4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-0187]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Premarket Approval of Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0231. Also include the FDA docket number found in brackets in the heading of this document.

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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Premarket Approval of Medical Devices

This information collection supports implementation of statutory and regulatory requirements that govern premarket approval of medical devices. Premarket approval is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. Due to the level of risk associated with class III devices, FDA has determined that general and special controls alone are insufficient to assure the safety and effectiveness of class III devices. Therefore, these devices require a premarket approval application (PMA) under section 515 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360e) to obtain marketing approval. PMA requirements apply differently to preamendments devices, postamendments devices, and transitional class III devices and some class III preamendment devices may require a class III 510(k). (See the PMA Historical Background webpage at https://www.fda.gov/medical-devices/premarket-approval-pma/pma-historical-background for additional information.) Section 515A of the FD&C Act (21 U.S.C. 360e-1) governs pediatric uses of devices.

The PMA is the most stringent type of device marketing application required by FDA. Applicants must receive FDA approval of a PMA prior to marketing the device. PMA approval is based on a determination that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s). Respondents to the information collection are PMA applicants, or persons who own the rights, or otherwise have authorized access, to the data and other information to be submitted in support of FDA approval. This person may be an individual, partnership, corporation, association, scientific or academic establishment, government agency or organizational unit, or other legal entity. The applicant is often the inventor/developer and ultimately the manufacturer. A class III device that fails to

meet PMA requirements is considered to be adulterated under section 501(f) of the FD&C Act (21 U.S.C. 351(f)) and may not be marketed.

FDA regulations in part 814 (21 CFR part 814) implement section 515 and 515A of the FD&C Act and establish procedures for the premarket approval of medical devices intended for human use, including the submission of information concerning use in pediatric patients. Regulations in part 814, subpart A (21 CFR 814.1 to 814.19) set forth general provisions pertaining to the confidentiality of data and information submitted to FDA in a PMA, research conducted outside the United States, service of orders, and product development protocols (PDPs). Provisions in part 814, subparts B and C (21 CFR 814.20 to 814.47) establish format and content elements that must be included in an application, explain submission and review schedules, and address the withdrawal and temporary suspension of a PMA. Postapproval requirements, including reports required under 21 CFR part 803 (medical device reporting), are covered in regulations in part 814, subpart E (21 CFR 814.80 to 814.84). Burden attributable to information collection associated with regulations in part 814, subpart H (21 CFR 814.100 to 814.126) pertaining to Humanitarian Use Devices is currently approved in OMB control number 0910-0332.

For operational efficiency, we are revising the information collection to include burden that may be associated with recommendations found in the Agency guidance document entitled "Providing Information about Pediatric Uses of Medical Devices" (May 2014), currently approved in OMB control number 0910-0748. The guidance document describes how to compile and submit the readily available pediatric use information required under section 515A of the FD&C Act. The guidance document is available for download from our website at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-information-about-pediatric-uses-medical-devices.

Relatedly, we are revising the information collection to include burden that may be associated with the submission of information on pediatric use of medical devices under section

515A of the FD&C Act, also currently approved in OMB control number 0910-0748. Section 515A(a) of the FD&C Act requires applicants who submit information to include readily available information providing a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure, and the number of affected pediatric patients. This information allows FDA to track the number of approved devices for which there is a pediatric subpopulation that suffers from the disease or condition that the device is intended to treat, diagnose, or cure and the review time for each such device application.

We are also revising the information collection to include burden applicable to implementing requirements under section 402(j)(5)(B) of the Public Health Service (PHS) Act (42 U.S.C. 282(j)(5)(b)), and set forth in regulations at 42 CFR part 11 (see 81 FR 64981, September 21, 2016). Specifically, applications under sections 505, 515, or 520(m) of the FD&C Act (21 U.S.C. 355, 360e, or 360j(m)), or under section 351 of the PHS Act (42 U.S.C. 262), or submission of a report under section 510(k) of the FD&C Act, must be accompanied by a certification. Where available, such certification must include the appropriate National Clinical Trial numbers. We have developed Form FDA 3674 ("Certifications to Accompany Drug, Biological Product, and Medical Device Applications/Submissions"), available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/form-fda-3674-certifications-accompany-drug-biological-product-and-device-applicationssubmissions, for respondents to submit the requisite information.

Respondents can make single submissions in an electronic format that includes eCopies, submissions submitted on CD, DVD, or flash drive and mailed to FDA and eSubmissions, submissions created using an electronic submission template (e.g., "electronic Submission Template and Resource" (eSTAR)). Consistent with our authority in section 745A(b) of the FD&C Act (21 U.S.C. 379k-1(b)), and performance goals found in our current Medical Device User Fee Amendments Commitment Letter, we developed eSTAR for use through the Center for

Devices and Radiological Health Customer Collaboration Portal. We use eSTAR as a tool to facilitate the preparation of submissions in electronic format (available on FDA's website at https://www.fda.gov/medical-devices/how-study-and-market-your-device/voluntary-estar-program and identified as Form FDA 4062 "Electronic Submission Template and Resource (eSTAR)" (for Non-In Vitro Diagnostic submissions) and Form FDA 4078 "Electronic Submission Template and Resource (eSTAR)" (for In Vitro Diagnostic submissions)). We believe respondents' use of eSTAR will significantly reduce burden attendant to application submissions by providing a uniform format for requisite elements and by enhancing user interface through the use of modernized technology.

