1302.90(a)	3,020	1	0.50	1,510	1,510
1302.90(b)(1)(i)–(iv), (b)(4)	79,509	1	0.33	26,238	26,238
1302.93(a)	26,503	1	0.25	6,626	6,626
1302.94(a)	3,020	1	0.166	501	501
1302.101(a)(4), 1302.102(b)–(c)	3,020	1	79.00	238,580	238,580
1302.102(d)(3)	110	1	10.00	1,100	1,100
1303.12	3,020	1	0.166	501	501
1303.22–24	956,120	1	0.33	315,520	315,520
1303.42–53	260	1	40.00	10,400	10,400
1303.70(c)	200	1	1.00	200	200
1303.72(a)(3)	3,020	1	2.00	6,040	6,040
1304.13	75	1	60.00	4,500	4,500
1304.15(a)	400	1	0.25	100	100

Estimated Total Annual Burden Hours: 3,153,774.

Authority: 42 U.S.C. 9836A.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–14123 Filed 6–29–21; 8:45 am]

BILLING CODE 4184–40–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1960]

Agency Information Collection Activities; Proposed Collection; Comment Request; MedWatch: The Food and Drug Administration Medical Products Reporting Program

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 information collection associated with FDA's MedWatch adverse experience reporting (AER) program.

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:

- *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–2014–N–1960 for ''MedWatch: The FDA Medical Products Reporting Program.'' 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 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: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

MedWatch: The FDA Medical Products Reporting Program

OMB Control Number 0910–0291—Extension

This information collection supports FDA laws and regulations governing adverse event reports and product experience reports for FDA-regulated products. The Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353b, 355, 360i, 360l, 379aa, and 393) and the Public Health Service Act (42 U.S.C. 262) authorize FDA to collect adverse event reports and product experience reports from regulated industry and to monitor the safety of drugs, biologics, medical devices, and dietary supplements. These reporting and recordkeeping requirements are found in FDA regulations, discussed in Agency guidance, and included in Agency forms. Although there are no laws or regulations mandating postmarket reporting for medical foods, infant formula, cosmetics, or tobacco products, we encourage voluntary reporting of adverse experiences associated with these products.

To facilitate both consumer and industry reporting of adverse events and experiences with FDA-regulated products, we developed the MedWatch program. The MedWatch program allows anyone to submit reports to FDA on adverse events, including injuries and/or deaths, as well as other product experiences associated with the products we regulate. While the MedWatch program provides for both paper-based and electronic reporting, this information collection covers paper-based reporting. Requirements regarding mandatory reporting of adverse events or product problems have been codified in parts 310, 314, 329, 600, and 803 (21 CFR 310, 314, 600, and 803), and specified in sections 503B, 760, and 761 of the FD&C Act (21 U.S.C. 353b, 379aa, and 379aa–1). Mandatory reporting of adverse events for human cells, tissues, and cellular- and tissue-based products (HCT/Ps) have been codified in § 1271.350 (21 CFR 1271.350). Other postmarketing reporting associated with requirements found in sections 201, 502, 505, and 701 (21 U.S.C. 321, 352, 355, and 371) of the FD&C Act and applicable to certain drug products with and without approved applications are approved under OMB control number 0910–0230.

Since 1993, mandatory adverse event reporting has been supplemented by voluntary reporting by healthcare professionals, patients, and consumers via the MedWatch reporting process. To carry out its responsibilities, the Agency needs to be informed when an adverse event, product problem, error with use of a human medical product, or evidence of therapeutic failure is suspected or identified in clinical use. When FDA receives this information from healthcare professionals, patients, or consumers, the report becomes data that will be used to assess and evaluate the risk associated with the product. FDA will take any necessary action to reduce, mitigate, or eliminate the public's exposure to the risk through regulatory and public health interventions.

To implement these reporting provisions for FDA-regulated products (except vaccines) during their post-approval and marketed lifetimes, we developed the following three forms, available for download from our website or upon request to the Agency: (1) Form FDA 3500 may be used for voluntary (*i.e.,* not mandated by law or regulation) reporting by healthcare professionals; (2) Form FDA 3500A is used for mandatory reporting (*i.e.,* required by law or regulation); and (3) Form FDA 3500B, available in English and Spanish, is written in plain language and may be used for voluntary reporting (*i.e.,* not mandated by law or regulation) by consumers (*i.e.,* patients and their caregivers). Respondents to the

information collection are healthcare professionals, medical care organizations and other user facilities (*e.g.,* extended care facilities, ambulatory surgical centers), consumers, manufacturers of biological, food products including dietary supplements and special nutritional products (*e.g.,* infant formula and medical foods), cosmetics, drug products or medical devices, and importers.

