4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-6175]

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) 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: Fax written comments 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 faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0249. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, 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

OMB Control Number 0910-0249--Extension

Section 701 of the Federal Food, Drug, and Cosmetic Act charges the Secretary of Health and Human Services, through FDA, with the responsibility of assuring recalls (21 U.S.C. 371, Regulations and Hearings, and 21 CFR part 7, Enforcement Policy, Subpart C, Recalls (Including Product Corrections)--Guidance on Policy, Procedures, and Industry Responsibilities which pertain to the recall regulations and provide guidance to manufacturers on recall responsibilities). The regulations and guidance apply to all FDA-regulated products (i.e., food, including animal feed; drugs, including animal drugs; medical devices, including in vitro diagnostic products; cosmetics; biological products intended for human use; and tobacco).

These responsibilities of companies conducting recalls include providing FDA with complete details of the recall including: (1) reason(s) for the removal or correction, risk evaluation, quantity produced, distribution information, firm's recall strategy, a copy of any recall communication(s), and a contact official (§ 7.46); (2) notifying direct accounts of the recall, providing guidance regarding further distribution, giving instructions as to what to do with the product, providing recipients with a ready means of reporting to the recalling firm (§ 7.49); and (3) submitting periodic status reports so that FDA may assess the progress of the recall. Status report information may be determined by, among other things, evaluation return reply cards, effectiveness checks and product returns (§ 7.53), and providing the opportunity for a firm to request in writing that FDA terminate the recall (§ 7.55(b)).

A search of the FDA database was performed to determine the number of recalls that took place during fiscal years 2014 to 2016. The resulting number of total recalls and terminations (8,560) from this database search were then averaged over the 3 years, and the resulting per year average of recalls and terminations (2,853) are used in estimating the current annual reporting and third party disclosure burden in this notice.

FDA estimates, in the following tables, the total annual reporting and third party burden to collect and provide the required information to be 584,477 hours.

In the *Federal Register* of November 17, 2017 (82 FR 54359), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received one comment that did not suggest any changes to the information collection or burden estimates.

The following is a summary of the estimated annual burden hours for recalling firms (manufacturers, processors, and distributors) to comply with the reporting requirements of FDA's recall regulations. Recognizing that there may be a vast difference in the information collection and reporting time involved in different recalls of FDA's regulated products, this summary reflects numbers across FDA.

FDA estimates the burden of this collection of information 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) and recall communications (§ 7.49)	2,853	1	2,853	25	71,325
Recall status reports (§ 7.53)	2,853	13	37,089	10	370,890
Termination of a recall (§ 7.55(b))	2,853	1	2,853	10	28,530
General industry guidance (§ 7.59)	2,853	1	2,853	15	42,795
Total					513,540

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

A. Firm Initiated Recall and Recall Communications

We request firms that voluntarily remove or correct foods and drugs (human or animal), cosmetics, medical devices, biologics, and tobacco to immediately notify the appropriate FDA District Office of such actions. The firm is to provide complete details of the recall reason, risk evaluation, quantity produced, distribution information, firms' recall strategy, and a contact official as well as requires firms to notify their direct accounts of the recall and to provide recipients with a ready means of reporting to the recalling firm. The estimates in table 1 are multiplied across the FDA product centers to arrive at a reporting burden estimate of 71,325 for firm initiated recall and recall communications.

B. Recall Status Reports

We request that recalling firms provide periodic status reports so FDA can ascertain the progress of the recall. This request only applies to firms with active recalls, and periodic status reports are estimated to be reported every 2 to 4 weeks. The estimates in table 1 are multiplied across the FDA product centers to arrive at a reporting burden estimate of 370,890 hours for recall status reports.

C. Termination of a Recall

We provide the firms an opportunity to request in writing that FDA end the recall. The Agency estimates it will receive 2,853 responses annually based on the average number of terminations over the past 3 fiscal years. The estimates in table 1 are multiplied across the FDA product centers to arrive at a reporting burden estimate of 28,530 for termination of a recall.

D. Enforcement Policy

We request that firms prepare and maintain a current written contingency plan for use in initiating and effecting a recall in accordance with §§ 7.40 through 7.49, 7.53, and 7.55; use

sufficient coding of regulated products to make possible positive lot identification and to facilitate effective recall of all violative lots and maintain such product distribution records as are necessary to facilitate location of products that are being recalled. Such records should be maintained for a period of time that exceeds the shelf life and expected use of the product and is at least the length of time specified in other applicable regulations concerning records retention. The estimates in table 1 are multiplied across the FDA product centers to arrive at a reporting burden estimate of 42,795 for enforcement policy.

E. Recall Communications

We request that firms notify their consignees of the recall and to provide recipients with a ready means of reporting to the recalling firm.

Table 2--Estimated Annual 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)	2,853	518	1,477,854	0.048 (2.88 minutes)	70,937

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

The estimates in table 2 are multiplied across the FDA product centers to arrive at a total third party disclosure burden estimate of 70,937.

FDA regulates many different types of products including, but not limited to, medical products, food and feed, cosmetics, and tobacco products. FDA notes that not all third-party disclosures provided by firms to their consignees are similar in nature and may entail different methods and mediums of communication. The total burden hours have decreased since the last information collection approval based on a reduction in the number of respondents.

Dated: February 21, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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