program assessment. These elements are enumerated and discussed on our website at *https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-november-2024* along with worksheets and assessments that allow FDA to determine conformance with the Retail Program Standards. State, local, territorial, tribal, and Federal regulatory agencies that participate in the voluntary program are required to report information demonstrating that a program self-assessment, a risk factor study of the regulated industry, and an independent outside audit (verification audit) have been completed. The information also includes Form FDA 3958, ''Voluntary National Retail Food Regulatory Program Standards FDA National Registry Report,'' which may be completed electronically at *https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-november-2024.*

We have created a dedicated email at *retailfoodprotectionstaff@fda.hhs.gov* to receive requests for program documentation and the following instruments to support the standardization of food safety inspection officer candidates:

- Form FDA 5017, ''Standardized Retail Food Safety Inspection Officer Waiver of Annual Maintenance Requirement,'' pertains to requests for waivers from maintenance requirements, referenced in section 3–403 of the ''FDA Procedures for Standardization of Retail Food Safety Inspection Officers.'' FDA uses the information submitted on Form FDA 5017 to determine a retail food safety inspection officer's eligibility for restandardization.
- Form FDA 5018, ''Standardized Retail Food Safety Inspection Officer Annual Maintenance Form,'' provides verification that a retail food safety inspection officer has met program standardization requirements in accordance with section 3–403 of the ''FDA Procedures for Standardization of Retail Food Safety Inspection Officers.''
- Form FDA 5019, ''Standardized Retail Food Safety Inspection Officer Nomination Form,'' allows FDA to collect qualification information from retail food safety inspection officer candidates.

Description of Respondents: Respondents to the information collection are State, local, territorial, and tribal regulatory agencies.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Voluntary national retail program standards (November 2024)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Program self-assessments for element Nos. 1 through 8	500	1	500	92.3	46,150
Program element No. 9; risk factor study and intervention strategy.	500	1	500	333	166,500
Program Verification audit	500	1	500	46.15	23,075
Program records; associated documentation/maintenance of worksheets, assessments, associated program tools.	500	1	500	94.29	47,145
Form FDA 3958; VNRFP National Registry Report	500	1	500	0.1 (6 minutes)	50
Requests for program documentation (dedicated email)	500	3	1,500	0.1 (6 minutes)	150
Form FDA 5017; Waiver of Annual Maintenance Requirement.	10	1	10	0.4 (24 minutes).	4
Form FDA 5018; Retail Food Safety Inspection Officer Annual Maintenance.	130	1	130	0.33 (20 minutes).	43
Form FDA 5019; Retail Food Safety Inspection Officer Nomination.	14	1	14	0.35 (21 minutes).	5
Total			4,154		283,122

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

Our estimate of burden for the associated program activities as identified in table 1 is based on our experience with the information collection, along with other regulatory standards programs we administer. Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–14435 Filed 7–16–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–7131]

Agency Information Collection Activities; Proposed Collection; Comment Request; Infant Formula Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of our infant formula regulations, including infant formula labeling, quality control procedures, notification requirements, and recordkeeping. The notice also solicits comment on electronic Form FDA 3978 that allows manufacturers of infant formula to submit reports and notifications in a standardized format.

DATES: Either electronic or written comments on the collection of

information must be submitted by September 15, 2026.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 15, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2026–N–7131 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Infant Formula Requirements.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Michael Ellison, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–402–2093, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Infant Formula Requirements—21 CFR Parts 106 and 107

OMB Control Number 0910–0256—Revision

Statutory requirements for infant formula under the Federal Food, Drug, and Cosmetic Act (FD&C Act) are intended to protect the health of infants and include a number of reporting and recordkeeping requirements. Among other things, section 412 of the FD&C Act (21 U.S.C. 350a) requires manufacturers of infant formula to establish and adhere to quality control procedures, notify us when infant formula that has left the manufacturers' control may be adulterated or misbranded, and keep records of infant formula distribution. We have issued regulations to implement the FD&C Act's requirements for infant formula in parts 106 and 107 (21 CFR parts 106 and 107). We also regulate the labeling of infant formula under the authority of section 403 of the FD&C Act (21 U.S.C. 343). Under our labeling regulations for infant formula in part 107, the label of an infant formula must include nutrient information and directions for use.

