

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹—Continued

21 CFR section; activity	Number of record-keepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours ²
117.475(c)(7) through (c)(9); supplier records	16,285	10	162,850	4	651,400
117.180(d); training records for preventive controls qualified individual	46,685	1	46,685	0.25 (15 minutes)	11,671
Subpart A—General Provisions					
507.4(d); documentation of animal food safety and hygiene training	7,469	0.75	5,579	0.05 (3 minutes)	279
Subpart C—Hazard Analysis and Risk-Based Preventive Controls					
507.31 through 507.55; food safety plan—including hazard analysis, preventive controls, and procedures for monitoring, corrective actions, verification, recall plan, validation, reanalysis, modifications, and implementation records.	7,469	519	3,876,411	0.1 (6 minutes)	387,641
Subpart E—Supply Chain Program					
507.105 through 507.175; written supply-chain program—including records documenting program.	7,469	519	3,876,411	0.1 (6 minutes)	387,641
Subpart F—Requirements Applying to Records That Must Be Established and Maintained					
507.200 through 507.215; general requirements, additional requirements applying to food safety plan, requirements for record retention, use of existing records, and special requirements applicable to written assurance.	7,469	519	3,876,411	0.1 (6 minutes)	387,641
Total					7,400,400

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.
² Total hours have been rounded.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

21 CFR section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
117.201(e); disclosure of food manufacturing facility address	37,134	1	37,134	0.25 (15 minutes)	9,284
507.27(b); labeling for the animal food product contains the specific information and instructions needed so the food can be safely used for the intended animal species.	330	10	3,300	0.25 (15 minutes)	825
507.7(e)(1); change labels on products with labels	1,120	4	4,480	1	4,480
507.7(e)(2); change address on labeling (sales documents) for qualified facilities.	974	1	974	1	974
507.25(a)(2); animal food, including raw materials, other ingredients, and rework, is accurately identified.	373	312	116,376	0.01 (36 seconds)	1,163.76
507.28(b); holding and distribution of human food by-products for use as animal food.	40,798	2	81,596	0.25 (15 minutes)	20,399
Total					37,125.76

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

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: May 31, 2024.
Lauren K. Roth,
Associate Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2381]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device Recall Authority

AGENCY: Food and Drug Administration, HHS.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are

required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions related to Medical Device Recall Authority.

DATES: Either electronic or written comments on the collection of information must be submitted by August 5, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of

August 5, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2024-N-2381 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device Recall Authority." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 240-994-7399, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal

Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Device Recall Authority—21 CFR Part 810

OMB Control Number 0910-0432—Extension

This collection of information helps to implement section 518(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360h(e)) and regulations in part 810 (21 CFR part 810) which set forth mandatory medical device recall authority provisions. Section 518(e) of the FD&C Act provides FDA with the authority to issue an order requiring an 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.

The person named in the order will have an opportunity for a regulatory hearing or to provide a written request to FDA asking that the order be modified, vacated, or amended. FDA may later amend the order to require a mandatory recall of the device. 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 issued part 810 to implement the provisions of section 518 of the FD&C Act. The information collected under the mandatory recall authority

provisions is used by FDA to implement mandatory recalls.

Description of Respondents: Respondents for this collection of information are firms, 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 part 810, during the timeframe(s) specified in the order.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Collection activity—21 CFR section	Number of respondents	Number 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

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

Collection activity—21 CFR section	Number of record-keepers	Number 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

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

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

Collection activity—21 CFR section	Number of respondents	Number 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

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

The burden per response, burden per recordkeeping, and burden per disclosure estimates are based on FDA’s recent experience with voluntary recalls under 21 CFR part 7. Based on an analysis of cease distribution and notification and mandatory recall order activity over the last 3 years, FDA expects no more than two of such actions per year as a conservative estimate.

Based on a review of the information collection since our last request for

OMB approval, we have made no adjustments to our burden estimate.

Dated: May 31, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–new]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the