Use of Form FDA 3500 (Voluntary Reporting)

This voluntary version of the form may be used by healthcare professionals to submit all reports not mandated by Federal law or regulation. Individual healthcare professionals are not required by law or regulation to submit reports to the Agency or the manufacturer, with the exception of certain adverse events following immunization with vaccines as mandated by the National Childhood Vaccine Injury Act of 1986. Reports for vaccines are not submitted via MedWatch or MedWatch forms, but are submitted to the Vaccines Adverse Event Reporting System (VAERS; see *http://vaers.hhs.gov*), which is jointly administered by FDA and the Centers for Disease Control and Prevention.

Hospitals are not required by Federal law or regulation to submit reports associated with drug products, biological products, or special nutritional products. However, hospitals and other user facilities are required by Federal law to report medical device-related deaths and serious injuries.

Under Federal law and regulation (section 761(b)(1) of the FD&C Act), a dietary supplement manufacturer, packer, or distributor whose name appears on the label of a dietary supplement marketed in the United States is required to submit to FDA any serious adverse event report it receives regarding use of the dietary supplement in the United States. However, FDA bears the burden to gather and review evidence that a dietary supplement may be adulterated under section 402 of the FD&C Act after that product is marketed. Therefore, the Agency depends on the voluntary reporting by healthcare professionals and especially by consumers of suspected serious adverse events and product quality problems associated with the use of dietary supplements. All dietary supplement reports were originally received by the Agency on paper versions of Form FDA 3500 (by mail or fax). Today, electronic reports may be sent to the Agency via an online submission route called the Safety Reporting Portal at *http://www.safetyreporting.hhs.gov/.* In that case, the Form FDA 3500 is not used.

Form FDA 3500 may be used to report to the Agency adverse events, product problems, product use errors, and therapeutic failures. The form is provided in both paper and electronic formats. Reporters may mail or fax paper forms to the Agency. A fillable .pdf version of the form is available at *https://www.accessdata.fda.gov/scripts/medwatch/* or electronically submit a report via the MedWatch Online Voluntary Reporting Form at *https://www.accessdata.fda.gov/scripts/medwatch/.* 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/.*

Use of Form FDA 3500A—Mandatory Reporting

Drug and Biological Products

Sections 503B, 505(j), and 704 of the FD&C Act (21 U.S.C. 374) require that important safety information relating to all human prescription drug products be made available to FDA in the event it becomes necessary to take appropriate action to ensure protection of the public health. Mandatory reporting of adverse events for HCT/Ps is codified in § 1271.350. Consistent with statutory requirements, information is required to be submitted electronically and therefore we account for most all reports under OMB control number 0910–0645, established to support electronic reporting to our MedWatch program. At the same time, regulations provided for waivers from the electronic submission requirements and we therefore account for paper-based reporting in this information collection.

Medical Device Products

Section 519 of the FD&C Act (21 U.S.C. 360i) requires manufacturers and importers, of devices intended for human use to establish and maintain records, make reports, and provide information as the Secretary of Health and Human Services may by regulation reasonably require to assure that such devices are not adulterated or misbranded and to otherwise assure its safety and effectiveness. The Safe Medical Device Act of 1990, signed into law on November 28, 1990, amends section 519 of the FD&C Act. The amendment requires that user facilities such as hospitals, nursing homes, ambulatory surgical facilities, and outpatient treatment facilities report deaths related to medical devices to FDA and to the manufacturer, if known. Serious illnesses and injuries are to be reported to the manufacturer or to FDA if the manufacturer is not known. These statutory requirements regarding mandatory reporting have been codified by FDA under 21 CFR part 803 (part 803). Part 803 mandates the use of the Form FDA 3500A for reporting to FDA on medical devices. While most reporting associated with medical device products is covered under OMB control number 0910–0437, we retain coverage for paper-based adverse experience report submissions in this collection.

Dietary Supplements

Section 502(x) in the FD&C Act implements the requirements of The Dietary Supplement and Nonprescription Drug Consumer Protection Act, which became law (Pub. L. 109–462) on December 22, 2006. These requirements apply to manufacturers, packers, and distributors of nonprescription human drug products marketed without an approved application. The law requires reports of serious adverse events to be submitted to the Agency by manufacturers of dietary supplements. Electronic reports for dietary supplements may be submitted using the Safety Reporting Portal at *http://www.safetyreporting.hhs.gov/.* Paper-based dietary supplement reports may be submitted using the MedWatch Form FDA 3500A.

Use of Form FDA 3500B—Consumer Voluntary Reporting

This voluntary version of the form may be used by consumers, patients, or caregivers to submit reports not mandated by Federal law or regulation. Individual consumers, patients, or caregivers are not required by law or regulation to submit reports to the Agency or the manufacturer. FDA supports and encourages direct reporting to the Agency by consumers of suspected adverse events and other product problems associated with human medical products, food, dietary supplements, and cosmetic products and invite these respondents to visit our

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