Failure to comply with any of the applicable labeling regulations will render an infant formula misbranded under section 403 of the FD&C Act. The purpose of these labeling requirements is to ensure that consumers have the information they need to prepare and use infant formula appropriately.

While the infant formula regulations help ensure the consistent production of safe and nutritionally adequate infant formulas for healthy term infants, they apply with one narrow exception. Section 412(h)(1) of the FD&C Act exempts an infant formula represented and labeled for use by an infant with an inborn error of metabolism, low birth weight, or who otherwise has an unusual medical or dietary problem from the requirements of subsections 412(a), (b), and (c) of the FD&C Act. These formulas are customarily referred to as ''exempt infant formulas.'' Section 412(h)(2) of the FD&C Act authorizes us to establish terms and conditions for the exemption of an infant formula from the requirements of subsections 412(a), (b), and (c) of the FD&C Act.

In support of exempt infant formulas, we have issued the Agency guidance document titled ''Exempt Infant Formula Production: Current Good Manufacturing Practices (CGMPs), Quality Control Procedures, Conduct of Audits, and Records and Reports'' (April 2016). The guidance document includes our recommendation that manufacturers of exempt infant formulas follow, to the extent practicable, subparts A, B, C, D, and F of 21 CFR part 106, and is available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-exempt-infant-formula-production.*

We have also developed electronic Form FDA 3978 (Infant Formula Tracking System (IFTRACK)) so that infant formula manufacturers may electronically submit reports and notifications in a standardized format to FDA. However, manufacturers that prefer to submit paper submissions in a format of their own choosing will still have the option to do so. Form FDA 3978 prompts a respondent to include reports and notifications in a standard electronic format and helps the respondent organize their submission to include only the information needed for our review. Screenshots of Form FDA 3978 and instructions are available at *http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/InfantFormula/default.htm.*

FDA has requested voluntary notifications pertaining to product samples found to be positive for Cronobacter spp. or Salmonella, even if the affected lot(s) have not been distributed. Associated recordkeeping requirements are found in 21 CFR 106.55(e). FDA has requested this information to help prevent future Cronobacter spp. illnesses associated with powdered infant formula. As part of a constituent update, available at *https://www.fda.gov/food/cfsan-constituent-updates/fda-calls-enhanced-safety-measures-letter-powdered-infant-formula-industry,* we issued a letter on March 8, 2023, to share current information to assist industry in improving the microbiological safety of powdered infant formula. As communicated in the letter, we shared the information with the expectation that infant formula manufacturers, packers, distributors, exporters, importers, and retailers will act to mitigate potential food safety risks in powdered infant formula in accordance with FDA regulations while further striving to improve operations, especially given the critical nature of these products.

Regulations in 21 CFR part 107, subpart E—Recalls (21 CFR 107.200 through 107.280) pertain to infant formula recalls. Specifically, § 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 § 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. 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. 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.

We use the information collection to determine industry compliance with Agency regulations which implement public health protection provisions of the FD&C Act applicable to infants and all infant formula. Respondent disclosures are used by consumers when purchasing, storing, and preparing infant formula to help ensure its safe use.

Section 424(a)(1) of the FD&C Act (21 U.S.C. 350m) requires a manufacturer of a critical food to notify FDA of a permanent discontinuance or an interruption of the manufacture of a critical food that is likely to lead to a meaningful disruption in the supply of the food in the United States. Section 201(ss) of the FD&C Act (21 U.S.C. 321(ss)) defines a ''critical food'' as a food that is (1) an infant formula or (2) a medical food as defined in section 5(b)(3) of the Orphan Drug Act. A manufacturer of a critical food is required to notify FDA of a permanent discontinuance in the manufacture or an interruption of the manufacture of such food that is likely to lead to a meaningful disruption in the supply of such food in the United States, and the reasons for such discontinuance or interruption, as soon as practicable, but not later than 5 business days after such discontinuance or such interruption. To help facilitate the process, FDA accepts notifications via email (*CriticalFoodShortage@fda.hhs.gov*).

