United States Food and Drug Administration

Infant Formula Recall Regulations

OMB Control No. 0910-0188

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Section 412(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350a(e)) 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 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 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 written FDA concurrence (§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). 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).

We therefore request OMB approval of the following information collection requirements contained in part 107:

21 CFR 107.230 – Reporting and Third-Party Disclosure

Requires the evaluation the hazard to human health, devise a written recall strategy, and furnish the appropriate FDA district office with copies of these documents and a copy of the notice of the recall, if one is required.

Requires prompt notification of each affected direct-account (customer) about the recall and if the recalled formula presents a risk to human health, the requirement that the recalling firm must also request that each establishment that sells the recalled formula post (at point of purchase) a notice of the recall.

21 CFR 107.240 - Reporting

Requires the recalling firm to notify the appropriate FDA district office of the recall by telephone within 24 hours, to submit a written report to that office within 14 days, and to submit a written status report at least every 14 days until the recall is terminated.

21 CFR 107.250 - Reporting

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 written FDA concurrence.

21 CFR 107.260 - Reporting and Third-Party Disclosure

Requires changing the extent of the recall and carrying out additional effectiveness checks where the recall strategy or implementation is determined to be deficient.

Requires issuing additional notifications where the recall strategy or implementation is determined to be deficient.

21 CFR 107.280 - Recordkeeping

Requires the recalling firm to maintain distribution records for at least 1 year after the expiration of the shelf life of the infant formula, to facilitate location of the product being recalled.

2. Purpose and Use of the Information Collection

The reporting, third-party disclosure, 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 or nutritional inadequacy or 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.

3. Use of Improved Information Technology and Burden Reduction

Section 107.240 requires that infant formula manufacturers notify the appropriate district office by telephone and by written confirmation. Therefore, FDA estimates that none (0%) of the written reports to FDA will be submitted electronically in the next three years. Regarding the third-party disclosure required by §§107.230 and 107.260, companies are free to use whatever forms of technology may best assist them in making direct-account (customer) notifications. Thus, the agency estimates that all (100%) of the direct-account (customer) notifications will be made electronically.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only Federal agency with the authority to conduct infant formula recalls. Thus, FDA is the only Federal agency that collects this information. In addition, there are no similar data that can be used or modified for this use. Each recall of an infant formula product is unique. The information needed to accomplish the recall is the exact shipping and distribution pattern for a specific lot or group of lots of a particular product. Therefore, the information being submitted to the agency will be original for each submission.

5. Impact on Small Businesses or Other Small Entities

FDA estimates that ten percent (10%) of respondents are small businesses. The production of processed foods requires that producers take on a very high degree of responsibility, especially for infant formula products. In the event of a recall, the safety of infants is involved and the first priority is the removal of hazardous foods (infant formulas) from channels of commerce. FDA will provide assistance to any firm in achieving this goal. Also, FDA aids small businesses in complying with its requirements through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the agency. FDA has provided a Small Business Guide on the agency's website at http://www.fda.gov/oc/industry/.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally. The information is only collected in the event of a recall. If the information collection is not conducted, or conducted less frequently than is

needed, FDA, in order to protect the public health, would be required to initiate seizure action or another type of regulatory action to remove these products from channels of commerce.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

   Respondents are required to report more often than quarterly and to prepare a written response in less than 30 days. In the event of a recall, §107.240 requires the recalling firm to notify the appropriate FDA district office of the recall by telephone within 24 hours, to submit a written report to that office within 14 days, and to submit a written status report at least every 14 days until the recall is terminated. This early notification allows the agency the opportunity to evaluate and comment on the recalling firm's strategy. In addition, such notification eliminates needless regulatory actions which the agency might otherwise take against violative products in order to protect the public health. For example, FDA would not normally initiate a seizure action against a violative infant formula if it knew that the shipment was being recalled by the responsible firm. Frequent reporting is required to protect the health of the infant consumer because these products are used as the sole source of sustenance for this highly vulnerable population group.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

   In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the Federal Register of June 15, 2017 (82 FR 27509). FDA received one comment which was unrelated to the information collection.

