



**UNIVERSITY OF CALIFORNIA**  
Agriculture and Natural Resources

Nutrition Policy Institute

Wednesday, December 9, 2020

Dr. Susan T. Mayne  
Director, Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
Department of Health and Human Services  
Silver Spring, Maryland 20993

Re : Docket Number FDA-2020-P-1718

Dear Dr. Mayne:

The University of California, Division of Agriculture and Natural Resources (UC ANR), Nutrition Policy Institute submits this comment in support of the Citizen Petition (hereinafter Petition) filed by Public Health Advocacy Institute and 29 other public health professionals and advocacy groups on July 29, 2020.

Researchers at the UC ANR Nutrition Policy Institute (NPI) have conducted and translated policy-relevant research to transform environments for healthy children, families and communities for nearly twenty years. NPI's research led to the development of one of the nation's most comprehensive healthy beverage policy for child care environments, California's Healthy Beverages in Child Care Act of 2012, which requires that only plain water, unflavored milk, limited amounts of 100% fruit juice and no sugar-sweetened beverages be provided.<sup>1</sup> Further, NPI researchers collaborated to develop recommendations for feeding infants and toddlers in child care and evaluating state policies to ensure they support best practices for healthy beverages.<sup>2</sup> Beyond childcare, NPI is also actively involved in ensuring healthy beverages are available for young children in retail food environments and evaluating the federal Special Supplemental Nutrition Assistance Program for Women, Infants and Children (WIC) to ensure it supports improved diet-quality, including beverage-quality, for enrolled infants and children.<sup>3</sup> Thus, the petition's relevance is in alignment with our research and advocacy efforts.

The actions requested by the petitioners are necessary to address consumer confusion and public health harms posed by two categories of drinks: "transition formulas," which are labeled and marketed for children 9 to 24 months old, and "toddler milks," which are labeled and marketed for children 12 to 36 months old.

### The Problem

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<sup>1</sup> Lee DL, et al. Status of Beverages Served to Young Children in Child Care After Implementation of California Policy 2012-2016. *Preventing Chronic Disease*, 2020.

<sup>2</sup> Ritchie LD, et al. Transition from Breastfeeding and Complementary Feeding to Toddler Nutrition in Child Care Settings. *Nestle Nutrition Institute Workshop Series*, 2020; Pérez-Escamilla R, et al. Best Practices for Promoting Healthy Nutrition, Feeding Patterns, and Weight Status for Infants and Toddlers from Birth to 24 Months. *Healthy Eating Research*, 2017; Lee DL et al. Alignment of State Regulations With Breastfeeding and Beverage Best Practices for Childcare Centers and Family Childcare Homes, United States. *Public Health Reports*, available online 9 November 2020.

<sup>3</sup> Borger C, et al. WIC Infant and Toddler Feeding Practices Study-2 (WIC ITFPS-2): Fourth Year Report. *United States Department of Agriculture*, 2020; Harpainter P, et al. Voluntary Kids' Meal Beverage Standards: Are They Sufficient to Ensure Healthier Restaurant Practices and Consumer Choice? *International Journal of Environmental Research and Public Health*, 2020.



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**Current labeling and marketing of these products causes consumers to confuse them with infant formula.**<sup>4</sup> These products often have similar branding, colors, packaging, and labels as infant formulas from the same manufacturers. As a result, labeling of these products misleads caregivers into purchasing nutritionally inferior and unnecessary products for their infants and toddlers.

**Transition formulas are misbranded infant formulas.** Many transition formula products are labeled as “infant formula” or “infant and toddler formula,” but are marketed for use by infants up to 12 months old and by children over 12 months old. Thus, they do not meet the legal definition of “infant formula,” defined by FDA regulation to mean a food simulating human milk for special dietary use by infants, and infants are defined in FDA regulations as persons “not more than 12 months old.”<sup>5</sup> Moreover, when used as currently labelled they prolong the use of infant formula past infancy against expert recommendations.

