



February 10, 2023

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Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
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Submitted via email to: [claudine.kavanaugh@fda.hhs.gov]

RE: Request that the FDA enforce and amend 21 C.F.R. §§ 101.3, 101.7, 102, 102.5 and 107 against misbranded “transition formula” products represented or purported to be for children 9 to more than 12 months of age; Amend 21 C.F.R. § 101.3, and Amend 21 C.F.R. § 102, Submitted July 28, 2020 (Docket No. FDA-2020-P-1718)

Dear Dr. Kavanaugh,

The Public Health Advocacy Institute (PHAI) submits this letter requesting an update on the status of the citizen petition we submitted to the FDA on July 28, 2020 (Docket No. FDA-2020-P-1718). We would also like to take this opportunity to update the agency on additional research about toddler milks and transition formulas that has become available since the petition was originally submitted.

Background

Our petition requested that the agency take actions to enforce 21 C.F.R. §§ 101.3, 101.7, 102.5 and 107 against misbranded “transition formula” products represented or purported to be for children 9 to more than 12 months of age. We requested that the agency amend 21 C.F.R. § 101.3 to expressly prohibit the use of the term “infant formula” or “formula” on any drink products represented or purported to be for use by children more than 12 months old. We also asked the agency to amend 21 C.F.R. § 102 to establish a common or usual name for nonstandardized beverages represented or purported to be for use by children 12 to 36 months old, and to require disclaimers to clarify age of use and proper nutrition for young children.

PHAI submitted this petition over two years ago on behalf of twenty-five organizations and individuals concerned about products commonly referred to as “transition formulas” and “toddler milks.” These beverages are not recommended by health and nutrition experts as part of a child’s healthy diet, including the Academy of Nutrition and Dietetics, the American Academy of Pediatric Dentistry, the American Academy of Pediatrics, and the American Heart Association. As our petition details, current labeling and marketing of these products creates consumer confusion with infant formula; and creates the impression that plain, unsweetened milk and whole foods are insufficient to meet the nutritional needs of otherwise healthy young children.

The FDA acknowledged receipt of the petition on July 29, 2020, and posted the petition on regulations.gov.¹ It has received 6,290 comments, including comments in support of the petition from the National Association of Pediatric Nurse Practitioners, Center for Science in the Public Interest (CSPI), Trust for America's Health, University of California Agriculture and Natural Resources Nutrition Policy Institute, and the Robert Wood Johnson Foundation’s Healthy Eating Research.²

On January 25, 2021, the FDA issued a tentative response to the petition stating that it had not been able to reach a decision on the petition within the first 180 days of its receipt “because of other agency priorities and the limited availability of resources.”³ At that time the FDA advised that it would complete its review of the petition and consider any amendments to its regulations “as warranted and in the context of other program priorities within the Center.”⁴ To date, no final response has been provided to our petition.

¹ Public Health Advocacy Institute, Citizen Petition from Public Health Advocacy Institute, Inc. on behalf of 1,000 Days, et al. (July 29, 2020), [regulations.gov/docket/FDA-2020-P-1718](https://www.regulations.gov/docket/FDA-2020-P-1718).

² Public comments to the petition are available at <https://www.regulations.gov/docket/FDA-2020-P-1718/comments>.

³ *U.S. Food & Drug Admin*, Response Letter to Citizen Petition from FDA CFSAN to Public Health Advocacy Institute, Inc. on behalf of 1,000 Days, et al. (Feb. 2, 2021), <https://www.regulations.gov/docket/FDA-2020-P-1718/document>.

⁴ *Id.*

Updates to the Petition’s Factual Grounds

Studies by Choi et al., and Romo Palafox et al. that were in press when our original petition was submitted have been published,⁵ and findings from the unpublished focus group data discussed in our original petition have been published.⁶

Since our petition was submitted, transition formulas and toddler milks have continued to proliferate, and new research has been published to support regulatory action to prevent potential consumer confusion and economic harm. A narrative review of existing literature (focusing on U.S.-based research) on the extent and impact of marketing of commercial products for infants (up to 12 months) and toddlers (12– 36 months) found that in response to increasing breastfeeding rates and stable numbers of infants and young children, infant formula manufacturers have sought to grow their business by introducing new product categories (e.g., toddler milks), adding ingredients (e.g., DHA, prebiotics), and appealing to the desire to solve consumer needs (e.g., picky eaters, unique toddler nutrition requirements).⁷ A World Health Organization marketing study conducted from 2019 to 2021 similarly found that toddler milks and transition formulas are part of a global marketing strategy to expand the infant formula industry’s portfolio of products and increase sales.⁸ The study examined a sample of high and low income countries, and found that the number of products, including transition formula and toddler milks, offered for sale during the study period increased.⁹

New entrants to the toddler drink market have taken advantage of the U.S. infant formula shortage. The president of a company that recently introduced a toddler drink product in Walmart stores noted that the infant formula shortage: “...affected everything from infant

⁵ Yoon Young Choi, Alexis Ludwig & Jennifer L. Harris, *US Toddler Milk Sales and Associations with Marketing Practices*, 23 PUB. HEALTH NUTRITION 1127 (2020); Maria J. Romo Palafox, Jennifer L. Harris & Jennifer L. Pomeranz, *Infant Formula and Toddler Milk Marketing Claims and Caregiver Provision to Young Children in the United States*, 16 MATERNAL & CHILD NUTRITION 1 (2020).

⁶ Frances Fleming-Milici, Lindsay Phaneuf & Jennifer L. Harris, *Marketing of Sugar-sweetened Children's Drinks and Parents' Misperceptions About benefits for Young Children*, 18 MATERNAL & CHILD NUTRITION 1 (2022).

