4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-4066]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0249. Also include the FDA docket number found in brackets in the heading of this document.

F**OR 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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

FDA Recall Regulations--21 CFR Part 7

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.

In the *Federal Register* of October 13, 2023, (88 FR 70995), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received offering general support for the information collection. The comment also suggested that reporting might be enhanced through the use of automated technology and that FDA monitor and utilize such technology to track improvement. Finally, the comment questioned the rationale for our estimate of the time necessary for preparing and submitting recall reports. Based on experience with compiling and submitting a report along with its attachments, the commenter communicated that less time was likely needed.

We appreciate this feedback and will continue to monitor burden associated with product recall activity. We also continue to look for ways to enhance our IT systems as our limited resources allow and public health priorities require. With regard to our current estimates, we note that our figures reflect what we believe to be the average burden incurred among more than 2,000 respondents, and in conjunction with more than 30,000 reports, annually, and therefore we have made no adjustment in our assumptions at this time.

We estimate the burden of the information collection as follows:

Table 1.--Estimated Annual Reporting Burden[1]

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	2,309	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	No. of Respondents	No. 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: April 24, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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