

United States Food and Drug Administration

Medical Device Recall Authority

OMB Control No. 0910-0432

SUPPORTING STATEMENT - Extension

Terms of Clearance: None.

Part A: Justification

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) regulations in part 810 (21 CFR part 810), Medical Device Recall Authority. FDA issued [21 CFR part 810](#) to implement the provisions of section 518(e) ([21 U.S.C. 360h\(e\)](#)) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Section 518(e) of the FD&C Act provides FDA the authority to issue an order requiring the appropriate person, including manufacturers, importers, distributors, and retailers of a device, if FDA finds that there is reasonable probability that the device intended for human use would cause serious adverse health consequences or death, to: (1) immediately cease distribution of such device; and (2) immediately notify health professionals and device user facilities of the order and to instruct such professionals and facilities to cease use of such device.

We therefore request extension of Office of Management and Budget (OMB) approval of the collections of information required by part 810 as discussed in this supporting statement. A description of the information collection requirements in part 810, subpart B, can be found in section 12a of this supporting statement.

2. Purpose and Use of the Information Collection

The information collected under the recall authority will be used by FDA to ensure that all devices entering the market are safe and effective, to accurately and immediately detect serious problems with medical devices, and to remove dangerous and defective devices from the market.

Almost all recalls are carried out under the voluntary recall procedures found in part 7 (21 CFR part 7). FDA interprets the standard in 810.10(a) and 810.13 to match closely with the elements of a class I voluntary recall under part 7, subpart C, for which the Agency has a long record of experience. FDA will initiate a mandatory recall under section 518(e) of the FD&C Act when FDA finds that there is a reasonable probability that a device would cause serious, adverse health consequences or death. A firm may initiate a voluntary recall of a violative device without FDA intervention. However, if FDA determines that such a voluntary recall is not effective in remedying a violation and there remains a reasonable probability that the violative device would cause serious, adverse health consequences or death, FDA will invoke the medical device recall authority in addition to the voluntary efforts that the manufacturer has already undertaken. FDA

will not order a mandatory recall if a voluntary recall has been effective in addressing the problems.

FDA believes that the regulation provides sufficient flexibility to minimize the burden on those required to take action, consistent with the determination that the device presents a risk or serious adverse health consequences or death. FDA expects that at most, one or two recalls per year would be ordered, which would not have occurred without this regulation. Section 518(e) of the FD&C Act sets out a procedure for the issuance of a mandatory device recall order. First, after finding that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, FDA shall issue a cease distribution and notification order requiring the appropriate person to: (1) immediately cease distribution of the device and (2) immediately notify health professionals and device user facilities of the order and to instruct such professionals and facilities to cease use of such device. FDA will then provide the person named in the cease distribution and notification order with the opportunity for an informal hearing on whether the order should be amended to require a mandatory recall of the device. If, after providing the opportunity for an informal hearing, FDA determines that such order is necessary, the Agency may amend the order to require a mandatory recall.

Respondents are private sector businesses including medical device manufacturers, importers, distributors, and retailers, that have been issued a cease distribution and notification order or mandatory recall order in accordance with the provisions under 21 CFR part 810, during the timeframe(s) specified in the order.

3. Use of Improved Information Technology and Burden Reduction

The FD&C Act, as amended, permits the use of electronic technologies in a manner that is consistent with FDA's overall mission and that preserve the integrity of the Agency's enforcement activities. Reports and records concerning recalls may be submitted to FDA in electronic format or retained in electronic files provided that they comply with [21 CFR Part 11](#) concerning electronic records and electronic signatures. Also, FDA currently allows respondents involved in recall actions to submit data to district offices electronically. FDA currently allows for these requests, along with other reports and records concerning mandatory recalls, to be submitted to the agency using electronic methods including email and FDA's eSubmitter program (<https://www.fda.gov/industry/fda-esubmitter>). FDA estimates that approximately 95% of the respondents will use electronic means to fulfill the Agency's requirement or request.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only agency responsible for the collection of this information. Therefore, no duplication of data exists. In addition, no data exists from any other source that can be used to recall devices subject to final regulation. We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

