



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1031]

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 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 information collection provisions associated with FDA recalls for products regulated by the Agency.

DATES: Submit either electronic or written comments on the collection of information by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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-2014-N-1031 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 part 7 (21 CFR part 7), subpart C promulgated to clarify and explain associated practices and

procedures. Regulations in part 7, subpart C §§ 7.49, 7.50, and 7.59 (21 CFR 7.49, 7.50, and 7.59) 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 requirements that enable us to monitor and assess the adequacy 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. 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.com>.

We estimate the burden of the collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Activity; 21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Firm initiated recall; § 7.46	2,779	1	2,779	25	69,475
Termination of recall; § 7.55	2,095	1	2,095	10	20,950
Recall status reports; § 7.53	2,779	13	36,127	10	361,270
Total			41,001		451,695

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

A review of Agency data shows that 8,337 recalls were conducted during fiscal years 2017 through 2019, for an average of 2,779 recalls annually. We assume an average of 25 hours is needed to submit the requisite notification to FDA, for a total annual burden of 69,475 hours. Similarly, during the same period, 6,287 recalls were terminated, for an average of 2,095 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 divided the average number of annual submissions (36,127) by the average number of annual respondents (2,779) and assume 10 hours is necessary for the corresponding information collection, resulting in 361,270 hours annually.

Table 2.--Estimated Annual Third-Party Disclosure Burden¹

Activity; 21 CFR Part	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Recall communications; § 7.49	2,779	445	1,236,655	0.05 (3 minutes)	61,832.75

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 445 disclosures per recall and attribute 3 minutes for each disclosure, resulting in 61,832.75 burden hours annually.

These estimates reflect an overall decrease in the average number of annual responses by 245,846 and a decrease in the average number of annual burden hours by 70,949.25 since our last submission for OMB review and approval of the information collection.

Dated: January 4, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-00125 Filed: 1/7/2021 8:45 am; Publication Date: 1/8/2021]