Finally, we discuss the guidance document entitled "Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency," announced in the *Federal Register* of March 27, 2023. The guidance document describes a phased-in approach intended to help avoid disruption in device supply and help facilitate compliance with applicable legal requirements. The recommendations discussed in the guidance document result in the one-time collection of information intended to ensure an orderly and transparent transition from temporary policies established during the COVID-19 public health emergency to normal operations. Because the information collection recommendations apply to specific medical devices already in distribution, we believe the information discussed is appropriately characterized as nonstandardized followup designed to clarify responses to approved collections of information, i.e., plans for continued compliance unique to that distributed device. We therefore believe the activity constitutes the collection of non-identical and/or followup information, as defined under 5 CFR 1320.3. At the same time, we expect some degree of fluctuation in future submissions under 21 CFR 814.20, as a result of implementation of the medical device transition plan.

In the *Federal Register* of January 30, 2023 (88 FR 5888), we published a 60-day notice requesting public comment on the proposed collection of information.

We estimate the information collection as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Activity/21 CFR Part/Section or FD&C Act Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Premarket Approval Submissions ("traditional" preparation; eCopy submission):					
21 CFR Part 814, Premarket Approval of Medical Devices					
Subpart A--General					
Research conducted outside the United States (814.15(b))	20	1	20	2	40
Subpart B--Premarket Approval Application (PMA)					
PMA application (814.20)	40	1	40	654.6	26,184
Information on clinical investigations conducted outside the United States (814.20(b)(6)(ii)(C))	10	1	10	0.5 (30 minutes)	5
PMA amendments and resubmitted PMAs (814.37(a)-(c) and (e))	1,356	1	1,356	167	226,452
PMA supplements (814.39(a))	762	1	762	0.5911 (35.5 minutes)	45,048
Special PMA supplement--changes being affected (814.39(d))	75	1	75	6	450
30-day notice (814.39(f))	1,181	1	1,181	16	18,896
Subtotal Parts A and B					317,075
Subpart C--FDA Action on a PMA					
Panel of experts request (814.44 and 515(c)(3) of the FD&C Act)	1	1	1	30	30
Subpart E--Postapproval Requirements					
Postapproval requirements (814.82(a)(9))	121	1	121	135	16,335
Periodic reports (814.84(b))	764	1	764	10	7,640
Total Subpart E					24,005
42 CFR part 11, Clinical Trials Registration and Results Information Submission, subparts D and E; and FDA Guidance "Form FDA 3674--Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions"					
Certification to accompany PMA submissions (Form FDA 3674)	40	1	40	0.75 (45 minutes)	30
FD&C Act section 515A Pediatric Uses of Devices:					
Pediatric information in a PMA, PDP, or PMA supplement	944	1	944	2.10	1,984
Pediatric use information outside approved indication	800	1	800	0.5 (30 minutes)	400
Subtotal	1,744	1	1,744		2,384
Premarket Approval Submissions (eSTAR preparation; eCopy submission):					
eSTAR setup	30	1	30	0.08 (5 minutes)	2
Total					343,496

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

Our estimate is based on the annual rate of receipt of PMA submissions, including PDPs and PMA supplements, for fiscal years 2019 through 2021 and our expectation of submissions to come in the next few years. We also account for referrals of PMAs to a panel for review, as provided for under 21 CFR 814.44(a). FDA may refer the PMA to a panel on its own initiative, and will do so upon request of an applicant, unless FDA determines that the application substantially duplicates information previously reviewed by a panel. We have adjusted our figures to reflect an overall decrease, which we attribute to respondents' use of modernized submission technologies including eSTAR. At the same time, we include in our estimate an initial burden attributable to respondents who need to set up an eSTAR account for the first time.

Table 2.--Estimated Annual Recordkeeping Burden[1]

Activity/21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Maintenance of records (814.82(a)(5) and (6))	552	1	552	17	9,384

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

The regulations require the maintenance of records, which are used to trace patients, and the organization and indexing of records into identifiable files to ensure a device's continued safety and effectiveness. These records are required of all applicants who have an approved PMA. Currently there are 815 active PMAs that could be subject to these requirements, based on FDA data, and approximately 33 new PMAs are approved each year. We estimate our annual recordkeeping burden based on an average of 552 PMA holders. The applicant determines which records should be maintained during product development to document and/or substantiate the device's safety and effectiveness. Records required under 21 CFR part 820 may be relevant to a PMA review and may be submitted as part of an application. In individual instances, records may be required as conditions of approval to ensure the device's continuing safety and effectiveness.

Dated: March 23, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-06485 Filed: 3/28/2023 8:45 am; Publication Date: 3/29/2023]