**Labeling of toddler milks may mislead caregivers into purchasing harmful products for their infants.** From 6 to 12 months of age, a child’s nutrient needs should be met primarily through human milk/and or infant formula and healthy food, and provision of toddler milks is potentially dangerous if served to infants in place of infant formula or breastmilk.<sup>6</sup> Toddler milks do not meet the definition of “infant formula” prescribed by applicable federal laws and regulations. In a survey of 544 caregivers of infants under 12 months, 14% reported serving a toddler milk to their child most often.<sup>7</sup>

**Toddler milks and transition formulas are not recommended by health and nutrition experts as part of a toddler’s healthy diet.** These products are nutritionally inferior and unnecessary when compared to expert recommended plain cow’s milk for children over 12 months old. A consensus statement from key national health and nutrition organizations concluded that for children over 12 months, toddler milks are not recommended as they offer no unique nutritional value beyond what would be obtained with healthy foods, and they may contribute added sugars to a child’s diet.<sup>8</sup>

**There is currently no common or usual name for toddler milks.** Manufacturers have labeled them as “toddler drink,” “toddler nutritional drink,” “toddler milk drink,” “toddler formula,” and “tailored nutrition for toddlers.” Establishing a consistent statement of identity and labeling requirements, like those that exist for infant formula, would help ensure that consumers do not inappropriately serve these products to infants. Furthermore, eliminating terms such as “formula” and “nutrition” would help reduce consumer misperceptions about the healthfulness of these products.

**There is potential economic harm to families from purchasing transition formulas and toddler milks for children over 12 months old.** These products can cost up to four times the equivalent volume of unsweetened and unflavored cow’s milk—the recommended type of milk for children 12 to 36 months and older.<sup>9</sup> Nutrition-related

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<sup>4</sup> Romo-Palafox MJ, Pomeranz JL, Harris JL. Infant formula and toddler milk marketing claims and caregivers’ provision to young children. *Maternal and Child Nutrition*, 2020.

<sup>5</sup> 21 C.F.R. 106.3.

<sup>6</sup> Lott M, et al. *Healthy Beverage Consumption in Early Childhood: Recommendations from Key National Health and Nutrition Organizations. Technical Scientific Report*. Healthy Eating Research. 2019

<sup>7</sup> Romo-Palafox MJ, et al., *supra* note 1.

<sup>8</sup> Lott M, et al. 2019, *supra* note 3.

<sup>9</sup> *Id.*



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claims on transition formulas and toddler milks may mislead caregivers into purchasing these expensive products because they believe these beverages are necessary to support their children's health.

**Recommended Actions**

Based on the evidence above, we support the Petition's request for FDA 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 old;
- 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; and
- Amend 21 C.F.R. § 102 to establish a common or usual name for non-standardized 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.

We also support the Petition's recommendation that these products be required to bear the statement of identity "milk-based drink powder for 12 to 36 month olds," "soy-based drink powder for 12 to 36 month olds," or a statement of identity identifying other non-dairy proteins used in the product. The statement of identity should also include other characterizing information, including "sweetened" or "flavored" (e.g., "sweetened and flavored milk-based drink powder for 12 to 36 month olds"), to adequately distinguish them from plain unsweetened milk. The statement of identity should not use the term "nutritional drink" or "nutrition," which is misleading and not adequately distinguished from its other common usages (e.g., nutritional shakes for weight management).

Furthermore, we strongly support the Petition's call for a required disclaimer on the labels of toddler beverages, such as "DO NOT SERVE TO INFANTS UNDER 12 MONTHS OLD," to prevent consumer confusion with infant formula and potential harm to infants, as well as a disclaimer stating that children 1 to 3 years old should get nutrition from plain milk and food, such as "This product is not recommended as part of a healthy diet in early childhood."

**Conclusion**

It is critical that the FDA take action and implement the recommendations of the Petition to prevent caregivers from being misled into purchasing nutritionally inferior and unnecessary products for their infants and toddlers, and to protect the health of young children.

Sincerely,

*Lorrene D. Ritchie*

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