

Submitted via regulations.gov

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

RE: Docket No. FDA-2025-N-1793 Ultra-Processed Foods; Request for Information

Dear Dockets Management Staff,

The Healthcare Nutrition Council (HNC), the Infant Nutrition Council of America (INCA), and the undersigned organizations are commenting on Docket No. FDA-2025-N-1793 titled Ultra-Processed Foods; Request for Information (RFI) that was posted by the U.S. Food and Drug Administration (FDA or agency) and the Department of Agriculture (USDA or Department) to the *Federal Register* on July 25, 2025. In addition, the undersigned organizations are in support of these comments.

HNC represents manufacturers¹ of enteral nutrition formulas and oral nutrition supplements (ONS), including those categorized as medical foods, and parenteral nutrition. The mission of HNC 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.² 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. The scientific advances manufacturers have made in the nutrient composition of infant formula to meet enhanced health outcomes for infants in the U.S. over several decades are reflected in the comments below.

HNC, INCA, and the undersigned organizations appreciate the FDA and USDA for taking time to review the current topic and for prioritizing our nation's health through better nutrition. As the agency and Department consider a path forward to address and define so-called ultra-processed foods (UPFs), we are commenting on this RFI to reiterate the importance of specialized nutrition products and the role they play in maximizing nutrient delivery to meet the unique needs and health outcomes of the populations they serve.

As explained below, we recommend that specialized nutrition products not be categorized in the same manner as non-nutrient-dense, conventional foods when considering defining so-called UPFs. Specialized nutrition products are foods designed for individuals with unique nutritional needs obligated by life-stage or health status. Consumers and patients rely on these products for acute and long-term nutritional support. In some cases, specialized nutrition products are medically necessary throughout an individual's lifespan. These products are distinguished from conventional foods in that they are intentionally formulated and processed to provide nutrition in

¹ HNC members are Abbott Nutrition, Nestle Health Science, and Nutricia North America.

² INCA members are Abbott Nutrition, Perrigo Nutrition, and Reckitt Mead Johnson.

a form that is tailored to the consumer's or patient's specific dietary needs and/or health condition. The FDA regulates these products as infant formulas, medical foods, or foods for special dietary use (FSDU) and spans product categories including, but not limited to, infant formula, exempt infant formula, toddler nutritional drinks (TND), metabolic formulas, tube feeding formulas, oral nutrition supplements (ONS), and oral rehydration solutions (ORS). Note: California AB 1264 was recently passed and aims to define UPF and exempts infant formula and medical foods from that definition.

Infant Formula

Breast milk is the best feeding option for infants; however, for parents who cannot or choose not to breastfeed or use breast milk, commercially manufactured infant formulas are the only safe and appropriate alternative. Infant formulas are defined in 21 C.F.R. § 106.3 as “foods which purport to be or are represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk.” The FDA has also recently published an RFI on the nutrient requirements for infant formula. Exempt infant formulas are 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 the FDA for pre-market review such request and rationale for exemption. Infant formulas are designed and processed to meet the specific nutritional needs of infants, supporting overall health outcomes. These formulas undergo extensive clinical and technical research to demonstrate that they promote growth and development, achieving health outcomes similar to those of infants fed breast milk. The complexity involved in developing and manufacturing both non-exempt and exempt infant formulas, along with the regulatory framework that allows manufacturers to innovate under FDA pre-market review, sets these products apart from conventional foods and emphasizes their significance as fundamentally different from foods associated with the UPFs concepts.

Toddler Nutritional Drinks (TND)

TND is a specially formulated nutritional product category designed to help meet the nutritional needs of toddlers aged 12 to 36 months. TND have a distinctive use and nutritional makeup different from infant formula; the two are not interchangeable, as infant formula is the only safe alternative to breast milk and is formulated to satisfy the normal nutritional requirements of infants in the first year of life. These products are typically milk or soy-based, and their labeling explicitly identifies the product as a TND intended for children 12 months and older on the front of the package label.

