UNITED STATES FOOD & DRUG ADMINISTRATION
Premarket Approval of Medical Devices
OMB Control No. 0910-0231 – Extension

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports implementation of statutory and regulatory requirements that govern premarket approval of medical devices. Premarket approval (PMA) 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 (PMA) application under section 515 of the FD&C Act (21 U.S.C. 360e) in order to obtain marketing approval. The PMA is the most stringent type of device marketing application required by FDA. Applicants must receive FDA approval of a PMA application 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).

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 (§§ 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. Provisions in part 814, subparts B and C (§§ 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. Post approval requirements, including reports required under 21 CFR part 803 (medical device reporting; see OMB control number 0910-0437), are covered in regulations in part 814, subpart E (§§ 814.80 to 814.84). Burden attributable to information collection associated with regulations in part 814, subpart H (§§ 814.100 to 814.126) pertaining to Humanitarian Use Devices is currently approved in OMB control number 0910-0332.

This information collection includes burden associated with the recommendations in the FDA guidance document entitled *Providing Information about Pediatric Uses of Medical Devices* (May 2014), which was incorporated into this collection during the previous renewal. The guidance describes how to compile and submit the readily available pediatric use information required under section 515A of the FD&C Act. The guidance is available at

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-information-about-pediatric-uses-medical-devices.

Section 515A(a) of the FD&C Act requires applicants to include readily available information describing any pediatric subpopulations that suffer from the disease or condition the device is intended to treat, diagnose, or cure, and the number of affected pediatric patients. FDA uses this information to track the number of approved devices for which there is a pediatric subpopulation that suffers from the disease or condition the device is intended to treat, diagnose, or cure, as well as the review time for each such device application.

Section 402(j)(5)(B) of the Public Health Service (PHS) Act (42 U.S.C. 282(j)(5)(B)), as implemented in 42 CFR part 11 (81 FR 64982, September 21, 2016), requires that applications submitted under sections 505, 515, or 520(m) of the FD&C Act (21 U.S.C. 355, 360e, or 360j(m)), section 351 of the PHS Act (42 U.S.C. 262), and reports submitted under section 510(k) of the FD&C Act be accompanied by a certification. Where applicable, the certification must include the appropriate National Clinical Trial (NCT) number(s). FDA has developed Form FDA 3674, *Certification to Accompany Drug, Biological Product, and Medical Device Applications/Submissions*, to collect the required information. The form itself is approved under OMB control number 0910-0120; however, the burden associated with submitting the certification as part of a PMA application is reflected in this information collection.

Finally, we discuss the guidance document entitled, "*Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the COVID-19 Public Health Emergency*," announced in the Federal Register of March 27, 2023 (88 FR 18153). The guidance document describes a phased 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 follow-up designed to clarify responses to approved collections of information, i.e., plans for compliance with applicable requirements unique to that distributed device. We therefore believe the activity constitutes the collection of non-identical and/or follow-up 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.

Accordingly, we are requesting OMB approval for the information collection activities included in the applicable regulations, and the guidance documents and agency forms discussed and identified in this supporting statement.

2. Purpose and Use of the Information Collection

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. We use the information submitted as the basis of our review.

3. Use of Improved Information Technology and Burden Reduction

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 with 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 developed eSTAR for PMA original & Panel-Track supplements. 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. We continue to make process improvements and technological enhancements consistent with our MDUFA V Commitment letter found at https://www.fda.gov/media/157074/download (included in OMB control number 0910-0511).

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

We do not believe the information collection imposes undue burden on small entities. Respondents to the information collection submit user fees in conjunction with FDA review of premarket approval of medical devices. Under statutory provisions, small businesses may qualify for reduced fees.

6. Consequences of Collecting the Information Less Frequently

The information collection is consistent with applicable statutory and regulatory requirements.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the *Federal Register* of April 10, 2026 (91 FR 18468). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift has been provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act of 1974

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted via Form FDA 3601 (Medical Device User Fee Cover Sheet[1]) username, password, name, email address, telephone number, and fax telephone number. The PII submitted via Form FDA 3514 (CDRH Pre-Market Review Submission Cover Sheet[2]) is name, address, phone number, fax number, and email address. The PII submitted via Form FDA 3674 (Certification of Compliance) is name, address, telephone number, and fax number. Information collected via Form 3601 is maintained in a Privacy Act system of records as described in HHS/FDA System of Records Notice (SORN) 09-10-0021 for FDA's User Fee System. Individuals completing Form 3601 will complete it via the webpage where a notice is displayed. Through appropriate form and webpage design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

The Freedom of Information Act (FOIA)

Under FOIA (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

[1] Form FDA 3601 is approved under OMB control number 0910-0511.
[2] Form FDA 3514 is approved under OMB control number 0910-0120.

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

Activity/21 CFR or FD&C Act Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (hours)	Total Hours
Premarket Approval Submissions ("traditional" and eSTAR preparation; eCopy submission):					
21 CFR Part 814, Premarket Approval of Medical Devices					
Subpart A--General					
Research conducted outside the United States (814.15(b))	18	1	18	2	36
Subpart B--Premarket Approval Application (PMA)					
PMA application (814.20)	61	1	61	654.6	39,931
Information on clinical investigations conducted outside the United States (814.20(b)(6)(ii)(C))	18	1	18	0.5 (30 minutes)	9
PMA amendments and resubmitted PMAs (814.37(a)-(c) and (e))	1,125	4	4,500	167	751,500
PMA supplements (814.39(a))	598	3	1,794	0.983 (59.11 minutes)	1,764
Special PMA supplement--changes being affected (814.39(d))	85	2	170	6	1,020
30-day notice (814.39(f))	1,499	15	22,485	16	359,760
Subtotal subpart B					1,153,984
Subpart C--FDA Action on a PMA					
Panel of experts request (814.42 and 515(c)(3) of the FD&C Act)	4	1	4	30	120
Subpart E--Postapproval Requirements					
Postapproval requirements (814.82(a)(9))	14	1	14	135	1890
Periodic reports (814.84(b))	860	2	1,720	10	17,200
Subtotal subpart E					19,090
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"[2]					
Certification to accompany PMA submissions (Form FDA 3674)	61	1	61	0.75 (45 minutes)	46
FD&C Act section 515A Pediatric Uses of Devices and FDA Guidance "Providing Information about Pediatric Uses of Medical Devices":					