⁷ Jennifer L. Harris & Jennifer L. Pomeranz, *Infant Formula and Toddler Milk Marketing: Opportunities to Address Harmful Practices and Improve Young Children’s Diets*, 78 NUTRITION REVIEWS 866 (2020).

⁸ WORLD HEALTH ORGANIZATION & UNITED NATIONS CHILDREN’S FUND (UNICEF), *HOW THE MARKETING OF FORMULA MILK INFLUENCES OUR DECISIONS ON INFANT FEEDING* (2022), <https://www.who.int/publications/i/item/9789240044609>.

⁹ *Id.*

formula through toddler beverages and conventional feeding products for young kids,” because the entire infant formula aisle “...has been decimated with a lot of vacancies. So it gives us the ability to start building awareness in an aisle that shops very frequently. We get a lot of foot traffic and visibility.”¹⁰ Further, the infant formula shortage raises important questions about infant formula companies’ utilization of manufacturing resources for products that health experts recommend against serving babies and toddlers when they are unable to meet the demand of products babies need.

New research into the use of transition formula and toddler milk and the impact of product labeling and marketing claims on caregiver feeding behavior further supports regulatory action. A survey of 1,645 U.S. caregivers of children aged 6–36 months found more than one-third of infant caregivers surveyed reported serving at least one non-recommended milk type to their infant in the past month, including toddler milk and/or cow’s milk, and most reported providing them daily.¹¹ The majority of toddler caregivers did not follow expert recommendations to provide only cow’s milk to their children. They most often reported serving commercially prepared infant formula, followed by toddler milk and plant milk.¹² Approximately one-half of those who served commercially prepared toddler milk or infant formula to their toddler reported serving it daily.¹³ As discussed in our original petition, purchases of these products also present an economic harm to consumers because transition formulas and toddler milks are considerably more expensive than plain cow’s milk.

A study that conducted in-depth interviews and focus groups with 33 infant and toddler caregivers in 2021 confirmed what researchers found in data collected in 2019¹⁴: caregivers struggled to differentiate between toddler milk and infant formula and “perceived toddler milk

¹⁰ Steve Ellwanger, *Infant Formula Shortage Helps Open Shelf Space for Other Beverages*, MEDIAPOST (Oct 6, 2022), <https://www.mediapost.com/publications/article/378502/infant-formula-shortage-helps-open-shelf-space-for.html>.

¹¹ Maria J. Romo Palafox & Jennifer L. Harris, *Caregiver’s Provision of Non-Recommended Commercially Prepared Milk-Based Drinks to Infants and Toddlers*, 53 J. OF NUTRITION EDUC. & BEHAVIOR 643 (2021).

¹² *Id.*

¹³ *Id.*

¹⁴ Frances Fleming-Milici, Lindsay Phaneuf & Jennifer L. Harris, *Marketing of Sugar-sweetened Children’s Drinks and Parents’ Misperceptions About benefits for Young Children*, 18 MATERNAL & CHILD NUTRITION 1 (2022).

as part of a larger category of ‘formula.’”¹⁵ Common reasons given for offering toddler milk to children by study participants were “convenience, nutritional profile, and perceived benefits tied to health claims present on the labels,”¹⁶ despite child health expert recommendations that these products are not necessary for young children and that young children should not consume added sugar.

New research also highlights the disproportionate impact of toddler milk marketing on Latino caregivers and young children. Toddler milk products contain added sugars that are linked to increased rates of childhood obesity. Consumption of toddler milk by vulnerable groups like U.S. Latino children who are at an elevated risk for obesity is of particular concern. An online survey of 58 Latino parents found that 28% of caregivers incorrectly believed that a popular toddler milk did not contain added sugars, and 72% stated that a common reason why parents serve children toddler milk is to “provide nutrients.”¹⁷ A national survey of 1,078 U.S. parents of children aged 2–12 years (48% Latino) similarly found that “most parents thought toddler milk was as healthy as or healthier than regular milk.”¹⁸ The study also found that Latino caregivers were more likely to have purchased toddler milk for their children than non-Latino parents.¹⁹

Conclusion

We urge the agency to include transition formula and toddler drink labeling and marketing in its overall efforts to address the safety, supply, marketing and labeling of infant formula. In a relatively short period of time, transition formulas and toddler drinks have become part of a continuum of infant feeding products. Due to regulatory gaps, these products are being labeled and marketed to caregivers in ways that lead to consumer confusion with infant formula, and the use of infant formula and toddler drink products in place of plain cow’s milk against

¹⁵ Ana Paula C. Richter et al., *Toddler milk feeding practices and the role of health claims: A qualitative study of parents with toddlers* (2022) (unpublished research).

¹⁶ *Id.*

¹⁷ Emily W. Duffy et al., *Parental Perceptions and Exposure to Advertising of Toddler Milk: A Pilot Study with Latino Parents*, 18 INT’L J. OF ENVTL. RES. AND PUB. HEALTH 528 (2021).

¹⁸ Emily W. Duffy et al., *Toddler Milk Perceptions and Purchases: The Role of Latino Ethnicity*, 24 PUB. HEALTH NUTRITION 2911 (2021).

¹⁹ *Id.*

expert feeding recommendations. Our petition sets out a regulatory approach that would: establish common names for these products; require disclaimers in order to reduce consumer confusion with infant formula; and make it clear when a toddler drink contains added sugar. Dr. Kavanaugh, my colleagues and I would welcome an opportunity to discuss these updates and our reasons for seeking this regulatory action in person or virtually at your convenience.

Sincerely,

A handwritten signature in blue ink that reads "Mark A. Gottlieb". The signature is written in a cursive style and is enclosed within a thin blue rectangular border.

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