DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1027]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Infant Formula Recall Regulations

AGENCY: Food and Drug Administration, Health and Human Services (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: Submit written comments (including recommendations) on the collection of information by September 11, 2020.

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 0910–0188. Also include the FDA docket number found in brackets in the heading of this document.

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

Infant Formula Recall Regulations—21 CFR 107.230, 107.240, 107.250, 107.260, and 107.280

OMB Control Number 0910–0188—Extension

Section 412(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(e)) (FD&C Act) provides that if the manufacturer of an infant formula has knowledge that reasonably supports the conclusion that an infant formula processed by that manufacturer has left its control and may not provide the nutrients required in section 412(i) of the FD&C Act or is otherwise adulterated or misbranded, the manufacturer must promptly notify the Secretary of Health and Human Services (the Secretary). If the Secretary determines that the infant formula presents a risk to human health, the manufacturer must immediately take all actions necessary to recall shipments of such infant formula from all wholesale and retail establishments, consistent with recall regulations and guidelines issued by the Secretary. Section 412(f)(2) of the FD&C Act states that the Secretary shall by regulation prescribe the scope and extent of recalls of infant formula necessary and appropriate for the degree of risk to human health presented by the formula subject to recall. FDA's infant formula recall regulations in part 107 (21 CFR part 107) implement these statutory provisions.

Section 107.230 (21 CFR 107.230) requires each recalling firm to conduct an infant formula recall with the following elements: (1) Evaluate the hazard to human health, (2) devise a written recall strategy, (3) promptly notify each affected direct account (customer) about the recall, and (4) furnish the appropriate FDA district office with copies of these documents. If the recalled formula presents a risk to human health, the recalling firm must also request that each establishment that sells the recalled formula post (at point of purchase) a notice of the recall and provide FDA with a copy of the notice. Section 107.240 (21 CFR 107.240) requires the recalling firm to conduct an infant formula recall with the following elements: (1) Notify the appropriate FDA district office of the recall by telephone within 24 hours, (2) submit a written report to that office within 14 days, and (3) submit a written status report at least every 14 days until the recall is terminated. Before terminating a recall, the recalling firm is required to submit a recommendation for termination of the recall to the appropriate FDA district office and wait for FDA's written concurrence (§ 107.250 (21 CFR 107.250)). Where the recall strategy or implementation is determined to be deficient, FDA may require the firm to change the extent of the recall, carry out additional effectiveness checks, and issue additional notifications (§ 107.260 (21 CFR 107.260)). In addition, to facilitate location of the product being recalled, the recalling firm is required to maintain distribution records for at least 1 year after the expiration of the shelf life of the infant formula (§ 107.280 (21 CFR 107.280)).

The reporting and recordkeeping requirements described previously are designed to enable FDA to monitor the effectiveness of infant formula recalls in order to protect babies from infant formula that may be unsafe because of contamination, nutritional inadequacy, or is otherwise adulterated or misbranded. FDA uses the information collected under these regulations to help ensure that such products are quickly and efficiently removed from the market.

Description of Respondents: Respondents to this collection of information are manufacturers of infant formula who are for-profit businesses in the private sector.

In the **Federal Register** of April 27, 2020 (85 FR 23367), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
107.230; Elements of infant formula recall	2	1	2	4,450	8,900
107.240; Notification requirements	2	1	2	1,482	2,964
107.250; Termination of infant formula recall	2	1	2	120	240
107.260; Revision of an infant formula recall	1	1	1	625	625

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total [2]					12,729

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] No burden has been estimated for the recordkeeping requirement in § 107.280 because these records are maintained as a usual and customary part of normal business activities. Manufacturers keep infant formula distribution records for the prescribed period as a matter of routine business practice.

The reporting and third-party disclosure burden estimates are based on Agency data, which shows that there are six manufacturers of infant formula and that there have been, on average, two infant formula recalls per year for the past 3 years. Based on this information, we estimate that there are, on average, approximately two infant formula recalls per year.

Thus, we estimate that two respondents conduct recalls annually pursuant to §§ 107.230, 107.240, and 107.250. The estimated number of respondents for § 107.260 is minimal because we seldom use this section; therefore, we estimate that there are one or fewer respondents annually for § 107.260. The estimated number of hours per response is an average based on our experience and information from firms that have conducted recalls. We estimate that two respondents will conduct infant formula recalls under § 107.230 and that it takes 4,450 hours to comply with the requirements of that section, for a total of 8,900 hours. We estimate that two respondents conduct infant formula recalls under § 107.240 and that it takes a respondent 1,482 hours to comply with the requirements of that section, for a total of 2,964 hours. We estimate that two respondents submit recommendations for termination of infant formula recalls under § 107.250 and that it takes a respondent 120 hours to comply with the requirements of that section, for a total of 240 hours. Finally, we estimate that one respondent needs to carry out additional effectiveness checks and issue additional notifications, for a total of 625 hours. Therefore, the total annual burden hours for reporting is 12,729 hours (8,900 + 2,964 + 240 + 625).

Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities. No burden has been estimated for the recordkeeping requirement in § 107.280 because these records are maintained as a usual and customary part of normal business activities. Manufacturers keep infant formula distribution records for the prescribed period as a matter of routine business practice.

TABLE 2—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
107.230; Elements of infant formula recall	2	1	2	50	100
107.260; Revision of an infant formula recall	1	1	1	25	25
Total					125

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

Table 2 reports FDA's third-party disclosure burden estimates for §§ 107.230 and 107.260. The estimated burden hours per disclosure is an average based on our experience with the information collection. The third-party disclosure burden in § 107.230 is the requirement to promptly notify each affected direct account (customer) about the recall, and if the recalled formula presents a risk to human health, the recalling firm must also request that each establishment that sells the recalled formula post a notice of the recall at the point of purchase. We estimate that two respondents conduct infant formula recalls under § 107.230 and that it takes a respondent 50 hours to comply with the third-party disclosure requirements of that section, for a total of 100 hours. The third-party disclosure burden in § 107.260 is the requirement to issue additional notifications where the recall strategy or implementation is determined to be deficient. We estimate that one respondent issues additional notifications under § 107.260 and that it takes a respondent 25 hours to comply with the third-party disclosure requirements of that section, for a total of 25 hours. The total annual third-party disclosure burden is 125 hours (100 + 25).

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: August 6, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–17542 Filed 8–11–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–2966]

Male Breast Cancer: Developing Drugs for Treatment; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.