

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

CITIZEN PETITION

July 28, 2020

Submitted via electronic submission through [regulations.gov](https://www.regulations.gov)

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Via electronic submission through [regulations.gov](https://www.fda.gov/regulatory-information/federalregister)

July 28, 2020

Division of Dockets Management
Department of Health and Human Services
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

On behalf of the undersigned, Public Health Advocacy Institute (PHAI) submits this petition and Attachments A-G to the Food & Drug Administration (FDA) in accordance with FDA regulations. This petition requests that the Commissioner 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;
- 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 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.

These actions are necessary to address two categories of drinks: “transition formulas,” which are labeled and marketed for children 9 to 18 or 24 months and “toddler milks,” which are labeled and marketed for children 12 to 36 months old. These beverages are not recommended by health and nutrition experts as part of a child’s healthy diet. 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.

From 2006 - 2015, advertising spending on transition formulas and toddler milks increased four-fold, and volume sales increased 2.6 times. However, transition formulas are not nutritionally appropriate for children over 12 months and toddler milks offer no unique nutritional value beyond what should be obtained from milk and other healthy foods. Furthermore, these products contribute added sugars to the diets of young children and create a potential economic harm to their families. These products can cost more than 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. The requested actions are within existing FDA authority and are warranted to ensure that caregivers are not misled into purchasing nutritionally inferior and unnecessary products for their infants and toddlers.

Respectfully submitted,

A handwritten signature in blue ink that reads "Mark A. Gottlieb". The signature is written in a cursive, flowing style.

Mark A. Gottlieb, JD
Executive Director
Public Health Advocacy Institute, Inc.

TABLE OF CONTENTS

PART A – ACTION REQUESTED

PART B – STATEMENT OF GROUNDS

I. Statement of the Problem

II. Legal Grounds

A. FDA Authority to Act Upon the Requests Contained in this Citizen Petition

B. Regulatory framework for the composition and labeling of infant formula

C. Regulatory framework for beverages for children 12 – 36 months

III. Factual Grounds

A. Transition Formula Product Composition and Labeling Practices

B. Toddler Milk Product Composition and Labeling Practices

IV. Recommended Actions

A. Transition Formula

B. Beverages for Children 12 – 36 Months Old

Part C – Environmental Impact

Part D – Economic Impact

Part E – Certification

ATTACHMENTS

ATTACHMENT A: Transition Formula & Toddler Milk Products for Sale in November 2019

ATTACHMENT B: Price Comparison of Cow's Milk, Transition Formula & Toddler Milk

ATTACHMENT C: Side-by-Side Comparison of Nutrient Content of Infant Formula vs. Transition Formula

ATTACHMENT D: Nutritional Composition of Toddler Milk vs. Plain Milk

ATTACHMENT E: Marketing Claims & Comparisons to Plain Milk & Whole Foods

ATTACHMENT F: Examples of Beverages Labeled as Nutrition Drinks, Nutritional Drinks, Nutrition Shakes

ATTACHMENT G: Incorrect Use of the Term “Toddler” to Encompass Infants Less Than 12 Months Old

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CITIZEN PETITION

PART A – ACTION REQUESTED

The Public Health Advocacy Institute (PHAI) submits this petition on behalf of the undersigned organizations and individuals under 21 U.S.C. §§ 321, 341, 343, 371(a) and 21 C.F.R. §§ 10.30, 102.19, 101.3. We request that the Commissioner take the following actions:

1. Take prompt enforcement action under 21 C.F.R. §§ 101.3, 101.7, 102.5 and 107 against misbranded “transition formula” represented or purported to be for children from 9 to more than 12 months of age.
2. 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.
3. 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.

The amendments to 21 C.F.R. § 101.3 requested are marked in ***bold and italicized*** in the text below:

PART 101 – FOOD LABELING

Subpart A – General Provisions

Sec. 101.3 Identity labeling of food in packaged form.

(a) The principal display panel of a food in package form shall bear as one of its principal features a statement of the identity of the commodity.

(b) Such statement of identity shall be in terms of:

(1) The name now or hereafter specified in or required by any applicable Federal law or regulation; or, in the absence thereof,

(2) The common or usual name of the food; or, in the absence thereof,

(3) An appropriately descriptive term, or when the nature of the food is obvious, a fanciful name commonly used by the public for such food.

(c) Where a food is marketed in various optional forms (whole, slices, diced, etc.), the particular form shall be considered to be a necessary part of the statement of identity and shall be declared in letters of a type size bearing a reasonable relation to the size of the letters forming the other components of the statement of identity; except that if the optional form is visible through the container or is depicted by an appropriate vignette, the particular form need not be included in the statement. This specification does not affect the required declarations of identity under definitions and standards for foods promulgated pursuant to section 401 of the act.

(d) This statement of identity shall be presented in bold type on the principal display panel, shall be in a size reasonably related to the most prominent printed matter on such panel, and shall be in lines generally parallel to the base on which the package rests as it is designed to be displayed.

(e) Under the provisions of section 403(c) of the Federal Food, Drug, and Cosmetic Act, a food shall be deemed to be misbranded if it is an imitation of another food unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.

(1) A food shall be deemed to be an imitation and thus subject to the requirements of section 403(c) of the act if it is a substitute for and resembles another food but is nutritionally inferior to that food.

(2) A food that is a substitute for and resembles another food shall not be deemed to be an imitation provided it meets each of the following requirements:

(i) It is not nutritionally inferior to the food for which it substitutes and which it resembles.

(ii) Its label bears a common or usual name that complies with the provisions of 102.5 of this chapter and that is not false or misleading, or in the absence of an existing common or usual name, an appropriately descriptive term that is not false or misleading. The label may, in addition, bear a fanciful name which is not false or misleading.

(3) A food for which a common or usual name is established by regulation (e.g., in a standard of identity pursuant to section 401 of the act, in a common or usual name regulation pursuant to part 102 of this chapter, or in a regulation establishing a nutritional quality guideline pursuant to part 104 of this chapter), and which complies with all of the applicable requirements of such regulation(s), shall not be deemed to be an imitation.

(4) Nutritional inferiority includes:

(i) Any reduction in the content of an essential nutrient that is present in a measurable amount, but does not include a reduction in the caloric or fat content provided the food is labeled pursuant to the provisions of 101.9, and provided the labeling with respect to any reduction in caloric content complies with the provisions applicable to caloric content in part 105 of this chapter.

(ii) For the purpose of this section, a measurable amount of an essential nutrient in a food shall be considered to be 2 percent or more of the Daily Reference Value (DRV) of protein listed under 101.9(c)(7)(iii) and of potassium listed under 101.9(c)(9) per reference amount customarily consumed and 2 percent or more of the Reference Daily Intake (RDI) of any vitamin or mineral listed under 101.9(c)(8)(iv) per reference amount customarily consumed, except that selenium, molybdenum, chromium, and chloride need not be considered.