While not labeled for or intended as sole source nutritional products, TND can help increase the consumption of nutrients often lacking in toddlers' diets. During the transition to the family diet, meeting nutrient recommendations can be difficult for many toddlers and their families. Picky or fussy eating is not uncommon in toddlers. In fact, young children with picky eating habits have been identified as being at risk of nutritional inadequacies.^{3,4,5} TND are intended to contribute to

³ Fraser K, Markides BR, Barrett N, Laws R. Fussy eating in toddlers: A content analysis of parents' online support seeking. *Matern Child Nutr.* 2021 Jul;17(3):e13171. doi: 10.1111/mcn.13171. Epub 2021 Mar 19. PubMed PMID: 33739624; PubMed Central PMCID: PMC8189205.

⁴ Bailey ADL, Fulgoni Iii VL, Shah N, Patterson AC, Gutierrez-Orozco F, Mathews RS, Walsh KR. Nutrient Intake Adequacy from Food and Beverage Intake of US Children Aged 1-6 Years from NHANES 2001-2016. *Nutrients.* 2021 Mar 3;13(3):827. doi: 10.3390/nu13030827. PMID: 33802295; PMCID: PMC8002201.

⁵ Mascola AJ, Bryson SW, Agras WS. Picky eating during childhood: a longitudinal study to age 11 years. *Eat Behav* (2010) 11(4):253–7. doi:10.1016/j.eatbeh.2010.05.006.

a toddler's diet and help meet nutrient recommendations as toddlers transition from breast milk and/or formula to the family diet.

TND are nutrient-dense beverages. In the context of a mixed diet, such beverages help a toddler meet their growing nutrient needs as breast milk and/or infant formula no longer become their sole source of nutrition. Due to the addition of necessary nutrients, the nutrient density of TND is notably higher than that of other beverages. Moreover, as an international expert panel concluded, TND for young children are formulated with many important nutrients that are in short supply in a toddler's diet, such as calcium, iron, vitamins D and C, zinc, and the omega-3 fatty acid DHA, and can be an effective and reliable way to help ensure children get the nutrients needed for healthy physical and mental growth and development.⁶

Medical Foods

A medical food is “a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation,” (21 U.S.C. 360ee(b)(3)). While “distinctive nutritional requirement” has not been defined by regulation, we view it to refer to the clinical need for a specific nutritional intake (compared to the intake of healthy populations) which may exist by reason of abnormal physiological manifestation or physical impairment associated with a disease or condition.

Medical foods⁷ play a critical role in supporting the nutritional needs of those with certain conditions or diseases, including rare diseases. For example, medical foods are crucial in meeting the nutritional needs of individuals with inborn errors of metabolism, helping to manage clinical complications and sustain life. Phenylketonuria (PKU) is an inborn error of metabolism, occurring in 1 in 25,000 infants in the U.S.,⁸ in which the individual is unable to metabolize phenylalanine. Without specialized nutrition intervention, phenylalanine accumulates in the body at harmful levels, which can lead to permanent cognitive impairment. Maple syrup urine disease (MSUD) is another inborn error of metabolism occurring in less than 1 in 185,000 infants worldwide.⁹ Specialized nutrition intervention is required to prevent branched amino acids and the corresponding keto acids from accumulating in the blood, resulting in life-threatening seizures, coma, and brain damage. In these and many other conditions, medical foods specifically developed for the individual condition help patients fully meet their nutritional needs as they modify their diets to carefully control the intake of the offending amino acid(s).

Other patients may rely on medical foods due to a “distinctive nutritional requirement” by reason of physical impairment associated with a disease or condition. For example, patients who cannot consume food orally must rely on adjustments in the delivery of the food to enable nutritional intake (e.g., enteral tube feeding). These patients often rely on medical foods as their sole source of nutrition, which are formulated and processed to ensure safe tube feeding.

⁶ Fact Sheet: Follow-Up Formula for Older Infants and Young Children, ISDI, 2024. [content/uploads/2020/09/ISDI-Factsheet-Follow-up-Formula.pdf](https://www.fda.gov/oc/ohrt/2020/09/ISDI-Factsheet-Follow-up-Formula.pdf)

⁷ A **medical food** is “a food which is formulated to be consumed or administered **enterally** under the **supervision of a physician** and which is intended for the specific **dietary management of a disease or condition** for which **distinctive nutritional requirements**, based on recognized scientific principles, are established by **medical evaluation**.” As defined in section 5(b)(3) of the Orphan Drug Act. 21 USC 360ee(b)(3).

