Postmarket Surveillance of Medical Devices

OMB Control No. 0910-0449 -- EXTENSION

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports FDA statutes and regulations. Section 522 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360l) provides the Food and Drug Administration (FDA) with authority to require manufacturers of medical devices to conduct postmarket surveillance at the time of approval or clearance, or at any time thereafter, of certain devices. Postmarket surveillance is the active, systematic, scientifically valid collection, analysis, and interpretation of data or other information about a marketed device. Section 522(b) requires that manufacturers of devices, upon receiving an order that surveillance is required to be conducted, shall submit a plan for surveillance to FDA. The data collected under a surveillance order helps address important public health questions on the safety and effectiveness of a device. We have promulgated regulations in 21 CFR part 822 to implement section 522 of the FD&C Act and to establish procedures and requirements for postmarket surveillance of class II and class III devices that meet any of the following criteria:

- Failure of the device would be reasonably likely to have serious adverse health consequences;
- The device is intended to be implanted in the human body for more than 1 year;
- The device is intended to be used outside a user facility to support or sustain life. If you fail to comply with requirements that we order under section 522 of the act and this part, your device is considered misbranded under section 502(t)(3) of the act and you are in violation of section 301(q)(1)(C) of the act; or
- The device is expected to have significant use in pediatric populations.

To assist respondents with understanding the applicable statutory and regulatory requirements, we also developed the interpretive agency guidance entitled, "Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act" (October 2022) (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarket-surveillance-under-section-522-federal-food-drug-and-cosmetic-act*). We are therefore requesting OMB approval for the information collection provisions set forth in 21 CFR part 822 governing the postmarket surveillance of medical devices and associated agency guidance as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

FDA uses the information to ensure the safety of medical devices. We have established an automated tracking system that efficiently identifies the reporting status of active 522 postmarket surveillance studies based on study timelines incorporated in postmarket surveillance plans and agreed upon by the FDA and manufacturers. This system represents our efforts to ensure that all

522 postmarket surveillance commitments are fulfilled in a timely manner. For more information we invite interested persons to visit the Postmarket Surveillance CDRH website (available at *https://www.fda.gov/medical-devices/postmarket-requirements-devices/522-postmarket-surveillance-studies-program*).

3. Use of Improved Information Technology and Burden Reduction

Under section 745A of the FD&C Act, FDA has authority to require the electronic submission of information, and to specify the format for certain submissions. Accordingly, our Center for Devices and Radiological Health (CDRH) issued and has implemented the guidance, "Providing Regulatory Submissions for Medical Devices in Electronic Format--Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act" (July 2020) (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-medical-devices-electronic-format-submissions-under-section-745ab*). Our current authority and information technology infrastructure allows respondents to satisfy information collection requirements by submitting a single copy of information in an electronic format. Information collection associated with electronic record submission requirements is currently approved in OMB Control Number 0910-0303.

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

The information collection poses no undue burden on small entities. At the same time, FDA continues to provide resources including topic-specific guidance and small business compliance guides, made available on our website. CDRH's Division of Industry and Consumer Education (DICE) also provides technical and other nonfinancial assistance to small firms expressly to aid them in complying with the requirements of the FD&C Act, including assistance in identifying ways manufacturers can avoid postmarket surveillance actions through the use of least burdensome practices. DICE activities include participating in and presenting conferences, workshops, and seminars on the application and interpretation of relevant regulations, consulting with individual firms/sponsors, and development and dissemination of educational materials. DICE staff is available to respond to questions and a toll-free telephone number was established to facilitate this communication link.

6. Consequences of Collecting the Information Less Frequently

The information collection is consistent with statutory and regulatory requirements.

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

There are no special circumstances associated with the information collection.