(iii) If the Commissioner concludes that a food is a substitute for and resembles another food but is inferior to the food imitated for reasons other than those set forth in this paragraph, he may propose appropriate revisions to this regulation or he may propose a separate regulation governing the particular food.

(f) A label may be required to bear the percentage(s) of a characterizing ingredient(s) or information concerning the presence or absence of an ingredient(s) or the need to add an ingredient(s) as part of the common or usual name of the food pursuant to subpart B of part 102 of this chapter.

(g) Dietary supplements shall be identified by the term "dietary supplement" as a part of the statement of identity, except that the word "dietary" may be deleted and replaced by the name of the dietary ingredients in the product (e.g., calcium supplement) or an appropriately descriptive term indicating the type of dietary ingredients that are in the product (e.g., herbal supplement with vitamins).

(h) Any beverage, in powder or liquid form, represented or purported to be for use by children more than 12 months old shall not be identified as "infant formula" or use the term "formula" in combination with any other term.

The amendments to 21 C.F.R. § 102 requested are marked in *bold and italicized* in the text below:

PART 102 - COMMON OR USUAL NAME FOR NONSTANDARDIZED FOODS

Subpart B - Requirements for Specific Nonstandardized Foods

Sec. 102.33 Beverages that contain fruit or vegetable juice.

(a) For a carbonated or noncarbonated beverage that contains less than 100 percent and more than 0 percent fruit or vegetable juice, the common or usual name shall be a descriptive name that meets the requirements of 102.5(a) and, if the common or usual name uses the word "juice," shall include a qualifying term such as "beverage," "cocktail," or "drink" appropriate to advise the consumer that the product is less than 100 percent juice (e.g., "diluted grape juice beverage" or "grape juice drink").

(b) If the product is a diluted multiple-juice beverage or blend of single-strength juices and names, other than in the ingredient statement, more than one juice, then the names of those juices, except in the ingredient statement, must be in descending order of predominance by volume unless the name specifically shows that the juice with the represented flavor is used as a flavor (e.g., raspberry-flavored apple and pear juice drink). In accordance with 101.22(i)(1)(iii) of this chapter, the presence of added natural flavors is not required to be declared in the name of the beverage unless the declared juices alone do not characterize the product before the addition of the added flavors.

(c) If a diluted multiple-juice beverage or blend of single-strength juices contains a juice that is named or implied on the label or labeling other than in the ingredient statement (represented juice), and also contains a juice other than the named or implied juice (nonrepresented juice), then the common or usual name for the product shall indicate that the represented juice is not the only juice present (e.g., "Apple blend; apple juice in a blend of two other fruit juices.")

(d) In a diluted multiple-juice beverage or blend of single-strength juices where one or more, but not all, of the juices are named on the label other than in the ingredient statement, and where the named juice is not the predominant juice, the common or usual name for the product shall:

- (1) Indicate that the named juice is present as a flavor or flavoring (e.g., "Raspcranberry"; raspberry and cranberry flavored juice drink); or
 - (2) Include the amount of the named juice, declared in a 5- percent range (e.g., Raspcranberry; raspberry and cranberry juice beverage, 10- to 15- percent cranberry juice and 3- to 8-percent raspberry juice). The 5-percent range, when used, shall be declared in the manner set forth in 102.5(b)(2).
- (e) The common or usual name of a juice that has been modified shall include a description of the exact nature of the modification (e.g., "acid-reduced cranberry juice," "deflavored, decolored grape juice").
- (f) If the product is a beverage that contains a juice whose color, taste, or other organoleptic properties have been modified to the extent that the original juice is no longer recognizable at the time processing is complete, or if its nutrient profile has been diminished to a level below the normal nutrient range for the juice, then the source fruits or vegetables from which the modified juice was derived may not be depicted on the label by vignette or other pictorial representation.
- (g)(1) If one or more juices in a juice beverage is made from concentrate, the name of the juice must include a term indicating that fact, such as "from concentrate," or "reconstituted." Such terms must be included in the name of each individual juice or it may be stated once adjacent to the product name so that it applies to all the juices, (e.g., "cherry juice (from concentrate) in a blend of two other juices" or "cherry juice in a blend of 2 other juices (from concentrate)"). The term shall be in a type size no less than one-half the height of the letters in the name of the juice.
- (2) If the juice is 100 percent single species juice consisting of juice directly expressed from a fruit or vegetable whose Brix level has been raised by the addition of juice concentrate from the same fruit or vegetable, the name of the juice need not include a statement that the juice is from concentrate. However, if water is added to this 100 percent juice mixture to adjust the Brix level, the product shall be labeled with the term "from concentrate" or "reconstituted."

Sec. 102.34 Beverages for children 12 – 36 months old

(a) For a powdered or liquid milk-based beverage represented or purported to be for use by children 12 to 36 months old, the common or usual name shall be a descriptive term such as “milk-based drink” and if the product contains added sugars, nonnutritive sweeteners or flavorings it shall include a qualifying term such as “sweetened” or “flavored” to advise the consumer that the product is not plain milk (e.g. “sweetened milk-based drink powder for 12 – 36 month olds,” “flavored sweetened milk-based drink powder for 12 – 36 month olds”) and comply with the other labeling requirements of this section.

(b) Non-dairy-milk-based powdered or liquid beverages represented or purported to be for use by children 12 – 36 months old shall use an appropriately descriptive term identifying the source of protein such as “soy-based drink powder for 12 to 36 month olds,” include qualifying terms such as “sweetened” and “flavored” when applicable and comply with the other labeling requirements of this section.

(c) The label shall also contain the following:

(1) A disclaimer that cautions against use of the product with infants, such as “DO NOT SERVE TO INFANTS UNDER 12 MONTHS OLD.”

(2) A statement indicating that children 12 to 36 months of age do not require these products for a healthy diet, such as “This product is not recommended by health and nutrition experts.”

(d) Label statements suggesting a recommended intake such as “one cup a day” are not permitted.