We estimate that the majority, approximately 95 percent, of respondents are small businesses. FDA aids small businesses in dealing with the requirements of the regulations by providing

assistance through Center for Devices and Radiological Health's Division of Industry and Consumer Education (DICE), and through the scientific and administrative staff, workshops in which FDA Staff participate, and through the CDRH website at <http://www.fda.gov/MedicalDevices/default.htm>. These efforts help to assure that the burden on all manufacturers, including small manufacturers, is minimized. FDA also provides all manufacturers uniform device reporting criteria to avoid confusion and minimize burden to the respondent.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory and regulatory requirements. Manufacturers are required to submit periodic progress reports to FDA only if FDA requires a cease distribution and notification order or a mandatory recall order. Therefore, respondents will respond to the information collection "occasionally." If this information is collected less frequently, FDA will be unable to monitor the progress of such orders.

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 June 5, 2024 (89 FR 48174). 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. Data will be kept private to the extent allowed by law.

The Privacy Act of 1974

This ICR does not collect personally identifiable information (PII). Collections specified in the recall order under 810.10(d); Requests for a regulatory hearing under 810.11(a); Written requests for review under 810.12(a-b); Mandatory recall strategy under 810.14; Periodic status reports under 810.16(a-b); and Termination requests under 810.17(a). While the collection does not involve solicitation or collection of personally identifiable information a company may choose to send name or other contact information for a company point of contact.

The Freedom of Information Act

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)). Recalls and other information submitted to FDA under 21 CFR Part 810 are releasable under 21 CFR Part 20. 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

The following estimates are based on FDA's recent experience with voluntary recalls under 21 CFR Part 7. Based on an analysis of cease and distribution and notification and mandatory recall order activity over the last 3 years, FDA expects no more than two mandatory recalls per year as a conservative estimate, as most recalls are done voluntarily.

Table 1.—Estimated Annual Reporting Burden

Collection Activity--21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Submission of information to FDA about device distribution and remedial actions to be taken, as specified in the order--810.10(d)	2	1	2	8	16
Submission of a written request for regulatory hearing--810.11(a)	1	1	1	8	8
Submission of a written request to FDA asking that the order be modified or vacated--810.12(a-b)	1	1	1	8	8

Submission of a strategy for compliance with cease distribution and notification or mandatory recall order--810.14	2	1	2	16	32
Submission of periodic status reports to FDA to enable the Agency to assess progress in compliance with the order--810.16(a-b)	2	12	24	40	960
Submission of a written request to FDA to certify compliance with and terminate the order--810.17(a)	2	1	2	8	16
Total Hours					1,040

Table 2.—Estimated Annual Recordkeeping Burden

Collection Activity--21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Documentation of communications to appropriate person(s)--810.15(b)	2	1	2	8	16

Table 3.—Estimated Annual Third-Party Disclosure Burden

Collection Activity--21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Communications to appropriate person(s) concerning a cease distribution and notification or mandatory recall order--810.15(a)-(c)	2	1	2	12	24
Follow up communications to appropriate person(s) who fail to respond to the initial communication--810.15(d)	2	1	2	4	8
Notifications provided by recipients of communications to appropriate consignees--810.15(e)	10	1	10	1	10
Total					42

The total burden hours for this ICR is 1,098 hours.

21 CFR 810.10(d) – Collections Specified in the Order - Reporting

FDA may require the person named in the cease distribution and notification order to submit certain information to the agency, e.g., distribution information, progress reports.

21 CFR 810.11(a) – Request for Regulatory Hearing - Reporting

A request for regulatory hearing regarding the cease distribution and notification order must be submitted in writing to FDA.

21 CFR 810.12 (a) and (b) – Written Request for Review - Reporting

In lieu of requesting a regulatory hearing under § 810.11, the person named in the cease distribution and notification order may submit a written request to FDA asking that the order be modified or vacated. A written request for review of a cease distribution and notification order shall identify each ground upon which the requestor relies in asking that the order be modified or vacated, address an appropriate cease distribution and notification strategy, and address whether the order should be amended to require a recall of the device that was the subject of the order and the actions required by such a recall order.

