Children's Wisconsin

September 11, 2025

U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

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

On behalf of Children's Wisconsin's Clinical Nutrition team, I write to respond to the Food and Drug Administration's (FDA) request for information on infant formula to share additional information related to labeling and preparation safety, as well as the importance of the Special Supplemental Nutrition Program for Women Infant and Children (WIC) program.

Children's Wisconsin (Children's) is the state's only independent health system dedicated solely to the health and well-being of kids. We serve children and families in every county across the state, with two inpatient hospitals and more than 40 primary, specialty and urgent care clinics. We care for every part of a child's health, from critical care at one of our hospitals, to routine check-ups in our primary care clinics. Children's focuses on all elements of pediatric well-being by providing dental care, school health nurses, foster care and adoption services, family resource centers, child health advocacy, health education, family preservation and support, mental health services, pediatric medical research and the statewide poison hotline.

Children's Clinical Nutrition team is dedicated to helping each child reach their potential through optimal and personalized nutrition. Registered dietitians work alongside the care teams with children and their families in the hospital, in specialty clinics and in primary care to help each child thrive. They provide nutritional screening, develop individualized care plans and provide comprehensive nutrition education. Each day, Children's providers and clinicians, including our registered dietitians, work with families who utilize infant formula products; it is paramount to ensure their utmost safety, quality and availability.

In the first six months of life, in the absence of human milk, infant formula provides infants their sole source of nutrition. As you know, adequate nutrition is the cornerstone of all forms of growth and development. Any adverse or inappropriate provisions of nutrition place these vulnerable infants at significant risk for poor short- and long-term health outcomes. For example, during the infant formula shortage in 2022, Children's had multiple patients admitted to the hospital for malnutrition and associated electrolyte disturbances due to lack of access to infant formula and/or inappropriate formula substitutions. Additionally, many families reached out to Children's desperate for help obtaining their medically necessary infant formulas.

One of the ways the FDA can work to ensure the safety and accessibility of infant formula is to make improvements to product labeling and product tracking. The naming system currently utilized by many formula manufacturers is not conducive to safe clinician or consumer/family use. Many products are similar in name and often begin with the manufacturer's name first, likely for brand loyalty. Often the second or even third word in the name is what differentiates the product from other products. This poses a safety risk in terms of error in purchase and use, especially with respect to products that vary with protein content, lactose content, and allergenicity. Additionally, the product names are often scientific in nature and include details

and instructions on the container that are not written within the recommended 4th grade reading level to promote health literacy.

In practice, when families share what formula their infant utilizes during clinic visits or hospital admissions, they often refer to the product by the generic manufacturer brand name and/or color of the can rather than the complete formula name. This can cause confusion for providers when trying to determine which product a family is using so they can assess nutritional adequacy and to aid in selecting an appropriate formula should the child be admitted to the hospital. While infant formula products have nearly identical names, their ingredients can vary greatly with significant implications for patient health. The lack of clear, distinguishing labeling often results in providers and families navigating this gap by pulling up pictures of the product in question online for verification to help avoid errors.

For many of our patients, food is medicine. As such, Children's suggests the FDA treat infant formula like medication and create naming guidance to decrease the risk for "look-alike, sound-alike" names to improve patient safety. Additionally, Children's supports instituting guidelines for consistent label colors across formula categories (standard cow milk, soy, goat milk, extensively hydrolyzed, partially hydrolyzed, and elemental) to help families identify similar formulas across brands. Children's also believes there could be improvements to labeling on the back of formula containers related to ingredients and formula preparation instructions to reduce errors and improve consumer transparency and readability. Many formulas list their ingredients with the scientific names which makes it difficult to recognize the essential vitamins and minerals that are included. As families are becoming more aware of ingredient labeling, Children's recommends that ingredients listed on the formula include their common names (e.g. calcium), with the scientific ingredient names remaining readily available on each manufacturer's health care provider page for professional use.

In addition to ingredients, the instructions for formula preparation are also listed on the back of the container. These instructions are not consistent across manufacturers and products which can lead to significant errors, especially in the setting of a formula shortage or change in WIC contracts where families may need to switch brands. For example, some standard infant formulas are prepared by mixing one ounce water with one scoop powder, while many others require two ounces water with one scoop powder. Some products on the market require "packed" scoops which adds further confusion for families. When formula is mixed inappropriately, this can lead to either over-diluted or over-concentrated formulas which can lead to electrolyte derangements and growth concerns, among other issues. Children's routinely sees infants admitted to the hospital with malnutrition and electrolyte derangements due to inappropriate formula mixing. To ameliorate this, Children's proposes that all infant formula products require the same preparation instructions to reduce the risk of improper mixing, especially for families with limited English proficiency and/or low health literacy.

With respect to WIC contracts mentioned above, Children's encourages the FDA to simplify the process to enable WIC programs to offer families a wider selection of infant formula options than are typically available under single-supplier contracts. This flexibility empowers families to access the nutritional support their babies need without burdensome documentation.

Lastly, Children's supports the recommendation proposed at the FDA's roundtable on this initiative to create a publicly accessible database of infant formulas. Functionally, it would be helpful for this database to be split into consumer and clinician sites as the information that consumers require is often different than that of health care providers. This database would help to provide information to all groups, irrespective of their knowledge of the science, on product

names, nutrient levels and ingredient lists. It would also be helpful for providers and consumers in the event of another formula shortage.

Thank you for your time and attention to this matter, as well as the FDA's efforts on Operation Stork Speed. While Children's appreciates FDA's request for updated literature and science regarding ingredients and nutrient levels, we encourage the FDA to also consider these other important aspects, such as labeling and marketing, that are critical to infant formula safety and quality.

Sincerely,

Lindsay Punzenberger
Director, Federal Government Relations
Children's Wisconsin