PART B – STATEMENT OF GROUNDS

I. Statement of the Problem

Feeding infants (up to 12 months old) and toddlers (12 to 36 months old) during the transition from exclusive breastfeeding or infant formula to the family diet is critical for establishing healthy dietary preferences in children.¹ The American Academy of Pediatrics (AAP) recommends exclusive breastfeeding for the first 6 months of life with the addition of complementary foods and the continuation of breastfeeding until at least 12 months of age.² Iron-fortified infant formula is recommended for infants who are not breastfed. After 12 months, whole plain pasteurized cow's milk, plain water, and healthy foods are advised.³ After 24 months, caregivers are advised to shift from whole milk to plain non-fat (skim) or low-fat milk.⁴

¹ Rafael Pérez-Escamilla, Sofia Segura-Pérez & Megan Lott, FEEDING GUIDELINES FOR INFANTS AND YOUNG TODDLERS: A RESPONSIVE PARENTING APPROACH (2017), https://healthyeatingresearch.org/wp-content/uploads/2017/02/her_feeding_guidelines_report_021416-1.pdf (report on behalf of the Robert Wood Johnson Foundation Healthy Eating Research Expert Panel on Best Practices for Promoting Healthy Nutrition, Feeding Patterns, and Weight Status for Infants and Toddlers from Birth to 24 Months).

² Breastfeeding Section, American Academy of Pediatrics, *Policy Statement: Breastfeeding and the Use of Human Milk*, 129 PEDIATRICS e827 (2012).

³ Megan Lott, Emily Callahan, Emily Welker Duffy, et al., HEALTHY BEVERAGE CONSUMPTION IN EARLY CHILDHOOD: RECOMMENDATIONS FROM KEY NATIONAL HEALTH AND NUTRITION ORGANIZATIONS. TECHNICAL SCIENTIFIC REPORT 5 (2019), <https://healthyeatingresearch.org/wp-content/uploads/2019/09/HER-HealthyBeverageTechnicalReport.pdf>.

⁴ *Id.* at 5.

However, additional drinks are represented or purported to be for children 12 to 36 months old, which fall into two main categories:

- (1) Transition formulas which are purported to be for children 9 to 18 or 24 months. Transition formulas are essentially infant formula products marketed for older infants and toddlers; and
- (2) Toddler milk which includes drinks purported to be for children ages 12 to 36 months. These products are typically milk- or soy-based with added vegetable oil, nutrients, and added sugars. They are sold in powder and liquid form and come in flavors like vanilla, honey and “natural milk.”

Attachment A provides examples of these products as currently offered for sale.

A panel of experts from the AAP, the American Academy of Pediatric Dentistry (AAPD), the American Heart Association (AHA) and the Academy of Nutrition and Dietetics (AND) reviewed the evidence for beverages consumed during early childhood and issued a Consensus Statement of their findings (hereinafter “2019 Expert Consensus Statement”). The review included an evaluation of “toddler milk” defined as a:

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 formulas,” or “weaning formulas” for children 9 to 24 months and “toddler milk,” “growing-up milk,” or “young child milk” for children 12 to 36 month.⁵

The expert panel concluded that “these products offer no unique nutritional value beyond what could be achieved through a nutritionally adequate diet; furthermore, they may contribute added sugars to the diet.”⁶ It also concluded that they may undermine

⁵ *Id.* at 1 (citations omitted).

⁶ *Id.* at 24.

sustained breastfeeding.⁷ The panel recommended longitudinal studies to determine whether toddler milk consumption negatively impacts the nutrient intake and dietary patterns of toddlers.⁸

In its analysis of sweetened flavored milks (e.g., chocolate or strawberry-flavored cow's milk), the panel concluded that they should be avoided to minimize intake of added sugars and to avoid contributing to early establishment of a preference for sweet taste.⁹ These same rationale would apply to flavored toddler milks that contain added sugars and/or flavors (e.g., vanilla, "natural milk" and honey flavored).

Transition formulas and toddler milks are a rapidly growing beverage category. A study of U.S. Nielsen data found that advertising spending on these drinks increased four-fold from \$5 million annually in 2006-2008 to more than \$20 million in 2013 – 2015, and that sales increased 2.6 times from 2006 – 2015.¹⁰ The average price of toddler milks decreased from \$0.84/oz. in 2006 to \$0.76/oz in 2015.¹¹ In contrast, advertising spending on infant formula increased from 2006 to 2010 and then declined back to 2006 levels in 2015.¹² During the same time period volume sales of infant formula decreased by 7%, and average prices increased 33% from \$0.97/oz. in 2006 to \$1.28/oz. in 2015.¹³ As a result, total combined dollar sales of infant formula and toddler milks grew

⁷ *Id.* at 6.

⁸ *Id.* at 23

⁹ *Id.*

¹⁰ Yoon Young Choi, Alexis Ludwig, Jennifer L. Harris. *US Toddler Milk Sales and Associations with Marketing Practices*, __ PUB. HEALTH NUTRITION __ (In Press).

¹¹ *Id.*

¹² *Id.*

¹³ *Id.*

from \$1,056 million in 2006 to \$1,351 million in 2015 despite declining sales of infant formula.

Growing toddler drink sales indicate a potential economic harm to families with young children. They can cost more than four times the price of the equivalent volume of plain cow's milk. (Attachment B). A gallon of whole plain cow's milk costs \$4.68/gallon versus \$16.13 - \$20.21/gallon for the transition formula and toddler milk brands. (Attachment B).

II. Legal Grounds

A. FDA Authority to Act Upon the Requests Contained in this Citizen Petition

The FDA has authority to issue “regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, or reasonable standards of fill of container.”¹⁴ The Commissioner may prescribe a common or usual name for a food “on his own initiative or on behalf of any interested person who has submitted a petition [in accordance with 21 CFR § 10.30].”¹⁵ Common or usual names of foods also may be established by “common usage.”¹⁶

The FDA has the authority to deem articles as misbranded if a product’s “labeling is false or misleading in any particular” and/or “if it is offered for sale under the name of another food.”¹⁷ When determining whether an article is misbranded because of misleading labeling or advertising, omissions of fact can also be taken into account:

¹⁴ 21 U.S.C. §§ 341, 371.

¹⁵ 21 C.F.R. §§ 102.5, .19.

¹⁶ 21 C.F.R. § 102.5(d).

¹⁷ 21 U.S.C. § 343.

...there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the articles to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.¹⁸

B. Regulatory framework for the composition and labeling of infant formula

Infant formula is defined as “a food which purports to be or is represented for special dietary use for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk.”¹⁹ FDA regulations define an infant as a person not more than 12 months old,²⁰ and establish good manufacturing standards and nutrient content requirements.²¹ Infant formula must bear a unique nutrition facts panel, and is exempt from the general nutrition labeling requirements for food contained in 21 CFR § 101.9.²² It also is required to display written and visual directions for use; a warning statement about safe product preparation; and a statement that caregivers consult a physician prior to use.²³

The FDA does not recognize different age categories within infancy and early childhood (e.g. 0-9 months or 9-24 months). In response to comments to rulemaking to revise the good manufacturing standards for infant formula, the FDA cited the definition of an infant as a person not more than 12 months old at 21 § CFR 105.3(e), and

¹⁸ 21 U.S.C. § 321(n).

