



February 10, 2021

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: Requests 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- more than 12 months of age; Amend 21 C.F.R. § 101.3, and Amend 21 C.F.R. § 102 (FDA-2020-P-1718)

Dear Dr. Mayne:

The Center for Science in the Public Interest submits this comment in support of the Citizen Petition filed by Public Health Advocacy Institute and 29 other public health professionals and advocacy groups on July 29, 2020.¹ The petitioners’ requests for enforcement of and updates to labeling regulations 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 anywhere from 12 to 36 months old. In this comment, we outline the real and potential risks posed by these beverages and describe how the Petition’s recommended remedies would help address these risks.

- I. Current marketing of toddler milks and transition formulas poses risks to the health of young children.
 - A. Toddler milks and transition formulas are marketed as healthy choices, but are not recommended by health and nutrition experts as part of a toddler’s healthy diet.

A consensus statement from the Academy of Nutrition and Dietetics, the American Academy of Pediatric Dentistry, the American Academy of Pediatrics (AAP), and the American Heart Association concluded that for children over 12 months old, toddler milks and transition formulas are not recommended because they offer no unique nutritional value beyond what would be obtained through a nutritionally adequate diet, and may contribute added sugars to a child’s diet.² The 2020-2025 Dietary Guidelines for Americans (DGA) also note: “There are no

¹ The Center for Science in the Public Interest was among the signatories of this petition.

² 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.

Note: the expert recommendations in this report state “1-5 years (12-60 months): Toddler milk is not recommended; nutrient needs should be met primarily through nutritionally adequate dietary patterns” (p24). “Toddler milk” is defined as “Milk drink supplemented with nutrients and often containing added sugars. These products are marketed as appropriate for children ages 9 to 36 months, and may be marketed as “transition formulas,” “follow-on

clear needs for toddler milks or drinks [...which] typically contain added sugars. A variety of nutrient-dense complementary foods and beverages without added sugars should be emphasized for achieving nutrient recommendations.”³

The 2020-2025 DGA recommend less than 25 grams of added sugar per day for children 2-3 years of age, and to avoid foods and beverages with added sugars for children younger than age 2.⁴ Toddler milks can contain up to 15g of added sugars per 8oz serving (see Example 1 at the end of this comment), considerably more than the 0g of added sugars in a serving of plain cow’s milk. Transition formulas typically use FDA’s infant formula nutrition label, as opposed to the Nutrition Facts label required for all other FDA-regulated food and beverages, and therefore are not labeled with total or added sugars content.⁵ However, their top ingredients typically include sources of added sugars such as corn syrup and sucrose. Furthermore, a study that looked at a convenience sample of labels on formula products from several countries found that dry formula marketed for children over 12 months in the United States contained an average of 7g of total sugars per reconstituted 100mL.⁶ By contrast, plain cow’s milk contains 5g of total sugars per 100mL, suggesting that formulas marketed for children over 12 months contribute more sugars to the diet than plain cow’s milk.

Toddler milks and transition formulas are commonly marketed with claims suggesting they are beneficial or necessary for brain development, strong bones and teeth, immune support, and toddler growth and development (see Example 2). These structure/function claims, which refer to the role of vitamins and other nutrients that are added to the products, mislead caregivers to believe that children who consume these products will have superior cognition, bone strength, immunity, or growth compared to children who consume a healthy diet of ordinary foods. They also connote a misleading image of overall healthfulness. However, these products contribute more added sugars to the diet and are more likely to lead children to exceed daily calorie recommendations when compared to expert-recommended plain cow’s milk for children over 12 months old, and do not add any essential nutrients to the diet that could not be otherwise obtained from foods. Structure/function claims appear on product packages as well as in advertisements, online point of purchase (e.g. Amazon), and on TV. Many caregivers are unaware that companies need little or no evidence to make these claims. The marketing of toddler milks and transition formulas with structure/function claims may confuse caregivers about the true appropriateness and healthfulness of these products.

B. Current labeling and marketing of toddler milks and transition formulas mislead consumers by representing formula products as healthy choices for toddlers.

formulas,” or “weaning formulas” for children 9 to 24 months and “toddler milk,” “growing-up milk,” or “young child drink” for children 12 to 36 months” (p1).

³ U.S. Department of Agriculture and U.S. Department of Health and Human Services, Dietary Guidelines for Americans, 2020-2025. 9th Edition. December 2020. Available at [DietaryGuidelines.gov](https://www.dietaryguidelines.gov).

