

September 15, 2026

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Submitted electronically via www.regulations.gov

RE: Docket No. FDA-2026-N-7131, Agency Information Collection Activities; Proposed Collection; Comment Request; Infant Formula Requirements

Dear Sir or Madam:

The Infant Nutrition Council of American (INCA) and the Healthcare Nutrition Council (HNC) appreciate the opportunity to comment on the Food and Drug Administration's (FDA or Agency) proposed revision of the information collection approved under OMB Control Number 0910-0256. HNC is an association representing manufacturers of infant formula and other critical foods, including enteral nutrition (EN) formulas, oral nutrition supplements (ONS), medical foods, and parenteral nutrition (PN). Our mission is to improve patient outcomes by advancing nutrition policies and actions that raise awareness and optimize access for people who require or benefit from advanced and specialized nutrition.

INCA is an association representing the leading domestic manufacturers of infant formula. INCA advocates for optimal infant health and the critical role of infant nutrition, supports families in feeding decisions, and provides evidence-based information to healthcare professionals. INCA member companies work diligently to ensure that caregivers and healthcare providers who rely on their products have access to safe, high-quality, and nutritious infant formula.

HNC and INCA support FDA's public health objective of obtaining timely, accurate, and useful information about infant formula and other critical foods. The collections addressed in the notice support important oversight functions, including infant formula quality and safety, product registration and submissions, recalls, and advance awareness of supply disruptions. At the same time, the Paperwork Reduction Act requires FDA to estimate burden accurately and minimize unnecessary or duplicative work. Those goals are especially important for critical foods, where regulatory resources should remain focused on safety, quality, and continuity of supply.

Our comments address four issues identified in the notice: practical utility; accuracy of FDA's burden estimates; quality, utility, and clarity; and opportunities to reduce burden through electronic tools and more efficient reporting practices.

I. Preserve and Continue Improving IFTRACK

HNC and INCA members generally view the Infant Formula Tracking System (IFTRACK) and electronic Form FDA 3978 as improvements over less standardized legacy submission processes. A centralized electronic pathway can help manufacturers organize submissions, support consistent data entry, and facilitate FDA review. INCA and HNC support continued availability and improvement of IFTRACK, as

well as FDA's proposal to retain a paper-submission option for manufacturers that prefer or need an alternative format.

FDA should consider evaluating IFTRACK based on the full workflow manufacturers follow to prepare and submit a report or notification, rather than the time spent entering information into the system alone. Depending on the submission, this workflow may include identifying affected products, assembling supporting records, coordinating review across regulatory, quality, manufacturing, supply chain, information technology, and legal personnel, obtaining internal approvals, entering or uploading information, resolving system access or validation issues, and responding to FDA follow-up questions.

Compared with the prior process - which required an original submission and two copies to be printed, assembled in three physical notebooks, and shipped by next-day delivery before a 5 p.m. deadline - IFTRACK saves time and improves tracking. Because IFTRACK is available 24 hours a day, manufacturers no longer need to meet a physical mailing cutoff. The system also provides real-time receipt confirmation, submission status, version history, and a centralized record of FDA follow-up, reducing reliance on manual tracking through email and spreadsheets.

To enhance the quality and utility of the information collected while reducing administrative burden, HNC recommends that FDA:

- Continue to permit manufacturers to copy or reuse unchanged establishment, product, contact, and other recurring information from a prior submission;
- Maintain structured fields and add a bulk-upload option, such as allowing a compressed file, when a submission covers multiple related products;
- Maintain the ability to add or remove authorized users, save drafts, delegate responsibilities, and transfer responsibility among company personnel;
- Maintain the amendment process for correcting or supplementing a submission and establish a clear process for withdrawing a submission without recreating the entire record;
- Maintain the existing confirmation, version history, and status-tracking functions that allow both FDA and the submitter to identify the current record;
- Maintain clear identification of required fields and publish instructions that distinguish optional or context-dependent information; and
- Create flexibility for manufacturers to submit labeling materials for exempt infant formulas only if new items are created or if existing are updated and reference a previous notification where materials were last submitted.

II. Maintain and Clarify Consolidated Notifications When the Same Change Applies to Multiple Formulas

Members report that IFTRACK currently permits a single notification to cover multiple formulas when the same change applies. We support retaining this capability and recommend that FDA clarify when it may be used. Requiring separate submissions that repeat the same narrative, supporting information, and attachments for each formula would increase burden without providing FDA

materially different information and could make relationships among affected products harder to identify.

HNC and INCA recommend that FDA continue to allow a manufacturer to submit one primary notification or report covering multiple formulas when the same change, event, or supporting basis applies to each formula. The submission could identify all affected formulas and provide product-specific information in a structured schedule or attachment. This optional approach should be used only when it gives FDA all information necessary for review.

Consolidated reporting would not reduce the substance of the information available to FDA. It would organize common information once, identify the affected formulas, and reserve separate product-level fields for information that differs. FDA should clarify when consolidated reporting is appropriate and how manufacturers should reference or update the affected product list.