¹⁹ 21 U.S.C. § 321(z).

²⁰ 21 C.F.R. § 105.3(e).

²¹ 21 C.F.R. §§ 106-107.

²² 21 C.F.R. §§ 107, 101.9(j)(7).

²³ 21 C.F.R. § 107.2.

concluded that the FDA does “not distinguish between formula for infants less than 6 months of age and formula intended for infants older than 6 months.”²⁴ However, the FDA has not engaged in any enforcement actions for products that do not comply with this conclusion.

Infant formula is subject to FDA regulations requiring that a food label bear a statement of identity containing the common or usual food name.²⁵ The statement of identity must be presented in bold type on the principal display panel and in a size reasonably related to the most prominent printed matter, including the brand name.²⁶ In general, a statement of identity:

...shall accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients. The name shall be uniform among all identical or similar products and may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name. Each class or subclass of food shall be given its own common or usual name that states, in clear terms, what it is in a way that distinguishes it from different foods.²⁷

Specifically, a statement of identity must be the name specified by applicable Federal law or regulation;²⁸ the common or usual name of the food;²⁹ an “appropriately descriptive term;” or when the nature of the food is obvious, a fanciful name commonly used by the public for such food.”³⁰

²⁴ Jennifer L. Pomeranz & Jennifer L. Harris, *Federal Regulation of Infant and Toddler Food and Drink Marketing and Labeling*, 45 AM. J. OF LAW & MED. 32, 45 (2019).

²⁵ 21 U.S.C. § 343(i)(1); U.S. FOOD & DRUG ADMIN., LABELING OF INFANT FORMULA: GUIDANCE FOR INDUSTRY 4 (2016).

²⁶ 21 U.S.C. § 343(f); 21 C.F.R. § 101.3.

²⁷ 21 C.F.R. § 102.5.

²⁸ 21 C.F.R. § 101.3(b)(1).

²⁹ 21 C.F.R. § 101.3(b)(2).

³⁰ 21 C.F.R. § 101(b)(3).

In its 2016 guidance document *Labeling of Infant Formula: Guidance for Industry*, the FDA emphasized that a statement of identity must contain all characterizing information in order to address its concern about “the number of infant formula products that bear the same or similar statements of identity but are different in composition or intended use.”³¹ For example, “a label stating ‘Infant Formula’ may not be sufficient to appropriately describe a product when it is, for example, ‘Soy-Based Infant Formula Powder.’”³²

C. Regulatory framework for beverages for children 12 to 36 months old

Beverages represented or purported for use by children aged 12 to 36 months old are not encompassed by the FDA’s infant formula regulations. They are not currently subject to any specific nutrient content, common name or claim requirements, required directions for use or required disclaimers.³³ These beverages do fall under the general statutory definition of “food” as “articles used for food or drink for man...”³⁴ As such, they are subject to FDA regulations requiring that a food label bear a statement of identity containing the common or usual food name,³⁵ and comply with nutrition labeling requirements for foods represented or purported for use by children 1 to 3 years of age.³⁶

³¹ U.S. FOOD & DRUG ADMIN., *supra* note 25, at 3.

³² *Id.* at 4.

³³ Jennifer L. Pomeranz, Maria J. Romo Palafox, Jennifer L. Harris, *Toddler Drinks, Formulas, and Milks: Labeling Practices and Policy Implications*, 109 PREVENTIVE MED. 11, 14 (2018).

³⁴ 21 U.S.C. § 321(f).

³⁵ 21 U.S.C. § 343(i)(1).

³⁶ 21 C.F.R. 101.9.

As discussed above, the statement of identity must be on the principal display panel of the product and “may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name.”³⁷ In industry guidance, the FDA stated that when interpreting Section 102.5, it “considers specific information targeting the intended population and describing the characterizing properties of the food to be information about the basic nature of the food that must be included as part of the statement of identity.”³⁸ The intended population of toddler milk is children ages 12 to 36 months old, so the statement of identity should clearly convey this age information to caregivers of young children. The statement of identity also cannot be confusingly similar to any other food, e.g. infant formula or plain milk.³⁹

III. Factual Grounds

A. Transition Formula Product Composition and Labeling Practices

Transition formula products are represented or purported for use for children ages 9 to 18 or 24 months. (Attachment A). They are marketed as specially formulated for the developmental needs of older infants and young toddlers.

1. Current labeling practices

Transition formulas use the infant formula label, but commonly use a statement of identity that combines the words infant and toddler. A study of toddler milks and infant formula labeling, using data from 2017, identified 5 products labeled as intended for children 9 months through 18 or 24 months.⁴⁰ All of these products utilized an infant

³⁷ 21 C.F.R. § 102.5.

³⁸ U.S. FOOD & DRUG ADMIN., *supra* note 25, at 5.

³⁹ 21 C.F.R. § 102.5.

⁴⁰ Pomeranz, et al., *supra* note 33, at 13.

formula label as opposed to the Nutrition Facts panel. The statements of identity primarily used for these products were “Infant and Toddler Formula.” One product was identified as “Infant Formula” but the product name contained the word “toddler.” A recent search of a major US retailer’s website identified a product named “Parent’s Choice Toddler Beginnings” with the statement of identity “Infant Formula with Iron, Milk-Based Powder” and a suggested age of use of “9 months & up.”⁴¹

2. Nutritional composition of transition formula

Transition formulas currently comply with nutrient content requirements for infant formula intended for infants less than 12 months old.⁴² For example, Mead Johnson Nutrition’s product Enfagrow Premium Toddler Transitions purports to contain “nutrient levels that help support active toddlers”⁴³ and provides a graphic on its website with side-by-side comparisons of the product composition of its Enfamil Premium Infant and Enfagrow Premium Toddler Transitions products. (Attachment C). The FDA’s nutrient specifications for infant formula establish the amounts of calcium, potassium and protein that all infant formulas must contain (DHA is not a required nutrient for infant formula).⁴⁴ The amounts listed in Attachment C for both the infant formula and toddler transitions product fall within the acceptable ranges for those nutrients set out in 21 CFR § 107.

The FDA’s nutrient specifications for infant formula are specifically designed to meet the nutritional needs of children less than 12 months old. Transition formula,

⁴¹ WALMART.COM, <https://www.walmart.com/ip/Parent-s-Choice-Toddler-Beginnings-Infant-Formula-with-Iron-20-oz/55522142>

⁴² 21 C.F.R. § 107.

