

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*.

The information collection also includes requirements in 21 CFR part 107, subpart E – Recalls (21 CFR 107.200 through 107.280). 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).

In December 2022, continuing efforts to protect infants and improve formula supply, the *Consolidated Appropriations Act, 2023* (Pub. Law 117-328) – Sec. 3401 provided for premarket submissions to FDA to address shortages. Specifically, at section 3401(g)(5), the statute provides for guidance regarding information sponsors may consider including in submissions as required under section 412 of the FD&C Act. Currently we communicate on our website at <https://www.fda.gov/food/infant-formula-guidance-documents-regulatory-information/regulations-and-information-manufacture-and-distribution-infant-formula#export>, that persons responsible for the manufacture or distribution of infant formula will be able to submit their registration and submission of information electronically in the future. We developed the draft

guidance document entitled, “*Notifying the Food and Drug Administration of a Permanent Discontinuance in the Manufacture or an Interruption of the Manufacture of an Infant Formula*,” (Shortages Guidance) (December 2024) and are inviting public comment under both our Good Guidance Practice regulations in 21 CFR 10.115, as well as the PRA provisions in 5 CFR 1320.8(d). See [89 FR 96261](#).

The information collection also includes recommended activity discussed in the guidance document, “*Protein Efficiency Ratio (PER) Rat Bioassay Studies to Demonstrate That a New Infant Formula Supports the Quality Factor of Sufficient Biological Quality of Protein*” among the related supporting material for the information collection. Specifically, regulations in 21 CFR 106.96(f) describe how an infant formula manufacturer must demonstrate that a formula meets the PER quality factor criteria. We developed the guidance document to help manufacturers and laboratories in the design, conduct, evaluation, and reporting of PER studies. The guidance is intended to explain how the PER study can be used to provide assurance that a new infant formula complies with current requirements, however we have made no adjustment to our currently approved burden estimate believing this task already falls within the scope of activity.

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 ensure the safety of infant formula and to monitor the necessity for and effectiveness of infant formula recalls.

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 July 17, 2026 (91 FR 44859), we published a 60-day notice requesting public comment on the proposed collections of information. Two comments were received. Both comments supported FDA's need for the information collections established by the regulatory requirements and recommended in associated guidance, as well as the Agency's use of IFTRACK and other electronic mechanisms utilized for collection. The comments also encouraged the continued development of automated collection techniques that would enhance our ability to efficiently receive and evaluate information. We appreciate all comments and will continue to explore enhanced collection methods and upgrade respective IT systems as our limited resources permit. Finally, while both comments discussed specific considerations and criteria FDA should apply in evaluating the safety of infant formula products and in assessing effort necessary to complete the required recordkeeping tasks, they suggested no change to the burden estimates proffered in our 60-day notice.

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 Hourly Burden Estimate*

Table 1.--Estimated Annual Reporting Burden¹

Collection Activity; Regulatory Authority	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Reports; Section 412(d) of the FD&C Act	5	13	65	10	650
Notifications; § 106.120(b)	1	1	1	4	4
Reports for exempt infant formula; § 107.50(b)(3) and (4)	3	2	6	4	24
Notifications for exempt infant formula; § 107.50(e)(2)	1	1	1	4	4
Requirements for quality factors - growth monitoring study exemption; § 106.96(c)	4	9	36	20	720
Requirements for quality factors - PER exemption; § 106.96(g)	1	34	34	12	408
New infant formula registration; § 106.110	4	9	36	0.50 (30 mins.)	18
New infant formula submission; § 106.120	4	9	36	10	360
Infant formula recalls; all elements and including associated recordkeeping	10	1	10	~1,285.4 hrs.	12854
Notification of a permanent discontinuance or an interruption of the manufacture of a critical food; draft guidance for Notifying FDA of a Permanent Discontinuance in the Manufacture or an Interruption of the Manufacture of an Infant Formula	8	1	8	2	16
Notify FDA of test results as discussed in constituent letter of March 8, 2023	20	1	20	0.25 (15 mins.)	5
TOTAL			253		15063

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

The estimates in table 1 are based on our experience with similar notification programs. Regarding activities found in the draft guidance, we estimate that each year 5 manufacturers of infant formula will submit notifications in compliance with section 424(a)(1) of the FD&C Act and following recommendations found in the draft guidance. We also estimate that each year 3 manufacturers of medical foods will submit notifications in compliance with section 424(a)(1) of the FD&C Act, for a total of 8 manufacturers of a critical food. We estimate that each manufacturer will submit 1 notification for 8 total annual notifications (8 manufacturers × 1 notification). Each submission will take an estimated 2 hours to complete for an annual reporting burden of 16 hours (8 notifications × 2 hours).

Table 2.--Estimated Annual Recordkeeping Burden^{1,2}

Information Collection Activity; Regulatory Authority	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Avg. Burden per Record	Total Hours
CGMP Requirements; 21 CFR part 106 subpart B	5	429.8	2,149	4.4	9,414
Quality control; audits; quality factors; records and reports; 21 CFR part 106 subparts C-E	5	726.8	3,634	6	21,818
Exempt infant formulas; 21 CFR part 107 subpart C	3	10	30	300	9,000
Exempt infant formula production; GMP; audits, recordkeeping, & reports	3	634	1,902	45	85,590
Risk management plan; draft guidance for Notifying FDA of a Permanent Discontinuance in the Manufacture or an Interruption of the Manufacture of an Infant Formula	11	1	11	60	660
Total ²					126,482

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

² Figures have been rounded.

Regarding recordkeeping found in the draft guidance, we estimate that each year 11 manufacturers of critical foods will create and maintain a risk management plan in compliance with section 424(b) of the FD&C Act. We estimate that each risk management plan will take an estimated 60 hours to create and maintain for an annual recordkeeping burden of 660 hours (11 records × 60 hours).

Table 3.--Estimated Annual Third-Party Disclosure Burden¹

Activity; 21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Nutrient labeling; §§ 107.10(a) and 107.20	5	13	65	8	520

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

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 (\$63.94/hour). We multiply this factor by the annual recordkeeping burden hours [126,482], resulting in an estimated annual cost to respondents of \$8,087,259.08 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 estimate Federal costs for implementing the infant formula provisions in 21 CFR parts 106 and 107 to be \$272,773.

15. Explanation for Program Changes or Adjustments

We have revised the information collection to include recommended activities and attendant burden found in the draft guidance titled “*Notifying FDA of a Permanent Discontinuance in the Manufacture or an Interruption of the Manufacture of an Infant Formula*” (December 2024). At the same time, we have removed burden attributable to the guidance “*Infant Formula Transition Plan for Exercise of Enforcement Discretion*” (September 2022) as we are no longer experiencing disruptions in the supply of infant formula in the United States and therefore did not extend the guidance’s end date. Cumulatively the change results in 96 fewer responses and 3,129 fewer burden hours annually. We have made no adjustments or changes to any other of the information collection elements.

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.