⁴ *Id.* Note: the 2020-2025 DGA recommend less than 10 percent of calories per day from added sugars starting at age 2, and daily nutritional goals based on a 1,000-calorie diet for children ages 2-3 years; 10% of 1,000 calories is 100 calories, which is equivalent to 25 grams of added sugars (at 4 calories per gram)

⁵ 21 C.F.R. 107.10

⁶ Bridge G, Lomazzi M, and Bedi R. A cross-country exploratory study to investigate the labelling, energy, carbohydrate and sugar content of formula milk products marketed for infants. *British Dental Journal*. 2020;228(3):198-212.

Infant formula products may only be marketed to children ages 0-12 months.⁷ The products that are the subject of these comments often have similar branding, colors, and packaging as infant formulas from the same manufacturers, and (as mentioned above) some even use the FDA-approved nutrition label specifically intended for infant formula products (see Example 1). They often bear statements of identity such as “infant formula,” “infant and toddler formula,” or “toddler formula,” but are marketed for children over 12 months of age. Labeling and marketing of transition formulas for both infants and toddlers, despite their different nutritional needs, may be confusing for caregivers of toddlers. As a result of the labeling and marketing of transition formulas and toddler milks, caregivers may be misled to believe that it is necessary to prolong the use of infant formula (or nutritionally similar products) past infancy.

C. Labeling of toddler milks may mislead caregivers into purchasing harmful products for their infants.

FDA regulations dictate specific levels of a variety of nutrients that are required in infant formula.⁸ However, FDA has not established such regulations for toddler milks, and therefore these products need not adhere to any particular nutrition criteria. As such, toddler milk products may or may not be formulated to satisfy federal nutrition standards for infant formula. Due to their similar labeling, caregivers of infants may confuse toddler milks with infant formulas and feed them to their infants. In a survey of 544 caregivers of infants under 12 months, 11% selected a toddler milk as the product they most often served to their child when caregivers were shown labels of infant formula and toddler milk products.⁹ Some of these caregivers may have incorrectly believed they had selected an infant formula product due to the confusingly similar labeling and branding of infant formula and toddler milk products.

D. 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 over 12 months old.¹⁰ Nutrition-related 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.

II. The petition’s requested actions from FDA would help address the real and potential harms presented by these products.

Taking enforcement action against transition formula products as misbranded under current infant formula regulations, and expressly prohibiting the use of the term “formula” on products

⁷ FDA regulations define “infant formula” 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.”

⁸ 21 C.F.R. § 107.1

⁹ 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.

¹⁰ Lott M, et al. 2019, *supra* note 1.

marketed for children over 12 months old, would help prevent caregivers from being misled to believe these products are necessary or healthy for toddlers.

Establishing labeling requirements, including a statement of identity for toddler beverages, such as “milk-based drink powder for 12 to 36 month olds” and a disclosure, “DO NOT SERVE TO INFANTS UNDER 12 MONTHS OLD,” would help prevent caregivers of infants from unintentionally purchasing products intended for toddlers.

Requiring that toddler beverages with added sugars or flavors bear the terms “sweetened” or “flavored” could help caregivers differentiate them from healthier choices like plain cow’s milk.

In addition to these actions requested in the petition, we encourage FDA to consider requiring prominent front-of-package disclosures on beverages marketed for children age 12-24 months that contain added sugars, stating: “This product contains added sugars. The Dietary Guidelines for Americans recommend to avoid food and beverages with added sugars for children younger than age 2.”

III. Conclusion

It is critical that the FDA take action and implement the recommendations of the Petition to prevent caregivers from being misled into purchasing products that health experts have stated are not recommended for young children.

Example 1: Gerber Good Start Products and Age Group Indicated on Label



Infant formula (0-12 months)



Transition formula (9-24 months)

- Top 4 ingredients include sucrose (added sugars) and corn maltodextrin (may be a source of added sugars)
- Bears FDA's infant formula nutrition label, as opposed to the Nutrition Facts label



Toddler milk (12-24 months)

- Contains 15g of added sugars per serving
- Bears similar branding and packaging as infant formula and transition formula

Example 2: Structure/Function Claims on Toddler Milk Products



- Immune health
- Supports brain development



- Immune support
- Brain & eye development



- Neuro Support- Supports Brain Development- Motor, Cognitive, Communication, Social
- DHA and Iron to Help Support Brain Development
- Calcium and Vitamin D for Strong Bones