⁴³ ENFAMIL.COM, https://www.enfamil.com/products/enfagrow-premium-toddler-transitions?gclid=Cj0KCQjwzozsBRCNARIsAEM9kBNdcGPKUJ2dTR4y yjJ24mKxI7YIFL3fwUbiH1g_cN5jSTm_kcJZ5J0aAmvQEALw_wcB&gclid=aw.ds

⁴⁴ 21 C.F.R. § 107.

however, is also represented and purported to be for use by children older than 12 months old, but it does not meet the nutrition needs of children older than 12 months old. For example, a nutritional analysis found that the Enfagrow Toddler Transitions product contained added sugar and less protein than the equivalent amount of plain whole cow's milk,⁴⁵ which is the type of milk recommended for children 12 to 24 months old.⁴⁶ The analysis concluded that Enfagrow Toddler Transitions “had the lowest NPI [*i.e.*, nutrition] score of any of the drinks analyzed (58 out of 100) with a formulation that would be healthy for an infant, but not the best choice for toddlers.”⁴⁷

3. Consumer research shows transition formula marketing results in prolonged use of expensive infant formula

A study of caregiver provision of infant formula and toddler milks to young children in the US found “widespread provision of infant formulas to US toddlers, which do not provide appropriate nutrition for their age.”⁴⁸ The study surveyed 1,645 primarily female caregivers of infants (6-11 months), young toddlers (12-23 months), and older toddlers (24-36 months). Participants were asked about which formula and other milk-based products they served their child in the past month. Due to potential consumer confusion about category names for types of products, researchers used a two-step process to ensure accurate reporting of products served. They first asked about all milk-

⁴⁵ Jennifer L. Harris, Frances Fleming-Milici, Willie Frazier et al., UNIV. OF CONN. RUDD CENTER FOR FOOD POLICY & OBESITY, BABY FOOD FACTS 2016: NUTRITION AND MARKETING OF BABY AND TODDLER FOOD AND DRINKS 24 (2017), http://www.uconnruddcenter.org/files/Pdfs/BabyFoodFACTS_FINAL.pdf.

⁴⁶ Lott et al., *supra* note 3.

⁴⁷ Harris et al., *supra* note 45 at 25.

⁴⁸ 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*, __ J. OF MATERNAL AND CHILD NUTRITION __ (2019) (in press).

based drinks using the following six options: Infant formulas (e.g., Enfamil, Gerber Good Start, Similac), Other formulas or powdered milks (e.g., Enfagrow, Gerber Good Start Grow, Nido, Similac Go & Grow), Regular milk: (e.g., cow's milk), Non-dairy milk (e.g., almond, coconut, soy), Other (with a fill-in box) and "None of the above" (including if participant only served breastmilk).⁴⁹ Researchers then showed caregivers who selected "Infant formulas" and/or "Other formulas" in the initial survey a list of brand names and logos for the categories selected and asked them to select all brands they had served to their child in the last month. Participants were also given an "Other" write-in option for products not on the list.

The study found that 39% of toddler caregivers selected an infant formula as the product they served most often to their toddler.⁵⁰ These study findings are in keeping with other research from high-income countries demonstrating caregiver confusion about provision of infant formula to toddlers.⁵¹

B. Toddler Milk Product Composition and Labeling Practices

Toddler milks are primarily composed of powdered milk, corn syrup solids or other added caloric sweeteners (lactose, sugar, glucose syrup solids, honey and corn syrup), and vegetable oil.⁵² A 2016 analysis of toddler milk brands identified six different toddler milk varieties offered by four brands (Enfagrow, Similac, Gerber Good Start, and

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ Nina J. Berry, Sandra Jones, Donald Iverson, *It's All Formula to Me: Women's Understanding of toddler milk ads*, 18 BREASTFEED REV. 21 (2010); Adriano Cattaneo, Paola Pani, Claudia Carletti et al., *Advertisements of follow-on formula and their perception by pregnant women and mothers in Italy*, 100 ARCHIVES OF DISEASES IN CHILDHOOD 323 (2015).

⁵² Harris et al., *supra* note 45, at 23.

Nido).⁵³ Toddler milks tend to have more sodium and less protein than cow's milk.⁵⁴ (Attachment D). A 2017 nutritional analysis of toddler milks found that "the nutritional quality of toddler milk brands was not superior to regular whole milk," and that "[t]oddler milk products...contained added sweeteners."⁵⁵

1. Toddler milk marketing claims

Manufacturers claim that toddler milks provide "extra nutrition" for picky eaters who may not be eating a well-balanced diet. Attachment E provides examples of current marketing materials for these products. A 2019 study, showed 1,090 toddler caregivers a picture of a package of commercially available toddler milk and assessed caregiver understanding of common claims on the product label.⁵⁶ Fifty-two percent of toddler caregivers interpreted messages on the toddler milk label to mean that the product provides nutrition not available from other sources, 33% thought that the product was necessary for toddlers to have correct nutrition, and 29% thought that toddler milk is better than plain whole milk.⁵⁷ In terms of the overall impression of the product, 70% of caregivers agreed that the product is a good drink for toddlers.⁵⁸

⁵³ *Id.* at 34-36.

⁵⁴ Lott et al., *supra* note 3, at 23.

⁵⁵ Harris et al., *supra* note 45, at 25.

⁵⁶ Maria J. Romo-Palafox, Haley Gershman, Jennifer L. Pomeranz, et al., MARKETING CLAIMS ON INFANT AND TODDLER MILK PACKAGES: WHAT DO CAREGIVERS THINK THEY MEAN? (2019), http://uconnruddcenter.org/files/Pdfs/Infant%20Formula%20and%20Toddler%20Milk%20Brief_9-23-19.pdf.

⁵⁷ *Id.*

⁵⁸ *Id.*

Marketing messages comparing toddler milk to cow's milk and other healthy foods are salient to parents. In focus groups of parents with children 9 to 36 months old to discuss toddler milk marketing claims, one parent noted "...I got sent a little pamphlet...[about] Enfagrow. And then it listed the milk, and then it listed the Enfagrow, and then it showed what the milk had and what the Enfagrow had...Yeah, so that kind of made me want to try it."⁵⁹ In terms of comparisons to healthy foods, one parent stated that "they're claiming to be better than just natural fruits and vegetables and normal food."⁶⁰ Another caregiver concluded, "they [formula companies] were marketing it as like a meal replacement. You know, like this is healthier for your child than whatever you're going to put together at home....shame on them for trying to market it like this is a better option for your child."⁶¹

US toddlers do have less than ideal diets with low consumption of fruits and vegetables and high consumption of sodium, saturated fat, and sugar.⁶² There is, however, no evidence that US toddlers consume inadequate macronutrients.⁶³ The 2019 Expert Consensus Statement recommends "[i]f nutrient-rich food intake appears to

⁵⁹ Frances Fleming-Milici, Jennifer L. Harris, Sally Mancini, Transcript of focus groups conducted in with parents of 9- to 36-month-old children in Hartford, CT and Washington, DC (August-October 2019) (unpublished data).