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

In the *Federal Register* of June 16, 2026 (90 FR 25318), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

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 collected is name, work address, work email address, work telephone number and occasionally work fax number. FDA determined that although PII is collected, the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate form and webpage design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

Under the Freedom of Information Act (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 Cost

12a. Annualized Hour Burden Estimate

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

21 CFR Part/Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
§§ 822.9 and 822.10; PS submission	3	1	3	120	360
§ 822.21; Changes to PS plan after approval	8	1	8	40	320
§ 822.28; Changes to PS plan for a device that is no longer marketed	1	1	1	8	8

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

§ 822.29; Waiver	1	1	1	40	40
§ 822.30; Exemption request	1	1	1	40	40
§ 822.38; Periodic reports	35	3	105	40	4,200
Total					4,968

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

Regulations in 21 CFR part 822, subpart A (§§ 822.1 through 822.4), set forth general provisions that explain the scope and purpose of postmarket surveillance under section 522 of the FD&C Act. Regulations in 21 CFR part 822, subparts B, C, and D (§§ 822.5-822.23), discuss notification orders; how surveillance plans are submitted to FDA and what must be included; and FDA review and action on the submission of surveillance plans. The regulations also prescribe responsibilities for manufacturers in 21 CFR part 822, subpart E (§§ 822.24-822-28). Provisions for waivers and exemptions under 21 CFR part 822 are set forth in 21 CFR part 822, subpart F (§§ 822.29-822.30). Finally, required records and reports are established in 21 CFR part 822, subpart G (§§ 822.31-822.38). Our estimate of burden is based on internal agency tracking data. Because sections 822.26, 822.27, and 822.34 entail no burden other than that necessary to identify the respondent, the date, the respondent's address, and the nature of the instrument (5 CFR 1320.3(h)(1)), we do not include this activity in our calculations.

The number of respondents to this information collection varies annually, subject to the number of original plans, plan changes, and interim and final reports (which are dependent on enrollment progress for each study) received by FDA.

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

21 CFR Part/Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
§ 822.31; Manufacturer records	3	1	3	20	60
§ 822.32; Investigator records	9	1	9	5	45
Total					105

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

We expect some manufacturers will be able to satisfy information collection requirements by using information or data already available and assume fewer records per activity. We calculate burden to investigator recordkeeping based on the assumption that each postmarket surveillance order is satisfied by a 3-year clinically based plan, using three investigators.

12b. Annualized Cost Burden Estimate

Table 3. – Annualized Burden Costs[1]

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Lawyer	5,073	$170	$862,410

[1] Figures rounded to the nearest whole dollar.

We assume the activities identified in *Question-12a* will be completed by an attorney. To estimate costs to respondents, we assume a wage rate for the labor category "*Lawyers*"* and doubled this figure to account for benefits and overhead ($84.84 x 2=$170 (rounded)). We then multiplied this wage rate by the estimated annual burden hours to calculate a total annualized cost burden of $862,410 ($170 x 5,073 hours).

* Bureau of Labor Statistics. National Occupational Employment and Wage Estimates. Occupational Employment Statistics (occupation code 23-1011) May 2023. *https://www.bls.gov/oes/current/oes_nat.htm*.

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

There are no capital or operating and maintenance costs associated with the information collection.

14. Annualized Cost to the Federal Government

We estimate an average allocation of 3 full time equivalent (FTE) employees, comprised of medical officers, dental officers, scientific, and engineering professionals and support staff, to review and process postmarket surveillance information. Assuming a cost of $348,722 per position (which is the agency's projected average cost of an FTE including benefits*), we estimate an annual cost to the Federal government of $1,046,166 ($348,722 x 3 FTEs).

*Based on the Food and Drug Administration fully loaded FTE cost model (domestic) for FY 2023 as provided by agency economists.

15. Explanation for Program Changes or Adjustments

Our estimated burden for the information collection reflects an increase of 1,890 total burden hours and a corresponding increase 45 total annual responses. This increase is based on internal FDA tracking data. The number of respondents varies annually, subject to the number of original plans, plan changes, and interim and final reports (which are dependent on enrollment progress for each study) received by FDA.

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

Consistent with established practice FDA will publish a Federal Register notice announcing OMB approval of the information collection associated with this guidance document 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.