U.S. Food and Drug Administration
Medical Device Recall Authority
21 CFR Part 810
OMB Control No. 0910-0432

SUPPORTING STATEMENT **Part A: Justification**

Terms of Clearance: None.

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) promulgated 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 to, if FDA finds that there is reasonable probability that the device intended for human use would cause serious adverse health consequences or death: (1) to immediately cease distribution of such device; and (2) to 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 is requesting approval from the Office of Management and Budget (OMB) for the extension of collection of information required by 21 CFR part 810, as promulgated by section 518(e) of the FD&C Act. Below is a description of the information collection requirements in part 810, subpart B:

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.

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 21 CFR Part 7, Subpart C, for which the agency has a long record of experiences. 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.

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 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.

5. Impact on Small Businesses or Other Small Entities

Using the guidelines set by the Small Business Administration (SBD) on what constitutes a small business, for manufacturing, a small business cannot exceed 500 employees. Approximately 95% of U.S. medical device manufacturing establishments are under 500 employees.

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). DICE helps to assure that the burden on 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

Respondents will respond to the information collection occasionally.

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. 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 February 22, 2018 (83 FR 7740). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

FDA will not provide payment or gifts to respondents of this collection information.

10. Assurance of Confidentiality Provided to Respondents

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 (21 U.S.C. 552(b) (I-90)). 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. Recalls and other information submitted to FDA under 21 CFR Part 810 are releasable under 21 CFR Part 20.

Analysis of Potential Privacy Risks and Requirements/Assurance of Privacy

In renewing this ICR, staff from FDA's Center for Device and Radiological Health, Office of the Center Director consulted the Center for Device and Radiological Health, Office of Communications and Education, Division of Information Disclosure and the FDA Privacy Officer to identify potential risks to the privacy of individuals whose information may be handled by or on behalf of FDA in association with the information collection, if finalized as proposed. In this case, the subject collection does not involve solicitation or collection of personally identifiable information (PII) by or on behalf of FDA/CDRH. Specifically, FDA/CDRH does not solicit or intend to collect personally identifiable information (PII) and will not maintain records subject to the Privacy Act or otherwise operate a Privacy Act System of Records in relation to this proposed collection.

11. Justification for Sensitive Questions

This information collection does not include questions pertaining to sexual behavior, attitude, religious beliefs, or any other matters that are commonly considered private or sensitive in nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

The following estimates are based on FDA's experience with voluntary recalls under 21 CFR Part 7. FDA expects no more than two (2) mandatory recalls per year, as most recalls are done voluntarily.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

Collection Activity--21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Collections Specified in the Order--810.10(d)	2	1	2	8	16
Request for Regulatory Hearing--810.11(a)	1	1	1	8	8
Written Request for Review--810.12(a-b)	1	1	1	8	8
Mandatory Recall Strategy--810.14	2	1	2	16	32
Periodic Status Reports--810.16(a-b)	2	12	24	40	960
Termination Request--810.17(a)	2	1	2	8	16
Total Hours					1,040

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

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

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
Notification to Recipients—810.15(a)-(c)	2	1	2	12	24
Notification to Recipients; Follow-up—810.15(d)	2	1	2	4	8
Notification of Consignees by Recipients—810.15(e)	10	1	10	1	10
Total					42

12b. Annualized Cost Burden Estimate

The agency has not issued any mandatory recall over the past three years. 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 virtually impossible to estimate what the cost of a recall would be to industry associated.

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. The average hourly wage cost including overhead is $34.00 for nurses and $100.00 an hour for a physician, which is based on the "May 2017 National Occupational Employment and Wage Estimates United States" that is available at http://www.bls.gov/oes/current/oes_nat.htm#29-0000. 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 $54,500 for physicians and $18,530 for nurses; $73,030 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	545	$1000.00	$54,500
Nurses	545	$34.00	$18,530
Total			$73,030

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 FTE to implement the Medical Device Recall authority regulation required by section 518(e) of the Act. The total estimated annual cost to the government is $292,383 based on the agency's projected average cost for an FTE including their benefits*.

*Based on the Department of Health and Human Services, Fiscal Year 2017, Food and Drug Administration, Justification of Estimates for Appropriations Committees--ALL PURPOSE table (pp. 9-11).

15. Explanation for Program Changes or Adjustments

There are no changes in burden hour estimate from the previous information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no tabulated results to publish for this information collection.

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

FDA is not requesting an exemption for display of the OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.