⁶⁰ *Id.*

⁶¹ *Id.*

⁶² Emily B. Welker, Emma F. Jacquier, Diane J Catellier et al., *Room for Improvement Remains in Food Consumption Patterns of Young Children Aged 2-4 Years*, 148 J. OF NUTRITION 1536S (2018); Regan L Bailey, Diane J Catellier, Shinyoung Jun et al., *Total Usual Nutrient Intakes of US Children (Under 48 Months): Findings from the Feeding Infants and Toddlers Study (FITS) 2016*, 148 J. OF NUTRITION 1557S (2018); Amira A Roess, Emma F Jacquier, Diane J Catellier et al., *Food Consumption Patterns of Infants and Toddlers: Findings from the Feeding Infants and Toddlers Study (FITS) 2016*, 148 J. OF NUTRITION 1525S (2018).

⁶³ Bailey et al., *supra* note 62.

be inadequate, other strategies to increase food acceptance should be tried first, such as repeated exposure to healthy foods.”⁶⁴ The American Academy of Family Physicians (AAFP) also recommends against serving toddler milk.⁶⁵ If caregivers have concerns about missing nutrients in toddlers’ diets, the AAFP suggests providing a multivitamin instead. Furthermore, the 2019 Expert Consensus Statement raised concerns about toddler consumption of added sugar contained in most toddler milks.⁶⁶ The AAP also does not recommend serving products with nonnutritive sweeteners, which are increasingly prevalent in the food supply as a replacement for added sugar, to young children.⁶⁷

2. Toddler milk statements of identity

A study of toddler milk labeled for sale in the US in 2017 analyzed 12 milk-based products for children 1 – 3 years old.⁶⁸ The study found no consistent statement of identity used on these products, and identified the following statements of identity in use: “toddler formula,” “milk drink,” “toddler drink,” “milk beverage,” “dry whole milk.”⁶⁹ One product has since been rebranded and now uses the statement of identity “toddler nutritional drink.”⁷⁰ These products also fail to include in the statement of identity characterizing information as to whether or not the product is sweetened, contains

⁶⁴ Lott et al., *supra* note 3, at 23.

⁶⁵ Nina R. O'Connor, *Infant Formula*, 79 AM. FAMILY PHYSICIAN 565 (2009).

⁶⁶ Lott et al., *supra* note 3.

⁶⁷ Carissa M. Baker-Smith, Sarah D. de Ferranti, William J. Cochran and Committee on Nutrition, Section on Gastroenterology, Hepatology, and Nutrition, *The Use of Nonnutritive Sweeteners in Children*, 144 PEDIATRICS e20192765 (2019).

⁶⁸ Pomeranz et al., *supra* note 33.

⁶⁹ *Id.* at 13.

⁷⁰ ENFAMIL.COM, https://www.enfamil.com/products/enfagrow-premium-toddler-nutritional-drink-natural-milk_

flavorings or the age-range for use. Information about added sugars is listed separately on the information facts panel and flavorings and age of use are typically listed separate from the statement of identity on the principal display panel. (See Attachment A).

Focus groups found that the use of similar packaging to infant formula and the use of the term infant formula on toddler milk was of concern to toddler caregivers. One caregiver stated:

“I think a formula is kind of a medical thing, because not that it's prescribed, but it's just different from buying a carton of milk, right? Because there's something special about infant formula. It's like created in this very specific way for a specific purpose, so even having this in that same can, it made me assume that it was similarly created with a specific medical intention, which clearly it is not.”⁷¹

After learning more about toddler milk and expert feeding recommendations, another caregiver concluded:

“One thing I didn't know is, I almost thought, it was infant formula, and then this was toddler formula. Now I understand, this is not called formula. It is a drink. It is not a formula. That is a big difference for me. I wasn't aware of that. I thought this was formula for a different age. This isn't formula for a different age. That's where I have to start.”⁷²

Clear disclosure of added sugar content also is important to toddler caregivers. During focus groups with parents to discuss toddler milk, one caregiver stated, “I didn't even know that the Enfagrow had sugar in it” and “it makes me think differently now.”⁷³ Another parent stated, “I was going to go with Enfagrow...but I didn't know that it contains added sugar.”⁷⁴

⁷¹ Fleming-Milici et al., *supra* note 59.

⁷² *Id.*

⁷³ *Id.*

⁷⁴ *Id.*

3. Consumer research shows a high likelihood of confusion created by toddler milk labeling.

Toddler milks are not nutritionally appropriate for infants. Many contain cow's milk protein, which is not recommended for infants; and they do not comply with the FDA's nutrient content requirements for infant formula.⁷⁵ Toddler milk products have similar containers, colors, and branding as infant formula products from the same manufacturers. (Attachment A). A 2016 study found that toddler milk was generally less expensive than infant formula supporting concerns that parents may purchase toddler milk for their babies instead of an infant formula for financial reasons.⁷⁶ Similar packaging has the potential to lead parents to believe that a less-expensive toddler milk is appropriate for their baby. Multiple product formulations aimed at different ages and stages of babies and toddlers likely confuse parents even further.

A study surveying infant caregivers about the milk-based products they served most often to their infant using a two-stage product identification process to ensure accuracy of reporting found that 11% of infant (6-12 months old) caregivers selected a toddler milk as the product they served most often.⁷⁷ Half of these infant caregivers (53%) initially reported that they only served infant formula to their infants, suggesting they believed the toddler milk was an infant formula.⁷⁸ A 2019 study showed 1,090 toddler caregivers the label from a canister of commercially available powdered toddler milk and then asked the caregivers a series of questions about the messages on the

⁷⁵ 21 C.F.R. § 107.

⁷⁶ Harris, et al., *supra* note 45, at 35-36.

⁷⁷ Romo-Palafox, et al., *supra* note 48.

⁷⁸ *Id.*

label.⁷⁹ The study found that 92% of caregivers believed the product was intended for toddlers, but 55% of toddler caregivers erroneously thought the product was also intended for infants.⁸⁰

IV. Recommended Actions

A. Transition Formula

This petition requests that the Commissioner use the authority granted under 21 USC § 343 to declare articles as misbranded and to enforce sections 101.3(b)(1), 102.5(a) and 107 of FDA regulations against “transition formula” represented to be for children 9 – 24 months of age. This petition also requests that the Commissioner amend section 101.3 of FDA regulations to expressly prohibit the use of the term “infant formula” or “formula” on drink products for children more than 12 months old.