21 CFR 810.14 – Mandatory Recall Strategy - Reporting

The person named in the cease distribution and notification order or a mandatory recall order must develop and submit a strategy to FDA for complying with the order that is appropriate for the individual circumstances.

21 CFR 810.15 (a) – (c) – Notifications to Recipients - Third-Party Disclosure

The person named in a cease distribution and notification order or a mandatory recall order must promptly notify each health professional, user facility, consignee, or individual of the order.

21 CFR 810.15(b) – Documentation of Notifications to Recipients – Recordkeeping

Telephone calls or other personal contacts may be made in addition to, but not as a substitute for, the verified written communication, and shall be documented in an appropriate manner.

21 CFR 810.15(d) – Notification to Recipients; Follow-up – Third-Party Disclosure

The person named in the cease distribution and notification order or mandatory recall order shall ensure that follow-up communications are sent to all who fail to respond to the initial communication.

21 CFR 810.15 (e) – Notification of Consignees by Recipients - Third-Party Disclosure

Health professionals, device user facilities, and consignees should immediately notify their consignees of the order.

21 CFR 810.16(a)-(b) – Periodic Status Reports - Reporting

The person named in a cease distribution and notification order or a mandatory recall order must submit periodic status reports to FDA to enable the agency to assess the person's progress in complying with the order. The frequency of such reports and the agency official to whom such reports must be submitted will be specified in the order.

21 CFR 810.17(a) – Termination Request - Reporting

The person named in a cease distribution and notification order or a mandatory recall order may request termination of the order by submitting a written request to FDA. The person submitting a request must certify that he or she has complied in full with all the requirements of the order and shall include a copy of the most current status report submitted to the agency.

12b. Annualized Cost Burden Estimate

The cost of a recall varies widely depending upon the number of products involved, the number of persons using the device, and the ease in finding these persons. Because we have not issued any mandatory recall orders in recent years, it is difficult to accurately estimate what the cost of a recall would be to associated industry.

The estimated annual cost for a company to pay an employee to respond to the information collection is based on the average hourly salary of the type of respondent multiplied by the total burden hours. We used the mean hourly wage rate for nurses (occupation code 29-1141, \$45.42) and for physicians (occupation code 29-1216, \$118.01), based on the "May 2023 National Occupational Employment and Wage Estimates United States," which is available at http://www.bls.gov/oes/current/oes_nat.htm#29-0000. We then doubled these hourly wages to

account for benefits and overhead (\$90.84 and \$236.02, respectively). Assuming the total burden hours are evenly distributed between nurses and physicians, we estimate that the average annualized burden cost for respondents to prepare and submit records and reports is approximately \$129,575 (rounded) for physicians and \$49,871 (rounded) for nurses; \$179,446 total.

Estimates of annualized cost burden are provided in the chart below:

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Physicians	549	\$236.02	\$129,575
Nurses	549	\$90.84	\$49,871
Total			\$179,446

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

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

14. Annualized Cost to the Federal Government

FDA anticipates the Federal government will use 1 full-time employee to implement the Medical Device Recall Authority regulation required by section 518(e) of the FD&C Act. The total estimated annual cost to the government is \$365,789. This estimate is based on the 2023 hourly wage rate for a GS-15 step 10 employee in the WASHINGTON-BALTIMORE-ARLINGTON, DC-MD-VA-WV-PA area (\$87.93),* then doubled to include benefits and overhead (\$175.86 = \$87.93 x 2). We then multiplied this fully-loaded wage rate by 2,080 hours per year (\$365,789 = \$175.86 x 2,080).

* https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2023/DCB_h.pdf

15. Explanation for Program Changes or Adjustments

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. There is a small reduction in recordkeeping responses to correct a data-entry error from the previous ROCIS entry.

16. Plans for Tabulation and Publication and Project Time Schedule

The information collection will not be published or tabulated.

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

FDA will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.