UNITED STATES FOOD & DRUG ADMINISTRATION

Medical Devices: Records and Reports on Devices Reports

OMB Control No. 0910-0359 - Revision

SUPPORTING STATEMENT – **Part A: Justification**:

1. Circumstances Making the Collection of Information Necessary

   This information collection supports Food and Drug Administration (FDA, the agency, us or we) regulations that implement section 519(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Section 519(g) of the FD&C Act requires device manufacturers and importers to report promptly to FDA certain actions concerning device corrections and removals, and to maintain records of all corrections and removals regardless of whether such corrections and removals are required to be reported to FDA. The regulations are codified in 21 CFR part 806: *Medical Devices; Reports of corrections and removals*. We are revising the collection to include reporting and recordkeeping associated with combination products found in 21 CFR part 4 (*Regulation of Combination Products*). Combination products are products that include two or more regulated components. Regulations in 21 CFR §§ 4.102 and 4.105 provide for specific postmarketing reporting and recordkeeping applicable to combination products that include a device constituent part and are therefore subject to the safety reporting and recordkeeping found in part 806. The regulations also provide for certain exemptions from the reporting requirements as described in 21 CFR part 806.1(b).

   We therefore request OMB approval for the information collection provisions found in 21 CFR part 806, and the information collection provisions found in 21 CFR part 4 pertaining to postmarketing safety reporting and related recordkeeping. We note that the product sharing provisions found in 21 CFR part 4.103 are currently approved OMB control no. 0910-0834.

2. Purpose and Use of the Information Collection

   The information collected in the reports of corrections and removals will be used by FDA to identify marketed devices that have serious problems and to ensure that defective devices are removed from the market. This will assure that FDA has current and complete information regarding these corrections and removals to determine whether recall action is adequate. Failure to collect this information would prevent FDA from receiving timely information about devices that may have a serious effect on the health of users of the devices.

3. Use of Improved Information Technology and Burden Reduction

   Although the regulations do not mandate electronic records, we encourage this approach. While mail-in submissions remain acceptable, we have established a web-based submission process to facilitate reporting. We estimate 50% of the respondents will use electronic means to fulfill the information collection requirements. Respondents to the information collection are for-profit device applicants seeking FDA approval of a marketing or licensing application.

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 estimate 80 percent of respondents are small businesses. We assist small businesses by providing guidance and information through our Division of Industry and Consumer Education (DICE) and the Device Registration and Listing Branch within the Center for Devices and Radiological Health. DICE holds workshops, conducts onsite evaluations, and provides other technical and nonfinancial assistance to small manufacturers. The workshops make available publications and educational materials, which include medical device establishment and listing requirements. The Division also maintains a toll-free telephone number and maintains a page on our website from which firms may obtain regulatory information. Finally, representatives our regional offices and scientific and administrative staff are available as appropriate through meetings and communications with the agency.

6. Consequences of Collecting the Information Less Frequently

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

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

   Applicable regulations require that postmarket safety reports be retained at least 10 years.

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

   In accordance with 5 CFR 1320.8(d), we published a 60-day notice soliciting public comment in the Federal Register of February 21, 2020 (85 FR 10168). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

No payment or gifts in any manner or form shall be provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

In preparing this supporting statement we consulted with our Privacy Office to ensure appropriate handling of information collected. We determined that, although PII is collected, it is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, we do not use name or any other personal identifier to routinely retrieve records from the information collected.

In addition, reports and other information submitted to FDA under 21 CFR part 806 is releasable if it falls within the scope of our regulation concerning "*Public Information*" (21 CFR part 20). However, FOIA exempts disclosures of certain government records from mandatory public disclosures (5 U.S.C. 522(b)(1-9)). One such provision exempts from public disclosure "*trade secrets*" and "*confidential commercial or financial information*" that is privileged (5 U.S.C. 522(b)(4)).

11. Justification for Sensitive Questions

This information collection does not include questions of a sensitive nature, such as those regarding sexual behavior and attitudes, religious beliefs, or other matters that are commonly considered private.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden

21 CFR; IC Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Response	Total Hours[1]	Total Operating & Maintenance Costs
Electronic process setup[2]	517	1	517	3.08	1,592	$25,850
806; device product corrections or removals	1,033	1	1,033	10	10,330	
4.102; combination product corrections or removals	20	1	20	10	200	

21 CFR; IC Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Response	Total Hours[1]	Total Operating & Maintenance Costs
TOTAL			0		0	

[1] Figures rounded.

[2] The burden hours for setup of the electronic process listed in the reporting burden table are divided by 3 to avoid double counting in the Office of Information and Regulatory Affairs Consolidated Information System. However, the one-time Average Burden per Response is 9.25 hours, resulting in a total one-time burden of 4,782 hours for the setup of the electronic process.

Table 2.--Estimated Annual Recordkeeping Burden

21 CFR; IC Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Avg. Burden per Recordkeeping	Total Hours[1]
806; device product corrections and removals	93	1	93	10	930
4.105; device-led combination products[1]	279	.45	126	.5	63
TOTAL			0		0

[1] Figures rounded.

12b. Annualized Cost Burden Estimate

We estimated the annual cost burden based on the updated wage rate for a Regulatory Affairs Professional.* The estimate includes electronic process set-up (4,782 hours**), preparation and assembly of submissions of corrections and removals (10,330 hours), corrections and removals for device-led combination products under 4.102(c)(1)(iii) (200 hours), maintenance of records under part 806 (930 hours), and additional recordkeeping by device-led combination products under 4.105(b) (63 hours).

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs***
Regulatory Affairs Professional	16,305	$59	$961,995

* Based on The Regulatory Affairs Professional Society (RAPS) overall base annual compensation of $122,711 for a U.S. regulatory affairs professional (https://www.raps.org/careers/scope-of-practice-survey). The hourly rate of $59 above assumes a 40-hour work week and is rounded to the nearest dollar.

** The actual burden hours for set-up of the electronic process listed in the reporting burden table are divided by three to avoid double counting.

***Total is rounded to the nearest dollar.

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

For respondents for who submit corrections and removals using the electronic process, the operating and maintenance costs associated with this information collection are approximately $50 per year to purchase a digital verification certificate (certificate must be valid for 1 to 3 years). This burden may be minimized if the respondent has already purchased a verification certificate for other electronic submissions to FDA. However, FDA is assuming that all respondents who submit corrections and removals using the electronic process will be establishing a new WebTrader account and purchasing a digital verification certificate. We therefore estimate the total operating and maintenance costs to be $25,850 annually (517 respondents x $50).

14. Annualized Cost to the Federal Government

We allocate approximately seven full time equivalent positions (FTEs) to ensure compliance with the Reports of Corrections and Removals regulations required by section 519(g) of the FD&C Act. Assuming each FTE is costs FDA/CDRH 263,094 * annually, and includes employee salary and overhead expenses; the annual cost to the government $1,841,658.

*Based on the FY 2019 FDA Budget Request – Executive Summary – All Purpose Table.

15. Explanation for Program Changes or Adjustments

The information collection reflects revision and adjustment. We have revised the collection to include reporting and recordkeeping resulting from provisions associated with combination products established by rulemaking (0910-AF82) and approved under OMB Control No. 0910-0834. At the same time, upon review we noted calculation errors in our last submission. Cumulatively these changes result in 653 additional responses, 1,293 fewer burden hours, and a reduction of $4,810 in costs.

16. Plans for Tabulation and Publication and Project Time Schedule

No tabulation of the data is planned or anticipated.

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

Display of expiration date or OMB approval of this request.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.