When used as currently labeled, transition formula prolongs the use of infant formula past infancy against expert feeding recommendations. As documented by the caregiver studies described above, transition formula labeling creates consumer confusion and may lead toddler caregivers to inappropriately serve infant formula to their toddlers.⁸¹ There also is a potential economic injury to families from the misbranding of these products as transition formula can be more than four times as expensive than plain whole cow’s milk.⁸²

1. Products purported to be for use by persons older than 12 months of age are misbranded because they do not meet the definition of “infant formula” proscribed by applicable federal laws and regulations.

⁷⁹ Romo-Palafox, et al., *supra* note 56.

⁸⁰ *Id.*

⁸¹ Romo-Palafox, et al., *supra* note 48.

⁸² Lott et al., *supra* note 3, at 45.

Section 101.3(b)(1) of FDA regulations require that the principal display panel for packaged foods bear as a principal feature a statement of identity of the commodity.⁸³ When a name has been specified or required by an applicable federal law or regulation that name shall be the statement of identity.⁸⁴ “Infant formula” has been specified by law 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.”⁸⁵ Infant formula composition, manufacturing and labeling is standardized by FDA regulations.⁸⁶

Five of the six transition formulas in Attachment A use the name “Infant formula with Iron: Milk Based Powder” or “Milk-Based Infant Formula with Iron” on products labeled for use by children 9-24 months. (Attachment A). These products are misbranded when they use the name “infant formula” in the statement of identity because infant formula is legally defined as a product for use by persons not more than 12 months old.

2. Products labeled as “infant and toddler formula” are misbranded because the statement of identity is confusingly similar to infant formula.

One of the transition formulas in Attachment A is labeled for use by infants 9 to 18 months and uses the statement of identity “Infant and Toddler Formula: Milk-Based Powder with Iron.” (Attachment A). “Infant and Toddler Formula” does not adequately distinguish the product from the legally defined name “infant formula.” An alternative name that would adequately distinguish products labeled for use by infants more than

⁸³ 21 C.F.R. § 101.3(b)(1).

⁸⁴ 21 C.F.R. § 101.3.

⁸⁵ 21 U.S.C. § 105.3(e), 321(z).

⁸⁶ 21 C.F.R. § 106-107.

12 months old (e.g. 9 – 18 months) from infant formula would violate FDA's infant formula labeling regulations and the recommendations contained in the FDA's 2016 industry guidance on infant formula labeling.⁸⁷

3. To ensure effective implementation of 21 C.F.R. § 107, the use of the term “infant formula” or “formula” should be expressly limited to products for infants less than 12 months old.

This petition requests that the Commissioner amend 21 C.F.R. § 101.3 to expressly prohibit the use of the term “infant formula” or “formula” on any product represented or purported to be for use by children who are not infants. Federal law prohibits offering a food for sale under the name of another food.⁸⁸ Section 102.5(a) of FDA regulations further states that the name of a food “may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name” and that “[e]ach class or subclass of food shall be given its own common or usual name that states, in clear terms, what it is in a way that distinguishes it from different foods.”⁸⁹ Despite these existing laws and regulations, the term “infant formula” and “formula” is being used in the statement of identity of foods that do not meet the legal definition of infant formula (e.g., transition formulas).

B. Beverages for Children 12 – 36 Months Old

This petition requests that the Commissioner 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

⁸⁷ U.S. FOOD & DRUG ADMIN., *supra* note 25.

⁸⁸ 21 U.S.C. § 343(b).

⁸⁹ 21 C.F.R. § 102.5.

use and proper nutrition for young children. This is especially important to protect infants from the potentially dangerous provision of toddler milk when they require the specific nutritional composition of breastmilk or infant formula to survive.

1. The need for a common name

In order to ensure effective implementation of 21 C.F.R. § 107, and to prevent consumer confusion, the FDA should use its statutory authority to establish a common name for milk-based beverages for children 12 to 36 months old.⁹⁰ There currently exists no consistent statement of identity for so-called “toddler milks.” Manufacturers have labeled them as “toddler drink,” “toddler nutritional drink,” “toddler milk drink,” “toddler formula,” and “tailored nutrition for toddlers.” (Attachment A).

In industry guidance on reference amounts of food customarily consumed (RACC), the FDA noted that “[m]ilk-based beverages mean that milk and milk-derived ingredients are the major ingredient of the beverage when prepared for consumption,”⁹¹ and provided the following examples:

- All milk, regular and flavored (e.g., chocolate milk) of any fat content;
- all milk-based meal replacements (e.g., nutritional shakes);
- all hot cocoa;
- Malted milk beverages and all other milk-based beverages (e.g., breakfast drink) with the exception of milkshakes.
- Milk-substitute beverages are non-dairy based beverages (e.g., soy, almond, rice, coconut).⁹²

Toddler milk is primarily composed of powdered nonfat milk or milk substitutes, corn syrup solids or other added caloric sweeteners (lactose, sugar, glucose syrup solids,

⁹⁰ 21 U.S.C. §§ 341, 371.

⁹¹ U.S. FOOD & DRUG ADMIN., REFERENCE AMOUNTS CUSTOMARILY CONSUMED; LIST OF PRODUCTS FOR EACH PRODUCT CATEGORY: GUIDANCE FOR INDUSTRY 4 (2018), <https://www.fda.gov/media/102587/download>.

⁹² *Id.*

honey and corn syrup), and vegetable oil fitting them squarely under the FDA's description of "milk-based beverages."⁹³ This petition requests 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 the non-dairy protein used in the product). The statement of identity should also include other characterizing properties such as "sweetened" or "flavored" (e.g., "sweetened and flavored milk-based drink powder for 12 to 36 month olds").

2. Misleading use of the term nutritional drink

The use of the term "nutritional drink" (Attachment A) is of particular concern because this statement of identity is not adequately distinguished from its common usage. As noted in FDA guidance, milk-based meal replacements are commonly referred to as "nutritional shakes" (e.g., instant breakfast drinks).⁹⁴ The term "nutrition drink," "nutritional drink" and "nutrition shake" also is commonly used for beverages for special dietary use to gain or maintain weight (e.g., Boost, Ensure). (Attachment F). These products are only indicated for children and adults with medical conditions that interfere with their ability to eat, or who are having trouble gaining or maintaining their weight.

Marketing nutrition drinks for use by otherwise healthy children and adults has been found to be misleading by the Federal Trade Commission (FTC) and under state consumer protection law. In 1997, Abbott Laboratories settled FTC charges that it made false and unsubstantiated claims in an extensive national advertising campaign to

⁹³ Lott et al., *supra* note 3, at 23; Harris et al., *supra* note 45, at 23.

