Dated: October 10, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4066]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Drug Administration Recall Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 FDA Recall Regulations.

DATES: Either electronic or written comments on the collection of information must be submitted by December 12, 2023.

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 December 12, 2023. 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–2023–N–4066 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; FDA Recall Regulations.'' 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: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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.

FDA Recall Regulations—21 CFR Part 7

OMB Control Number 0910–0249—Extension

This information collection helps support implementation of section 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371) pertaining to product recalls, and regulations in 21 CFR part 7, subpart C (21 CFR 7.40 through 7.59) promulgated to clarify and explain associated practices and procedures by FDA. Sections 7.49, 7.50, and 7.59 (21 CFR 7.49, 7.50, and 7.59) of the regulations apply specifically to product recalls, which may be undertaken voluntarily and at any time by manufacturers and distributors, or at the request of the Agency.

Recalls are terminated when all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy. The regulations also provide for corrective actions to be taken regarding violative products and establish specific guidelines that enable us to monitor and assess the effectiveness of a firm's efforts in this regard. The provisions include reporting to FDA on the initiation and termination of a recall, as well as submitting recall status reports and making required communication disclosures. The regulations also permit FDA to evaluate whether a recall has been completed in a manner which assures that unreasonable risk of substantial harm to the public health has been eliminated and that violative products have been corrected or removed from the market. Specific guidance regarding recalls is set forth in § 7.59, although product-specific guidance documents may also be developed to assist respondents to the information collection. Agency guidance documents are issued in accordance with our good guidance regulations in 21 CFR 10.115, which provide for public comment at any time.

Consistent with § 7.50, all recalls monitored by FDA are included in an ''Enforcement Report'' once they are classified and may be listed prior to classification when FDA determines the firm's removal or correction of a marketed product(s) meets the definition of a recall. Recall data in the Enforcement Report can be accessed through the weekly report publication, the quick and advanced search functionalities, and an Application Programming Interface (API). Instructions for navigating the report, accessing and using the API, and definitions of the report contents are found at *https://www.fda.gov/safety/enforcement-reports/enforcement-report-information-and-definitions.*

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; 21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Firm initiated recall; § 7.46	2,309	1	2,309	25	57,725
Termination of recall; § 7.55	2,128	1	2,128	10	21,280
Recall status reports; § 7.53	2,309	13	30,017	10	300,170
Total			34,454		379,175

[1] There are no capital or operating and maintenance costs associated with this collection.

A review of Agency data shows that 6,928 recall events were conducted during fiscal years 2020 through 2022, for an average of 2,309 recalls annually. We assume an average of 25 hours is needed to submit the requisite notification to FDA, for a total annual burden of 57,725 hours. Similarly, during the same period, 6,385 recalls were terminated, for an average of 2,128 recall terminations annually, and we assume an average of 10 hours is needed for the corresponding information collection activity. To determine burden associated with recall status reports, we multiplied the average number of annual respondents (2,309) by the average number of status reports per recall (13), producing the number annual submissions (30,017), which, assuming 10 hours per response, results in a burden of 300,170 hours annually.

TABLE 2—ESTIMATED THIRD-PARTY DISCLOSURE BURDEN [1]

Activity; 21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Recall communications; § 7.49	2,309	1,108	2,559,200	0.05 (3 minutes)	127,960

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

To determine burden associated with recall communication disclosures described in § 7.49, we calculated an average of 1,108 disclosures per recall and attribute 3 minutes for each disclosure, resulting in 127,960 burden hours annually. We provide no estimate for recordkeeping in § 7.59 as these activities are provided as guidance only, and we regard them to be usual and customary to these respondents.

Cumulatively, these adjustments reflect an overall decrease in our estimate, which we attribute to a corresponding decrease in FDA-regulated product recalls since our last evaluation of the information collection.

Dated: October 10, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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