UNITED STATES FOOD & DRUG ADMINISTRATION

Infant Formula Requirements

OMB Control No. 0910-0256 – Revision

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports FDA regulations, and associated forms and guidance, pertaining to infant formula requirements. Statutory provisions for infant formula under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) were enacted to protect the health of infants and include specific current good manufacturing practice (CGMP), labeling (disclosure), and a number of reporting and recordkeeping requirements. Section 412 of the FD&C Act (21 U.S.C. 350a) requires manufacturers of infant formula to establish and document the adherence to quality control procedures, notify FDA when a batch of infant formula that has left the manufacturers' control may be adulterated or misbranded, and keep records of infant formula distribution. Notification requirements are also included in the regulations regarding the quantitative formulation of the infant formula; a description of any reformulation or change in processing; assurances that the formula will not be marketed until regulatory requirements are met as demonstrated by specific testing; and assurances that manufacturing processes comply with the regulations. The regulations are found in 21 CFR part 106: *Infant Formula Requirements Pertaining to Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Records and Reports, and Notifications*; and 21 CFR part 107: *Infant Formula*.

On our own initiative and for efficiency of agency operations, we are revising the information collection to include requirements in 21 CFR part 107, subpart E – Recalls (21 CFR 107.200 through 107.280) currently approved in control no. 0910-0188. Specifically, 21 CFR part 107.230 requires manufacturing firms conducting infant formula recalls to:

(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.

Similarly, regulations in 21 CFR part 107.240 require recalling firms to:

(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, recalling firms are 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). Finally, to facilitate identifying the 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 revised information collection, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

FDA uses the information collected to monitor the effectiveness of infant formula recalls and as part of our efforts to ensure the safety of infant formula.

3. Use of Improved Information Technology and Burden Reduction

The information collection utilizes FDA automated systems. We continue to enhance our collection technologies as our limited resources permit.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

We believe no undue burden is imposed on small entities. We assist small businesses in complying with our regulations through small business representatives, and scientific and administrative staffs within the agency. Additional assistance is available for small businesses via the agency's website at https://www.fda.gov/industry/small-business-assistance. We provide additional resources for infant formula at https://www.fda.gov/food/workshops-meetings-webinars-food-and-dietary-supplements/webinar-series-discuss-infant-formula-transition-plan-exercise-enforcement-discretion-11172022.

6. Consequences of Collecting the Information Less Frequently

Information collection schedules are consistent with applicable statutory and regulatory requirements.

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

There are no special circumstances associated with this information collection.

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

In the *Federal Register* of October 6, 2022 (87 FR 60689), we provided notice communicating updates to the information collection and invited public comment on the proposed collections of information. 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

The Privacy Act of 1974

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. Although personally identifiable information (PII) or information of a personal nature is collected, it is collected in the context of the subject individuals' professional capacity and the FDA-related work performed for their employer (e.g., point of contact at a regulated entity).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 Privacy 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.

The Freedom of Information Act (FOIA)

Under FOIA (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours

12a. Annualized Hour Burden Estimate

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	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.

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.

The reporting and third-party disclosure burden estimates are based on current available data showing eight 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. Accordingly, because we believe that associated records are maintained as a usual and customary part of normal business activities, we include no separate burden estimate for recordkeeping requirements found in in 21 CFR § 107.280.

12b. Annualized Cost Burden Estimate

To calculate the annual hour cost burden to respondents, we assume the average hourly wage for an employee preparing and submitting the request for certification to be that equivalent to a GS-14/Step-4 level in the locality pay area of Washington-Baltimore in 2020 ($63.94/hour). Doubling this cost to account for overhead, we multiply these wages $127.88/hour by the annual number of burden hours, resulting in an estimated annual cost to respondents of $1,643,769.52 annually.

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 information collection.

14. Annualized Cost to the Federal Government

Upon evaluation, we believe Federal costs allocated to implementing the infant formula recall requirements are included in the currently approved $272,773 we estimate for administering the information collection.

15. Explanation for Program Changes or Adjustments

We have revised the information collection to include activities applicable to regulations in 21 CFR part 107, subpart E (21 CFR 107.200 through 107.280) pertaining to **infant formula recalls**, currently approved in OMB control no. 0910-0188. This results in an increase of 10 responses and 12,854 hours of burden annually to the information collection. Upon OMB approval of this request we intend on discontinuing control no. 0910-0188.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

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

FDA continues to display the OMB control number, its expiration date, and communicates the significance of this information to respondents of the information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.