⁹⁴ U.S. FOOD & DRUG ADMIN., *supra* note 88.

promote its Ensure nutritional beverages for healthy, active adults.⁹⁵ The FTC noted that “[n]utritional beverage products like Ensure may provide a benefit if you have a medical condition that makes it difficult to eat or if you are using them in place of an occasional skipped meal”...but “Abbott went too far, however, when it suggested that doctors recommend Ensure for healthy, active people, like those pictured in the ads, in order to stay active and healthy.”⁹⁶

Similarly in 2013, Abbott Laboratories entered into an agreement with the New York Attorney General's office to discontinue unsubstantiated marketing that its Pediasure Sidekicks shakes provided “targeted nutrition” for children’s “unique needs.”⁹⁷ The product was brought to the attention of regulators by advocates who complained that the “ad misleadingly implied that pediatricians recommend Sidekicks for healthy, thriving children.”⁹⁸

During focus groups with toddler caregivers to discuss toddler milk labeling, various caregivers expressed confusion between toddler milk and nutrition drinks:

- “...they were marketing it as like a meal replacement”
- “...my concept of these was I thought it was something that, like, your doctor would tell you to buy. If your child wasn't growing on the curve or needed to gain

⁹⁵ Press Release, Federal Trade Commission, Abbott Settles FTC Charges of Deceptive Claims for Its "Ensure" Nutritional Products (Jan. 2, 1997), <https://www.ftc.gov/news-events/press-releases/1997/01/abbott-settles-ftc-charges-deceptive-claims-its-ensure>.

⁹⁶ *Id.*

⁹⁷ Press Release, N.Y. State Office of the Attorney General, A.G. Schneiderman Announces Settlement With Maker Of Pediasure Sidekicks Supplement For Misleading Advertising (Dec. 4, 2013), <https://ag.ny.gov/press-release/2013/ag-schneiderman-announces-settlement-maker-pediasure-sidekicks-supplement>.

⁹⁸ *Id.*

more weight, like, that's what I kind of assumed those were for, as like a supplement for that.”

- “I think that a lot of people turn to this kind of drink when they feel like, oh, my kid can't support their nutrition by eating-- by the foods they're eating.”
- “...that was my assumption about these, that they were just for kids who were failure to thrive.”
- “The doctor told me it's unnecessary. He's doing fine. So my own anxiety led me to buy these products when it wasn't necessary.”⁹⁹

The statement of identity “toddler nutritional drink” or “tailored nutrition for toddlers” is confusingly similar to the common usage of the terms used for meal replacement beverages and beverages for other special dietary uses. (Attachment F). In light of prior findings that marketing products labeled for special dietary uses to otherwise healthy adults and children is misleading and caregiver confusion about appropriate use of these drinks, milk-based beverages intended for use by children 12 to 36 months old that use a statement of identity of “nutritional drink” should be deemed misbranded.

3. Misleading use of the term toddler

The term “toddler” is referenced as a common term for children 1 to 3 years old in FDA food labeling regulations.¹⁰⁰ FDA guidance for industry on RACC’s further states that “[t]he term ‘infant’ refers to a person described as either through or up to 12 months

⁹⁹ Fleming-Milici et al., *supra* note 59.

¹⁰⁰ 21 C.F.R. § 101.9.

of age. The term ‘young children’ refers to children 1 through 3 years of age and is often used synonymously with ‘toddlers.’”¹⁰¹

FDA infant formula labeling guidance emphasizes the importance of including “specific information targeting the intended population and describing characterizing properties of food” in the statement of identity.¹⁰² It is unknown whether the term “toddler” is adequately specific due to its use on transition formulas also labeled for use by infants less than 12 months of age. (Attachment A). For example, one major infant formula and toddler milk manufacturer incorrectly describes the developmental phase of toddlerhood as “9 months to 3 years” on its website. (Attachment G). A regulatory change is needed to ensure that the specific age range “children 12 – 36 months old” is included in the statement of identity for milk-based beverages for young children.

4. Statements of identity should contain characterizing information as to sweeteners and flavorings to ensure products are adequately distinguished from plain unsweetened milk

When considering whether a product is misbranded, the FDA shall take into account “the extent to which the labeling or advertising fails to reveal facts material in light of such representations.”¹⁰³ Current marketing and labeling of these milk-based products focuses on their superiority to plain cow’s milk. Marketing claims include: “Milk-based drink that helps fill nutritional gaps” and “provides key nutrients iron, vitamin C & E and DHA that milk alone can’t provide.” (Attachment E).

The 2019 Expert Consensus Statement does not recommend these products because they may contribute added sugars to the diet, and expressed concerns about

¹⁰¹ U.S. FOOD & DRUG ADMIN., *supra* note 88.

¹⁰² U.S. FOOD & DRUG ADMIN., *supra* note 25.

¹⁰³ 21 U.S.C. § 321(n).

the use of flavorings that may contribute to a preference for sweet foods and drinks. The statements of identity used for these products currently do not make clear to consumers when a product is flavored or sweetened. When applicable, this characterizing information should be included in the statement of identity to avoid misbranding and to prevent confusion with unflavored and unsweetened cow's milk.

5. Required factual disclaimers are warranted to prevent consumer confusion with infant formula and to ensure proper child nutrition.

Surveys of caregivers demonstrate a substantial risk of provision of toddler milks to infants. A required disclaimer on the label such as "DO NOT SERVE TO INFANTS UNDER 12 MONTHS OLD" is warranted to prevent consumer confusion with infant formula, and to prevent potential harm to infants.

A disclaimer stating that children 1 to 3 yrs. 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" is warranted to ensure proper child nutrition. Such a disclaimer also would address the potential economic harm to families from buying milk-based beverages that can be more than three times as expensive as the equivalent volume of plain cow's milk.¹⁰⁴

6. There is no recommended daily intake of these products for young children.

Labels should not make any claims that could be construed as a recommended daily intake. A product currently for sale features a picture of a sippy cup on the principal display panel with the text "1 cup a day" followed by "has key nutrients like iron, vitamin C & E and DHA that milk alone can't provide." (Attachment A). This

¹⁰⁴ Lott et al., *supra* note 3, at 45.

statement is misleading because toddler milks are not recommended as part of a healthy diet for young children.¹⁰⁵ There is a RACC for milk-based drinks and flavored and unflavored powdered milk-drink mixes for adults of 1 cup (240ml of liquid or of powder when mixed with water).¹⁰⁶ This is a recommended serving size for one eating occasion for adults—not a recommended daily intake for young children.

Part C – Environmental Impact

This petition is excluded from the requirement for an environmental assessment or impact statement under 21 C.F.R. § 25.30(k).

Part D – Economic Impact

Information on the economic impact of this petition will be provided upon request.

Part E – Certification

The undersigned certifies that, to the best of knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition

Respectfully submitted,



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¹⁰⁵ 21 U.S.C. 343(a).

¹⁰⁶ U.S. FOOD & DRUG ADMIN., *supra* note 88.

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