⁸ National Institutes of Health (NIH). U.S. National Library of Medicine. MedlinePlus. “Phenylketonuria.” Retrieved from: <https://medlineplus.gov/genetics/condition/phenylketonuria/#frequency>.

⁹ National Institutes of Health (NIH). U.S. National Library of Medicine. MedlinePlus. “Maple syrup urine disease.” Retrieved from: <https://medlineplus.gov/genetics/condition/maple-syrup-urine-disease/#frequency>.

Oral Nutrition Supplements (ONS)

ONS are regulated as medical foods or FSDU and are included in clinical guidelines for patient care, often prescribed or recommended by healthcare professionals (HCPs), proven effective for the target population, HSA/FSA eligible (when prescribed), and may be covered by Medicaid and certain health insurance plans. ONS are high-quality, scientifically based and nutrient-dense foods for special dietary needs, such as for the dietary management of malnutrition, and are typically available as ready-to-drink liquids (milk-style or juice-style) and powders consumed in healthcare facilities or at home. Other forms, such as puddings, may also be available.

Many ONS products are specifically designed to have higher caloric and/or nutrient content, as well as targeted nutrient profiles, to help meet the nutritional needs of patients. These products, which have higher calorie and/or protein content, serve a distinct purpose, aiding individuals in reaching their nutritional goals and, thus, achieving better health outcomes. For example, patients recovering from surgery may require ONS to meet their caloric needs, but also can benefit from arginine, which becomes conditionally essential following injury and/or trauma. Similarly, patients undergoing chemotherapy may require ONS to meet their nutritional needs (e.g., calorie and protein requirements) due to food volume restrictions and the impact of treatment on their tolerance. Similarly, patients undergoing hemodialysis may require ONS to help meet calorie and protein needs while managing intake of minerals and electrolytes. Pediatric patients with failure to thrive or at risk for malnutrition may also require an ONS for calorie intake and to support catch-up growth.

Research indicates that ONS are used for dietary management of malnutrition both in hospital settings and among individuals in the community. Using ONS with caregiver education reduced 30-day readmission rates and length of stay in hospitals among older adults with malnutrition by 2 days on average.¹⁰ The NOURISH study found malnourished patients randomized to receive high-protein ONS for 90 days post-discharge had improved nutritional status and decreased mortality compared to those in the placebo group.^{11,12} Other studies have found use of ONS in hospitalized patients reduced 30-day readmission rates, reduced length of stay, reduced incidences of pressure ulcers, reduced risk of complications from chronic disease, decreased length of antibiotic therapy, and ultimately reduced health care costs.^{13,14,15}

ONS have also been shown to reduce hospitalization and medical care costs in non-hospital and community settings.^{16,17} For example, the use of ONS as part of a nutrition-focused quality improvement program in home health agencies for patients with (or at risk of) malnutrition led to

¹⁰ Silver, Heidi; Kelsey Jones Pratt, Michelle Bruno, Joe Lynch, Kristi Mitchell, and Sharon McCauley. Effectiveness of the malnutrition quality improvement initiative on practitioner malnutrition knowledge and screening, diagnosis, and timeliness of malnutrition-related care provided to older adults admitted to a tertiary care facility: a pilot study. *Journal of the Academy of Nutrition and Dietetics*. 2017; 118(1): 101-109.

¹¹ Goates, Scott; Kristy Du, Carol Braunschweig, and Mary Beth Arensberg. Economic Burden of Disease-Associated malnutrition at the State Level. *PLOS ONE*. 2016; 11(9): 1-15.

¹² Deutz, NE; Matheson, EM; Matarese, LE; Luo, M; Baggs, GE; Nelson, JL; Hegazi, RA; Tappenden, KA; and Ziegler, TR. Readmission and mortality in malnourished, older, hospitalized adults treated with a specialized oral nutritional supplement: A randomized clinical trial. *Clin Nutr*. 2016; 35(1): 18-26.

¹³ Goates, Scott; Kristy Du, Carol Braunschweig, and Mary Beth Arensberg. Economic Burden of Disease-Associated malnutrition at the State Level. *PLOS ONE*. 2016; 11(9): 1-15.

