

# UNITED STATES FOOD & DRUG ADMINISTRATION

## Infant Formula Recall Regulations

OMB Control No. 0910-0188

### SUPPORTING STATEMENT – **Part A: Justification**

#### 1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) regulations. 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, we 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 extension of OMB approval of the information collection requirements contained in 21 CFR part 107 as discussed in this supporting statement.

## 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. We use 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.

## 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, we estimate 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, we estimate that all (100%) of the direct-account (customer) notifications will be made electronically.

## 4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. We are the only Federal agency with the authority to conduct infant formula recalls. Thus, we are 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

We estimate 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. We will provide assistance to any firm in achieving this goal. We aid small businesses in dealing with the requirements of the FD&C Act through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the agency. We also provide assistance via our Small Business Assistance webpage on the agency's website at <https://www.fda.gov/industry/small-business-assistance>.

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, we would not normally initiate a seizure action against a violative infant formula if we 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), we published a 60-day notice for public comment in the *Federal Register* of April 27, 2020 (85 FR 23367). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments, or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

*Privacy Act:* In preparing this supporting statement, we consulted with our FDA Privacy Office to ensure appropriate handling of any personally identifiable information (PII) or information of a personal nature collected. In this collection, the PII collected is for business contact purposes only and includes business name, business address, and business telephone numbers. The business contact information is maintained and stored at the vendor facility. We further determined that although PII is collected and stored at the vendor facility, the collection is not subject to the Privacy Act of 1974, and the particular notice and other requirements of the Act do not apply. Specifically, we (including vendors or service providers acting on behalf of FDA) do not use name or any other personal identifier to retrieve records from the information collected. We also minimized the PII to be collected to protect the privacy of the individuals.

## 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 Cost

### *12a. Annualized Hour Burden Estimate:*

Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

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	1	1	1	625	625
Total					12,729

<sup>1</sup> 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.

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<sup>1</sup>

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

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

### 12b. Annualized Cost Burden Estimate

The annual hour cost burden to respondents is approximately \$1,643,769.52 per year. We estimate 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 2020, approximately \$63.94/hour. Doubling this wage to account for overhead costs, we estimate the average hourly cost to respondents to be \$127.88/hour. Thus, the overall estimated cost incurred by the respondents is \$1,643,769.52 (12,854 burden hours x \$127.88/hour).

Table 3.--Estimated Annual Cost Burden

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Reporting	12,729	\$127.88	\$1,627,784.52
3 <sup>rd</sup> -Party Disclosure	125	\$127.88	\$15,985.00
Total			\$1,643,769.52

### 13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or 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 \$338,790. This is based on the salaries of five (5) FTEs at an average salary of GS-13/Step 4 level in the locality pay area of Washington-Baltimore in 2020 (\$112,930/year), who each spend an estimated 3/10 of their time on infant formula recalls (5 FTE x \$112,930/yr x 0.3 = \$169,395). To account for overhead, this cost is increased by 100 percent, making the estimated cost to the Federal government \$338,790.

### 15. Explanation for Program Changes or Adjustments

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

### 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.