



American Society of Pediatric Nephrology

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September 11, 2025

The Honorable Marty Makary
Administrator
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2025-N-1134 – Infant Formula Nutrient Requirements; Request for Information

Dear Dr. Makary:

On behalf of the American Society of Pediatric Nephrology (ASPN), we appreciate the opportunity to submit comments on the Request for Information on Infant Formula Nutrient Requirements. Founded in 1969, ASPN is a professional society composed of pediatric nephrologists and allied health professionals whose goal is to promote optimal care for children with kidney disease and to disseminate advances in the clinical practice and basic science of pediatric nephrology. ASPN currently has over 700 members, making it the primary representative of the Pediatric Nephrology community in North America.

ASPN appreciates the FDA's efforts to review and update infant formula nutrient requirements in order to ensure nutritional adequacy and safety for infants. While we recognize that the RFI is focused on formula intended for healthy, full-term infants, we urge the agency ensure that specialized formulas remain available for infants and children with chronic medical conditions that require specialized nutrition, including for our patients with kidney disease. Pediatric patients with kidney disease often require specialized formula with reduced electrolytes and altered nutritional components given the complexities of the disease. Diseased kidneys are not able to process the content of standard formulas. These include Similac PM 60/40, which is an infant formula often used for children with kidney disease; Renastart and Renastep, pediatric formulas for children with chronic kidney disease (CKD) and end-stage kidney disease (ESKD); and Calcilo XD, a formula specially made for children with calcium homeostasis disorders.

For all infant formulas, the goal is for the formula to be a substitute for breast milk and to serve as the sole source of nutrition for growing and developing infants. All of the ingredients included in formula must be generally recognized as safe (GRAS), and functional ingredients are added to the formulations to make products more like breast milk, including long-chain polyunsaturated

fatty acids, nucleotides, prebiotics, and probiotics.¹ For infants who have a lactose intolerance, rice starch may be substituted in to make the formula more tolerable. As the FDA reviews the infant formula requirements, we urge you to look at the health benefits added by each ingredient, and to ensure that our children continue to receive the best nutrition possible in their early months.

ASPN appreciates the opportunity to offer comments on this RFI. Please contact our Washington representative Stefanie Rinehart at srinehart@dc-crd.com if we can provide additional information or clarification regarding these comments.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Meredith Atkinson', is positioned above the printed name.

Meredith Atkinson
President

¹ Green Corkins K, Shurley T. What's in the Bottle? A Review of Infant Formulas. Nutr Clin Pract. 2016 Dec;31(6):723-729. doi: 10.1177/0884533616669362. Epub 2016 Sep 25. PMID: 27646861.