

- Obstetrics, Reproductive and Urologic Drugs Advisory Committee
- Oncologic Drugs Advisory Committee
- Pediatric Advisory Committee
- Peripheral and Central Nervous System Advisory Committee
- Pharmacy Compounding Advisory Committee
- Psychopharmacologic Drugs Advisory Committee
- Pulmonary-Allergy Drugs Advisory Committee
- Risk Communication Advisory Committee (Administratively Inactive)
- Science Board to the Food and Drug Administration
- Technical Electronic Product Radiation Safety Standards Committee
- Tobacco Products Scientific Advisory Committee
- Vaccines and Related Biological Products Advisory Committee

5. *Justification that the information or advice provided by the Federal advisory committee or subcommittee is not available from another Federal advisory committee, another Federal Government source, or any other more cost-effective and less burdensome source.*

The Cellular Tissue and Gene Therapies Advisory Committee provides independent expert advice to FDA on the available data relating to the safety, effectiveness, and appropriate use of human cells, human tissues, gene therapies, and xenotransplantation products which are intended for transplantation, implantation, infusion, and transfer in the prevention and treatment of a broad spectrum of human diseases and in the reconstruction, repair, or replacement of tissues for various conditions.

The topics considered by the Cellular, Tissue, and Gene Therapies Advisory Committee require specialized expertise in the fields of cellular therapies, tissue transplantation, gene therapies, and xenotransplantation. These may include biostatistics, bioethics, hematology/oncology, human tissues and transplantation, reproductive medicine, general medicine, and various medical specialties including surgery and oncology, immunology, virology, molecular biology, cell biology, developmental biology, tumor biology, biochemistry, rDNA technology, nuclear medicine, gene therapy, infectious diseases, and cellular kinetics, and related specialties. Potential topics that may need committee input include products related to the topics outlined in Section (6) below. These and other issues cannot be appropriately addressed by another standing committee without diminishing the

depth and relevance of the expert input provided to the Agency.

6. *If the consultation is a committee renewal, a summary of the previous accomplishments of the committee and the reasons it needs to continue.*

Summary of Previous Accomplishments: On July 30, 2026, the Committee met to discuss and make recommendations on Biologics License Application (BLA) 125827, from Replimune, Inc. for vusolimogene oderparepvec. The proposed indication (use) is in combination with nivolumab for the treatment of adult patients with advanced melanoma who have previously received an anti-PD-1 containing regimen.

On July 29, 2026, the Committee met to discuss and make recommendations on Biologics License Application (BLA) 125842 from Capricor, Inc. for deramiocecel (human allogeneic cardiosphere-derived cells) the treatment of cardiomyopathy in Duchenne muscular dystrophy (DMD).

On November 21, 2024, the Committee met to discuss and make recommendations on supplemental biologics license application (sBLA) 125586/546 from Astra Zeneca for Andexxa (coagulation factor Xa (recombinant), inactivated -zhzo), for patients treated with rivaroxaban or apixaban when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding.

7. *Explanation of why the committee/subcommittee is essential to the conduct of agency business.*

Reasons for Continuation: The Committee plays a critical role in enabling FDA to meet the requirements of section 505(n)(1) and (s)(1) of the Federal Food, Drug, and Cosmetic Act by providing expert scientific advice and recommendations. Without the Cellular, Tissue, and Gene Therapies Advisory Committee, FDA's ability to obtain external input on issues related to human cells, human tissues, gene therapies, and xenotransplantation products which are intended for transplantation, implantation, infusion, and transfer in the prevention and treatment of a broad spectrum of human diseases and in the reconstruction, repair, or replacement of tissues for various conditions would be significantly limited.

In conclusion, this public interest determination documents that renewing the committee is in the public interest, essential to the conduct of agency business, and that the information to be obtained is not already available through another advisory committee or source within the Federal Government.

This notice is issued under the Federal Advisory Committee Act as amended (5 U.S.C. 1001 *et seq.*). For general information related to FDA advisory committees, please visit us at <http://www.fda.gov/AdvisoryCommittees/default.htm>.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–7131]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Infant Formula Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by November 13, 2026.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910–0256. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–402–5733, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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.

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 IFTTRACK 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. We therefore retain those figures, which are 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 record-keepers	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 BURDEN¹

Activity; 21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average LI≤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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Health Center Program Performance Period Extensions; Correction

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice; correction.

SUMMARY: HRSA published a document in the **Federal Register** on September 24, 2026, concerning performance period extensions for health centers scheduled to compete for a January, February, or March FY 2027 Service Area Competition. The document did not include one service area that was not eligible for a performance period extension at the time of publication but has since become eligible.

FOR FURTHER INFORMATION CONTACT:

Patricia Burbano, Lead Public Health Analyst, Office of Program and Policy Development, Bureau of Primary Care, Health Resources and Services Administration, at pburbano@hrsa.gov and 301–443–7238.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of September 24, 2026, 2026–19578 (91 FR 60626), page 60632, column titled “Grant No.” add “H80CS06645” to the last row; column titled “Budget period start” add “JAN;” column titled “Name” add “Sayre Health Center;” column titled “City” add “Philadelphia;” column titled “State” add “PA;” and column