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), when finalized, will provide FDA's interpretation regarding the circumstances under which infant formula manufacturers should notify FDA. The draft guidance, available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-notifying-fda-permanent-discontinuance-manufacture-or-interruption,* provides recommendations for notifications to include certain information and how respondents should notify FDA of a permanent discontinuance or interruption of supply of infant formula.

Section 424(b) of the FD&C Act requires a manufacturer of a critical food to develop, maintain, and implement a redundancy risk management plan that identifies and evaluates risks to the supply of the food

for each establishment in which a critical food is manufactured. A risk management plan may identify and evaluate risks to the supply of more than one critical food manufactured at the same establishment. A risk management plan may also identify mechanisms by which the manufacturer would mitigate the impacts of a supply disruption through alternative production sites, alternative suppliers, stockpiling of inventory, or other means. Records of a risk management plan are subject to FDA inspection and copying.

Description of Respondents: Respondents to this information collection are manufacturers of infant formula and include manufacturers of critical foods in the limited instance of a meaningful disruption in the supply of the food in the United States.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; 21 CFR section	Number of respondents	Number 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 minutes)	18
New infant formula submission; § 106.120	4	9	36	10	360
Elements of infant formula recall; § 107.230	2	1	2	4,450	8,900
Notification requirements; § 107.240	2	1	2	1,482	2,964
Termination of infant formula recall; § 107.250	2	1	2	120	240
Revision of an infant formula recall; § 107.260	1	1	1	625	625
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 minutes)	5
Total					14,938

[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]

Activity; FD&C act or 21 CFR part	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per record	Total hours
SUBPART B: CGMP Requirements; Part 106	5	429.8	2,149	4.4	9,414
SUBPARTS C–G: Quality control; audits; quality factors; records and reports; Part 106	5	726.8	3,634	6	21,818
SUBPART C; Exempt infant formulas; Part 107	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 BURDEN [1]

Activity; 21 CFR section	Number of respondents	Number 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
Elements of infant formula recall; § 107.230	2	1	2	50	100
Revision of an infant formula recall; § 107.260	1	1	1	25	25
Total					645

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

Based on a review of the information collection since our last request for OMB approval, we are revising the information collection to include activities recommended in the draft guidance titled ''Notifying FDA of a Permanent Discontinuance in the Manufacture or an Interruption of the Manufacture of an Infant Formula.'' We are also removing burden associated with the guidance titled ''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 in-effect end date. Lastly, we are correcting an inadvertent omission of 22 responses from the previous approval.

The draft guidance added 676 hours and 19 responses to the information collection. We also are adding 22 responses to correct an inadvertent omission. However, removal of the enforcement discretion guidance will reduce the burden estimate by 3,805 hours and 137 responses. Calculating hours and responses for the addition of the draft guidance and the correction along with the subtraction of the enforcement discretion guidance results in a net reduction of 3,129 hours (3,805 hours reduced for enforcement discretion guidance—676 hours added for draft guidance) and 96 responses (137 responses reduced for enforcement discretion guidance—19 responses added for draft guidance—22 responses added for the correction).

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–14438 Filed 7–16–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–7129]

Agency Information Collection Activities; Proposed Collection; Comment Request; Adverse Event Program for Medical Devices: (Medical Product Safety Network (MedSun))

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the Adverse Event Program for Medical Devices (Medical Program Safety Network (MedSun)).

DATES: Either electronic or written comments on the collection of information must be submitted by September 15, 2026.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 15, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2026–N–7129 for ''Agency Information Collection Activities; Proposed