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

Activity/21 CFR or FD&C Act Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (hours)	Total Hours
Pediatric information in a PMA, PDP, or PMA supplement	659	6	3,954	2.10 (2 hours, 6 minutes)	8,303
Pediatric use information outside approved indication	6	1	6	0.5 (30 minutes)	3
Subtotal					8,306
Premarket Approval Submissions (eSTAR preparation):					
eSTAR setup	1,529	6	9,174	0.08 (5 minutes)	734
Total					1,182,316

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Form FDA 3674 is approved under OMB Control No. 0910-0120. This ICR includes burden only for PMA submissions.

Our estimate is based on the annual rate of receipt of PMA submissions, including PDPs and PMA supplements, for fiscal years 2022 through 2024 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 § 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 (a)(6))	860	2	1,720	17	29,240

[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 860 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 860 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.

12b. Annualized Cost Burden Estimate

Assuming that activities identified in *12a* are performed by labor categories consistent with that of "*Lawyer*" ($72.67/hr) as defined by the Bureau of Labor Statistics (BLS), we use an hourly wage rate of $145.34 for a lawyer consistent with 2025 data for our calculations. We factor this figure by two to account for overhead, multiply the total by the annual burden hours and estimate annual respondent costs to be $ 176,087,549.04 [$145.34 x 1,211,556 hrs.].

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

There is no capital, start-up, operating or maintenance cost associated with this information collection.

14. Annualized Cost to the Federal Government

We estimate costs of administering the collection to be $58,310,000; which assumes 170 FTEs x $343,000 (fully-loaded FY25 data), for the review of premarket approval submissions.

15. Explanation for Program Changes or Adjustments

Our estimate is based on the annual rate of receipt of PMA submissions, including PDPs and PMA supplements, for fiscal years 2022 through 2024 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 § 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.

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The overall burden increase of approximately 244% for reporting and 212% for recordkeeping represents a substantial change in the estimated regulatory burden for the PMA program. The increases are driven primarily by changes in estimated submission frequency rather than changes in the number of regulated entities or per-response burden estimates. The most significant factor

is the dramatic increase in responses per respondent across multiple categories, particularly for 30-day notices (15× increase), PMA amendments (4× increase), pediatric information (6× increase), and eSTAR setup (6× increase). These changes suggest that the current estimates better capture the actual submission patterns and regulatory interactions that occur throughout the lifecycle of approved medical devices, reflecting more frequent modifications, updates, and communications between industry and FDA than were captured in the previous estimates based on 2019-2021 data.

Table 1.--Estimated Annual Reporting Burden

Activity/CFR Section	Previous Approved Annual Burden Hours	Requested Annual Burden Hours	Difference (Hours) (+/-)	Rationale for change (Estimate Revision/Programmatic)
Research conducted outside the United States (814.15(b))	40	36	-4	Estimate Revision
PMA application (814.20)	26,184	39,931	+13,747	Estimate Revision
Information on clinical investigations conducted outside the United States (814.20(b)(6)(ii)(C))	5	9	+4	Estimate Revision
PMA amendments and resubmitted PMAs (814.37(a)-(c) and (e))	226,452	751,500	+525,048	Estimate Revision
PMA supplements (814.39(a))	45,048	1,764	-43,284	Estimate Revision
Special PMA supplement--changes being affected (814.39(d))	450	1,020	+570	Estimate Revision
30-day notice (814.39(f))	18,896	359,760	+340,864	Estimate Revision
Panel of experts request (814.42 and 515(c)(3) of the FD&C Act)	30	120	+90	Estimate Revision
Postapproval requirements (814.82(a)(9))	16,335	1,890	-14,445	Estimate Revision
Periodic reports (814.84(b))	7,640	17,200	+9,560	Estimate Revision
Certification to accompany PMA submissions (Form FDA 3674)	30	46	+16	Estimate Revision
Pediatric information in a PMA, PDP, or PMA supplement	1,984	8,303	+6,319	Estimate Revision
Pediatric use information outside approved indication	400	3	-397	Estimate Revision
eSTAR setup	2	734	+732	Estimate Revision
TOTAL	**343,496**	**1,182,316**	+838,820	

Table 2.--Estimated Annual Recordkeeping Burden

Activity/CFR Section	Previous Approved Annual Burden Hours	Requested Annual Burden Hours	Difference (Hours) (+/-)	Rationale for change (Estimate Revision/Programmatic)
Maintenance of records (814.82(a)(5) and (a)(6))	9384	29,420	+20,036	Estimate Revision

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB control number, its expiration date, and an explanation of its significance will be displayed with the information collection as required by 5 CFR 1320.5. Consistent with established practice FDA publishes a Federal Register notice announcing OMB approval of the information collection associated with its guidance documents and will display in that notice both the OMB control number and its current expiration date. In addition, the OMB control number will be displayed on the guidance document cover page and include a link to www.reginfo.gov to identify the current expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.