¹⁴ Philipson, TJ; Snider, JT; Lakdawalla, DN; Stryckman, B; and Goldman, DP. Impact of oral nutritional supplementation on hospital outcomes. *Am J Manag Care*. 2013; 19(2): 121-128.

¹⁵ Mullin, GE; Fan, L; Sulo, S; and Partridge, J. The Association between Oral Nutritional Supplements and 30-Day Hospital Readmissions of Malnourished Patients at a U.S. Academic Medical Center. *Journal of the Academy of Nutrition and Dietetics*. 2019; 119(7): 1168-1175.

¹⁶ Elia, M; Normand, C; Laviano, A; and Norman, K. A systematic review of the cost and cost effectiveness of using standard oral nutritional supplements in community and care home settings. *Clin Nutr*. 2016; 35:125-137.

¹⁷ Arnaud-Battandier, F; Malvy, D; Jeandel, C; Schmitt, C; Aussage, P; Beaufrere, B; and Cynober, L. Use of oral supplements in malnourished elderly patients living in the community: a pharmaco-economic study. *Clin Nutr*. 2004; 23:1096-1103.

significant reductions in the relative risk of hospitalization (by 12-24%) and cost savings of \$1,500 per patient treated.¹⁸ Medicare patients aged 65 years and older who were provided ONS had a 16% reduction in length of hospital stay and a 15.8% cost savings.¹⁹ A review of the cost and cost-effectiveness of using standard ONS in community and care homes showed a mean cost savings of 9.2%.²⁰

Oral Rehydration Solutions (ORS)

ORS are formulated for individuals experiencing or at risk of dehydration due to a range of factors such as diarrhea, vomiting, fever, physical exertion, or exposure to high temperatures. These solutions provide an optimal glucose-to-electrolyte ratio to efficiently restore essential fluids and electrolytes, addressing mild to moderate dehydration in both pediatric and adult populations. Similar to ONS, ORS products are frequently recommended by healthcare professionals and are available for use in clinical environments or at home.

Ingredients and Processing (RFI Questions 2 and 3)

The processing and ingredients used in making specialized nutrition products discussed above are chosen to support the specific nutrition needs of people who use and rely on them. As previously stated, these products differ significantly from conventional foods in that they are specifically designed to meet the needs of individuals with special dietary requirements.

Specialized nutrition products are complex food matrices that include ingredients, such as nutrients, as well as food additives that serve specific functional purposes. These ingredients are compliant with regulations and have research-based clinical and scientific evidence demonstrating their safety and suitability for use. Using individual ingredients to characterize specialized nutrition products as “ultra-processed,” or using their placement within the list of ingredients on the label as suggested in the FDA’s questions within the RFI, would overlook the entire context of these products and their ingredients, which are designed to meet specific health needs. For example, because ingredients are listed in order of predominance by weight, sugar (used for both caloric contribution and sensory in nutrient-dense, specialized nutrition products) would appear towards the beginning of an ingredient list, compared to lower-weight vitamins and minerals. Additionally, regarding the FDA’s question related to whether the addition of flavors should constitute a food as ultra-processed, INCA and HNC reiterate that flavors are often used to improve the palatability of nutrient-dense specialized nutrition products that would otherwise have an unacceptable taste due to their nutrient content, thereby increasing patient compliance. Other ingredients that may appear near the end of an ingredient list are used to maintain the integrity of vitamins and minerals in the product, keep nutrients suspended in the solution or formula, maximize nutrient delivery, tailor a formulation for tube feeding, or otherwise offer a solution to meet the unique nutrition requirements of the person’s dietary and health needs.

Several different physical, chemical, and biological processing methods can be used in the production of specialized nutrition products. It has been suggested that the use of processing techniques or ingredients not available in the common kitchen qualifies a food as ultra-processed. However, it can be unsafe to make specialized nutrition products at home. Nutrient

¹⁸ Riley, K; Sulo, S; Dabbous, F; Partridge, J; Kozmic, S; Landow, W; VanDerBosch, G; Falson, MK; and Sriram, K. Reducing Hospitalizations and Costs: A Home Health Nutrition-Focused Quality Improvement Program. *JPEN*. 2019; 0(0): 1-11.

