

UNITED STATES FOOD & DRUG ADMINISTRATION

Medical Devices; Reports of Corrections and Removals

OMB Control No. 0910-0359

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* and, related to combination products, 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).

The information collection includes an electronic submission form entitled, “*Device Correction/Removal Report for Industry*,” and available in portable document format (pdf) developed to assist respondents with submitting information and to improve operational efficiency.

We therefore request extension of OMB approval for the information collection provisions found in 21 CFR Part 806 and 21 CFR Part 4, pertaining to postmarketing safety reporting and related recordkeeping, and the FDA form, “*Device Correction/Removal Report for Industry*.”

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.

Respondents to the information collection are for-profit device applicants seeking FDA approval of a marketing or licensing application.

### 3. Use of Improved Information Technology and Burden Reduction

Reports of corrections and removals may be submitted to FDA via mail, email, or using FDA's Electronic Submission Gateway (ESG). We estimate that approximately 50 percent of submitters will use the ESG. Our estimate of the reporting and recordkeeping burden is based on Agency records and our experience with this program, as well as similar programs that utilize FDA's ESG.

To assist device manufacturers and importers with submitting reports of corrections or removals, we developed a fillable pdf electronic submission format, "Device Correction/Removal Report for Industry," that can be submitted to the Agency by email. Instructions for the fillable form are provided in pop-up text boxes that appear over each data field. The fillable form will feed data to the FDA Recall Enterprise System (RES) Database. We expect that use of the fillable form will expedite processing of the reports of corrections or removals submitted by device manufacturers or importers by eliminating the need for human data entry currently performed by FDA staff. Additionally, the cost burden associated with use of the ESG for such submissions (see section 13 of this Supporting Statement), may be reduced if respondents utilize the new PDF form and submit it to the Agency using email, mitigating the need for a digital verification certificate.

We estimate 95 percent of the respondents will use electronic means to fulfill the information collection requirements.

### 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.

### 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 postmarketing safety reports be retained for a period of 2 years beyond the expected life of the device, even if the manufacturer or importer has ceased to manufacture or import the device (see 21 CFR 806.20(c)).

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

We published a 60-day notice for public comment in the *Federal Register* of April 11, 2023 (88 FR 21677). 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

### *The Privacy Act of 1974*

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. Although this ICR collects personally identifiable information (PII), it is collected in the context of the subject individuals' professional capacity and the FDA-related work performed for their employer (e.g., point of contact at a regulated entity). The PII submitted include submitted name, firm point of contact name, work phone number, and work email. 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 Privacy Act do not apply. Specifically, the contractor or 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.

### *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 Cost

### 12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden

21 CFR; IC Activity	Form	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Response	Total Hours <sup>1</sup>	Total Operating & Maint. Costs
Electronic process setup <sup>2</sup>		517	1	517	3.08	1,592	\$25,850
806; device product corrections or removals	FDA Form: "Device Correction / Removal Report for Industry"	1,033	1	1,033	10	10,330	
4.102; combination product corrections or removals(including sharing information with other constituent part applicants under 4.103)		20	1	20	10	200	
<b>TOTAL</b>				<b>0</b>		<b>0</b>	

<sup>1</sup> Figures rounded.

<sup>2</sup> We estimate that approximately 50 percent of respondents will submit corrections and removals using the electronic process. 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 <sup>1</sup>
806; device product corrections and removals	93	1	93	10	930
4.105; device-led combination products <sup>1</sup>	279	.45	126	.5	63
<b>TOTAL</b>			<b>0</b>		<b>0</b>

<sup>1</sup> Figures rounded.

### 12b. Annualized Cost Burden Estimate

Assuming that activities identified in 12a are performed by labor categories consistent with that of "Lawyer" (occupation code 23-1011) as defined by the Bureau of Labor Statistics (BLS), we use a mean hourly wage rate of \$78.74/hour for a lawyer consistent with 2022 data for our

calculations.<sup>1</sup> We factor this figure by two to account for benefits and overhead (\$157.48), multiply the total by the annual burden hours and estimate annual respondent costs to be \$2,065,350 (rounded) [\$157.48 x 13,115 hours].

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Lawyer	13,115	\$157.48	\$2,065,350

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

For respondents who submit corrections and removals using the ESG, 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 reduced if the respondent has already purchased a verification certificate for other electronic submissions to FDA. This burden may also be reduced if respondents utilize the new PDF template, “Device Correction/Removal Report for Industry,” and submit it to the Agency using email, mitigating the need for a digital verification certificate. However, for the purpose of estimating the burden, FDA is assuming that all respondents who submit corrections and removals using the ESG, we assume approximately 50 percent of respondents, will establish a new WebTrader account and purchase 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 assume allocation of 7 full time equivalent (FTE) positions to review and process reports of corrections and removals. Based on an internal cost model, we assume a fully-loaded cost of \$297,561 per position and calculate the estimated annual Federal costs to be \$2,082,927.

15. Explanation for Program Changes or Adjustments

Although we made no changes to our burden estimates since last evaluation of the information collection, we have added the fillable pdf electronic form, “*Device Correction/Removal Report for Industry*,” as discussed previously.

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

FDA will display the expiration date as required.

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<sup>1</sup> [http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm), accessed 5/1/23.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.