9. Explanation of Any Payment or Gift to Respondents

   FDA does not provide any payment or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

    FDA provides no assurance of confidentiality to firms that voluntarily decide to, or are required to, conduct recalls.

11. Justification for Sensitive Questions

    This information collection does not involve any questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

FDA estimates the burden of this collection of information as follows:

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

21 CFR Section; activity	No. of Respondents	No. 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 [2]	1	1	1	625	625
Total					12,729

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

The reporting and third-party disclosure burden estimates are based on FDA's records, which show 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, FDA estimates that there will be, on average, approximately two infant formula recalls per year over the next 3 years.

Thus, FDA estimates that two respondents will conduct recalls annually under §§ 107.230, 107.240, and 107.250. The estimated number of respondents for § 107.260 is minimal because FDA seldom uses this section; therefore, FDA estimates that there will be one or fewer respondents annually for § 107.260. The estimated number of hours per response is an average based on FDA's experience and information from firms that have conducted recalls. FDA estimates that two respondents will conduct infant formula recalls under § 107.230 and that it will take a respondent 4,450 hours to comply with the requirements of that section, for a total of 8,900 hours. FDA estimates that two respondents will conduct infant formula recalls under § 107.240 and that it will take a respondent 1,482 hours to comply with the requirements of that section, for a total of 2,964 hours. FDA estimates that two respondents will submit recommendations for termination of infant formula recalls under § 107.250 and that it will take a respondent 120 hours to comply with the requirements of that section, for a total of 240 hours. Finally, FDA estimates that one respondent will need to carry out additional effectiveness checks and issue additional notifications, for a total of 625 hours.

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	No. of Respondents	No. 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 FDA's experience. 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. FDA estimates that two respondents will conduct infant formula recalls under § 107.230 and that it will take 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. FDA estimates that one respondent will issue additional notifications under § 107.260 and that it will take a respondent 25 hours to comply with the third-party disclosure requirements of that section, for a total of 25 hours.

12b. Annualized Cost Burden Estimate

The annual hour cost burden to respondents is approximately $1,517,800 per year. FDA estimates that the average hourly wage for the employee preparing and submitting the request for certification would be equivalent to a GS-14/Step-4 level in the locality pay area of Washington-Baltimore in 2017, approximately $59.04/hour. Doubling this wage to account for overhead costs, FDA estimates the average hourly cost to respondents to be $118.08/hour. Thus, the overall estimated cost incurred by the respondents is

$1,517,800.32 (12,854 burden hours x $118.08/hour = $1,517,800.32, rounded to $1,517,800).

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Reporting	12,729	$118.08	$1,503,040.32
3rd-Party Disclosure	125	$118.08	$14,760
Total			$1,517,800.32

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating, or maintenance costs associated with this collection.

14. Annualized Cost to the Federal Government

The estimated cost to the Federal government to respond to the current level of infant formula recalls is approximately $312,824. This is based on the salaries of five (5) FTE's at an average salary of GS-13/Step 4 level in the locality pay area of Washington-Baltimore in 2017 ($104,275/year), who each spend an estimated 3/10 of their time on infant formula recalls (5 FTE x $104,275/yr x 0.3 = $156,412). To account for overhead, this cost is increased by 100 percent, making the estimated cost to the Federal government $312,824.

15. Explanation for Program Changes or Adjustments

There is no change in the estimated burden for this collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Once a recall of infant formula has been determined to be necessary, the firm is required to notify each of its affected accounts of the recall, and instruct each consignee to report whether or not they are in possession of the recalled infant formula and include a means to do so. If necessary, a public warning is to be given.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

We are not seeking approval to not display the expiration date for OMB approval of this information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.