III. Ensure Burden Estimates Reflect the Full Work Required to Comply

FDA estimates annual burdens of 14,938 hours for reporting, 126,482 hours for recordkeeping, and 645 hours for third-party disclosures. The notice states that there are no capital costs or operating and maintenance costs associated with these collections. INCA and HNC urge FDA to validate these estimates using recent, direct input from affected manufacturers and to explain the assumptions supporting each estimate.

A reliable burden estimate should account for all work reasonably necessary to complete the collection, not only data entry or transmission of a final document. Relevant activities may include:

- Determining whether an event, change, or record triggers a reporting requirement;
- Collecting, reviewing, reconciling, and formatting information from multiple facilities or business functions;
- Preparing supporting materials and product-specific schedules;
- Internal scientific, quality, regulatory, legal, and management review;
- Entering information, uploading documents, performing quality-control checks, and obtaining submission confirmation;
- Responding to FDA questions or correcting a submission;
- Training personnel and administering user access; and
- Developing, validating, maintaining, or modifying information systems used to generate and retain the required information.

The number of respondents and responses should also reflect the current market structure and the fact that a single manufacturer may operate multiple establishments, manufacture multiple formulas, or be subject to more than one information collection in a year. FDA should state whether its estimates treat related submissions for multiple formulas as separate responses and whether the estimated time per response includes the preparation and review activities described above.

IV. Make Critical-Food Supply Notifications Clear, Coordinated, and Proportionate

The revised collection incorporates notifications under section 424(a)(1) of the Federal Food, Drug, and Cosmetic Act concerning a permanent discontinuance or manufacturing interruption that is likely to lead to a meaningful disruption in the U.S. supply of a critical food. It also includes redundancy risk management plans required by section 424(b). These provisions apply to infant formula and medical foods, both of which may serve individuals with specialized nutritional needs and may have limited substitutes.

INCA and HNC recognize the practical utility of timely information that helps FDA monitor and respond to potential supply disruptions. To make the collection clear and useful, FDA should align requested information with the final guidance, issue detailed written guidance for critical-food notifications, and provide consistent interpretations of key terms, including when an interruption is likely to lead to a meaningful disruption. That guidance should define key terms, explain submission procedures, identify a dedicated point of contact, and confirm whether email is an accepted notification pathway. FDA should also explain how manufacturers should update an earlier notification as circumstances change and when FDA considers the notification closed.

The notice estimates two hours for each critical-food discontinuance or interruption notification. That estimate should include the work required to assess whether the statutory threshold is met, collect information across affected facilities and products, evaluate projected supply effects, determine the reasons for the interruption, coordinate internal review, prepare the notification, and respond to FDA follow-up. It should also account for situations involving more than one affected product or establishment.

V. Reevaluate the Estimated Burden for Redundancy Risk Management Plans

FDA estimates that 11 manufacturers will create and maintain one redundancy risk management plan annually and that each plan will require 60 hours. HNC recommends that FDA distinguish between initial development and recurring maintenance, review, testing, and updates. Initial development may include mapping supply risks, evaluating facilities and suppliers, identifying mitigation mechanisms, coordinating across business functions, documenting the plan, securing approval, and establishing implementation processes. Ongoing burden may include periodic review and revisions following operational, supplier, product, or facility changes.

Section 424(b) permits a plan to address more than one critical food manufactured at the same establishment. FDA's burden methodology should recognize this flexibility without assuming that a multi-product plan requires the same effort as a single-product plan. FDA should also avoid duplicative requests when relevant information is already maintained in existing business-continuity, emergency-management, quality, or supply-chain systems, provided the statutory elements can be readily identified and made available during an inspection.

VI. Additional Recommendations to Improve Clarity and Reduce Burden

Across the information collections addressed in the notice, INCA and HNC recommend that FDA apply the following principles:

- Request information once and avoid requiring the same information through multiple FDA channels;
- Use standardized terminology and instructions across regulations, guidance documents, email notifications, and IFTRACK;
- Limit required information to what FDA needs to perform the specific regulatory function;
- Maintain consolidated reporting and structured attachments when multiple products or establishments are affected by the same facts;
- Maintain current functions for confirmation, reviewer identification, submission status, review timelines, and closeout;
- Ensure electronic systems are reliable, accessible, and capable of accommodating common industry reporting structures; and
- Consult affected manufacturers before finalizing burden assumptions or making material changes to electronic reporting tools.

Conclusion

INCA and HNC support FDA's efforts to collect information necessary to protect infant health and support the safety, quality, and availability of infant formula and other critical foods. INCA and HNC ask FDA to preserve and improve IFTRACK, maintain and clarify the optional consolidated pathway for common changes affecting multiple formulas, and revise its burden analysis to reflect the full work and costs associated with reporting, recordkeeping, third-party disclosures, supply notifications, and redundancy risk management plans. INCA and HNC also encourage FDA to continue engaging directly with affected manufacturers as it refines these collections and related electronic tools.

Thank you for the opportunity to provide comments. INCA and HNC remains committed to partnering with FDA to support the safety, quality, and availability of infant formula and other critical foods while ensuring that reporting and recordkeeping requirements are clear, efficient, and appropriately estimated. If you have any questions or would like additional information, please contact Shelby Guillen Dominguez, Healthcare Nutrition Council, at sguillendominguez@kellencompany.com.

Respectfully submitted,



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