¹⁹ Thomas DR, Zdrowski CD, Wilson MM, et al. Malnutrition in subacute care. *Am J Clin Nutr*. 2002;75:308-313.

²⁰ Medical Nutrition International Industry. ‘Better care through better nutrition: value and effects of medical nutrition’ 4th Edition. 2018. Retrieved from:

https://www.medicalnutritionindustry.com/files/user_upload/documents/medical_nutrition/2018_MNI_Dossier_Final_web.pdf

levels and ratios must be carefully controlled in these products to prevent deficiency or toxicity. In the case of infant formula, commercially manufactured infant formulas are the only safe alternative to breastfeeding. Since specialized nutrition products tend to have high nutrient densities, they are also inherently prone to ingredient interactions over manufacture and shelf life, so special considerations must be made to ensure a final product with adequate nutritional value and high physical quality.^{21,22} For example, the heat used in liquid processing steps during manufacturing can lead to degradation of labile nutrients and initiate Maillard browning, which can impact protein quality.²³ These nutrient losses can be exacerbated in liquid products that are commercially sterilized using retort processing.²⁴ Special care is taken to minimize product exposure to common catalysts, such as light, oxygen, and excessive heat, but select food additives may also be necessary to ensure the overall stability, quality, and nutritional composition of these formulas. HNC and INCA members have undertaken comprehensive research. They are committed to the responsible use of food additives and technologies that improve the composition, quality, and overall feeding experience of specialty nutrition products.

Nutrient Density (RFI Questions 1, 4, and 5)

The FDA and USDA are seeking feedback on the term “ultra-processed” and whether it effectively captures concerns about certain food products. Some approaches have recognized terms, such as “calorie-rich and nutrient-poor,” to highlight the nutritional value of a food. The preamble of the RFI noted the unintended consequences of some so-called UPF definitions, which could cause confusion and discourage the intake of beneficial foods, such as nutrient-dense, fortified foods. There are general limitations to classifying foods based on level of processing, as more levels of processing do not necessarily mean a product becomes less healthful or formulated to meet specific dietary and health needs and benefits. Many specialized nutrition products are intentionally designed to be nutrient-dense and can provide supplemental or sole-source nutrition to fulfill an individual’s special dietary needs. Commercially manufactured specialized nutrition products may be the only safe alternatives to meet the nutritional needs of the populations they are designed, formulated, processed, and regulated to serve. As noted in the RFI, “foods commonly considered to be ultra-processed encompass a broad range of industrially processed foods, such as soft drinks and many packaged snacks.” We want to emphasize that specially formulated, processed foods that are prescriptively nutrient-dense or otherwise designed for specific nutritional and health needs, such as specialized nutrition products and infant formula, should not be captured in the same category as these types of non-nutrient-dense foods.

We appreciate your consideration of these comments.

Please contact Berit Dockter, MPP, RD, LD, Associate Director, HNC (bdockter@healthcarenutrition.org) and Robert C. Post, PhD, MEd, MSc, Scientific and Regulatory Affairs Director, INCA (rpost@infantnutrition.org), if you have any questions about the points presented in this submission.

Sincerely,

²¹ D. -H. Montagne, P. Van Dael, M. Skanderby, & W. Hugelshofer, Infant Formulae – Powders and Liquids. (2009). *Dairy Powders and Concentrated Products* (1st ed., pp. 294–331). Wiley. <https://doi.org/10.1002/9781444322729.ch9>.

²² Masum, A. K. M., Chandrapala, J., Huppertz, T., Adhikari, B., & Zisu, B. (2021). Production and characterization of infant milk formula powders: A review. *Drying Technology*, 39(11), 1492–1512. <https://doi.org/10.1080/07373937.2020.1767645>.

²³ Nasirpour, A., Scher, J., & Desobry, S. (2006). Baby foods: Formulations and interactions (a review). *Critical Reviews in Food Science and Nutrition*, 46(8), 665–681. <https://doi.org/10.1080/10408390500511896>.

²⁴ Birlouez-Aragon, I. (2004). Assessment of protein glycation markers in infant formulas. *Food Chemistry*, 87(2), 253–259. <https://doi.org/10.1016/j.foodchem.2003.11.019>.

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National Organization for Rare Disorders
National PKU Alliance
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