



# HEALTHCARE NUTRITION COUNCIL

Improving outcomes through awareness and action

*Submitted via Regulations.gov*

September 10, 2025

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

**RE: Docket No. FDA-2025-N-1134 Healthcare Nutrition Council Comments on Infant Formula Nutrient Requirements; Request for Information**

Dear Division of Dockets Management,

The Healthcare Nutrition Council (HNC) is commenting on the U.S. Food and Drug Administration's (FDA) request for information (RFI) "Infant Formula Nutrient Requirements" that was published in the *Federal Register* on May 14, 2025. HNC represents manufacturers<sup>1</sup> of enteral nutrition (EN) formulas and oral nutrition supplements (ONS), including those categorized as 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 that require or benefit from advanced and specialized nutrition.

*Exempt Infant Formulas*

FDA has articulated in the RFI that the nutrient review process is intended to focus on formulas routinely fed to healthy, term infants. However, HNC submits the following comments related to exempt infant formulas—those formulas intended for infants who have inborn errors of metabolism, low birth weight, or who otherwise have unusual medical or dietary problems (21 C.F.R. § 107.3 and 21 C.F.R. § 107.50). Exempt infant formulas must meet the same compositional requirements as routine, non-exempt infant formulas defined in 21 C.F.R. § 107.100 except where a medical, nutritional, scientific, or technological rationale supports a deviation from those criteria and whereby the manufacturer submits to FDA for pre-market review such request and rationale for exemption. Given the unique medical considerations for these infants as well as the complexity in developing and manufacturing exempt infant formulas, HNC encourages FDA to consider these formulas and potential differences that may be necessary from routine infant formulas.

HNC shares FDA's commitment to ensuring the nutritional adequacy of infant formula. Breast milk is the best feeding option for babies, but for parents who cannot or choose not to breastfeed, or for infants who have special dietary needs such as an inborn errors of metabolism requiring a specialized exempt infant formula, commercially prepared infant formulas are the only safe and suitable alternative. Although FDA stakeholders have previously commented that the infant formula standard has not been innovated since 1998, FDA's current regulatory framework enables innovation of infant formula composition through a required pre-market notification and review process, in which FDA: 1) reviews any new ingredient, 2) reviews

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<sup>1</sup> HNC members are Abbott Nutrition, Nestle Health Science, and Nutricia North America.

the infant formula with the new ingredient, and 3) determines no objections to the proposed innovation prior to the manufacturer introducing the formula to the market. Under this framework, HNC members have brought many specialized infant formulas to the market to meet unique nutrient needs, including formulas for pre-term infants, formulas for infants with inborn errors of metabolism, and formulas for infants requiring an extensively hydrolyzed protein or amino-acid based formula due to food allergies or other complex medical conditions.

### *Ingredients in Exempt Infant Formulas*

U.S. infant formulas, including the exempt infant formulas, are purposefully formulated with careful selection of each ingredient. These formulas are safe, suitable, and effective in supporting the nutrition needs, growth, and development of infants in the United States.

Fat is essential to infant growth and development as it provides infants with the essential fatty acids they cannot synthesize endogenously. Seed oils (or vegetable oils) are a source of these essential fatty acids. While the use of seed oils in infant formula has been questioned recently, HNC reiterates that seed oils provide these essential fatty acids infants require for growth and development and are used globally in all infant formulas because there are no alternate sources, produced at scale and suitable for infants, that can provide essential fatty acids in the amounts and proportions required by infants. HNC reiterates that the oil blends in infant formula products that are currently on the U.S. market have been carefully formulated to deliver the essential nutrients infants need and have been subject to clinical trials to bring those products to market.

Carbohydrate is essential to meet energy intake needs and supplies glucose to the developing brain. The dominant digestible source of carbohydrate in human milk is lactose, and as such, lactose is the preferred carbohydrate source for routine cow's milk-based infant formulas. However, HNC reiterates that the regulation must remain sufficiently flexible to permit other safe and easily digestible carbohydrate sources where appropriate. Recent criticisms of low-lactose formulas (containing alternate carbohydrate sources) are based on the relatively low prevalence of lactose intolerance/maldigestion in infancy. Despite the fact that primary lactose intolerance is indeed rare in infancy, transient lactose intolerance can occur. Furthermore, infants with galactosemia and cow's milk protein allergy have special dietary requirements that necessitate the use of alternate carbohydrate sources, so alternate carbohydrate sources (such as corn syrup solids, corn syrup, or glucose), need to remain available for exempt infant formulas. HNC members stand by the availability of formulas in the United States that offer options to both caregivers and healthcare practitioners, so long as these formulas have been demonstrated to support growth, development, and tolerance in infants.

While the regulation establishing essential nutrient composition of infant formula has not been updated since the addition of selenium in 2016 (80 Fed. Reg. 35834 (June 23, 2015)), HNC feels it's important for FDA to remind consumers that U.S. infant formulas have evolved dramatically over the past several decades. It is also important that consumers and healthcare practitioners understand that U.S. formulas are safe, suitable, and effective in meeting infant nutrient needs and supporting early development. Any suggestion that questions the safety, suitability, and effectiveness of U.S. infant formulas is not only inaccurate but can adversely impact consumer confidence in the U.S. infant formula supply and in U.S. manufacturing capabilities.



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## *Conclusion*

While FDA has articulated in the RFI that the nutrient review process is intended for healthy, term infants, HNC feels it's important to address exempt infant formulas. Given the unique medical considerations for these infants as well as the complex considerations in developing and manufacturing exempt infant formulas, HNC encourages FDA to consider these formulas and potential differences that may be necessary from routine infant formulas.

HNC is available to collaborate with FDA if more information is needed and appreciates your consideration of these comments. Please contact Berit Dockter MPP, RD, LD [bdockter@healthcarenutrition.org](mailto:bdockter@healthcarenutrition.org) if you have any questions.

Sincerely,

A handwritten signature in black ink that reads "Carla A. Saunders". The signature is written in a cursive, flowing style.

Carla Saunders  
Executive Director