



One Constitution Plaza, Suite 600
Hartford, Connecticut 06103
www.uconnruddcenter.org

November 6, 2016

Susan T. Mayne
Director, Center for Food Safety and Applied Nutrition
c/o Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Docket ID: FDA-2016-D-2241-0002

Re: Draft Guidance for Industry on Substantiation for Structure/Function Claims in Infant Formula Labels and Labeling

Dear Dr. Mayne:

On behalf of the University of Connecticut Rudd Center for Food Policy and Obesity (Rudd Center), we appreciate this opportunity to provide comments on the Center for Food Safety and Applied Nutrition's (CFSAN) proposed Guidance for Industry on Substantiations for Structure/Function Claims Made in Infant Formula Labels and Labeling.

The Rudd Center is a multi-disciplinary research center dedicated to promoting solutions to childhood obesity, poor diet, and weight bias through research and policy. For eight years, the Rudd Center has studied the food industry's marketing of unhealthy food and drinks to children and its influence on children's diet, weight, and health.

The Rudd Center supports the CFSAN's Proposed Guidance for Industry on Substantiations for Structure/Function Claims Made in Infant Formula Labels and Labeling.

We commend the CFSAN for the Proposed Guidance for companies to provide competent and reliable scientific evidence to substantiate on-label marketing claims about the effects of ingredients or additives in infant formula on the structure or function of infants' bodies. We agree with all the critical elements and quality considerations for intervention studies stated in the guidance. Furthermore, we applaud the CFSAN for urging manufacturers and distributors to consider which scientific evidence is clinically meaningful, rather than focus on results that are statistically significant. Finally, we agree that structure/function claims should encompass the context of labeling as a whole, including all statements, phrases, and graphics.

Recently published research by the Rudd Center documents the widespread use of structure/function claims printed in infant formula labels and the need to substantiate such claims.

On November 1, 2016 the Rudd Center issued Baby Food FACTS, a report documenting the nutrition and marketing of food and drink products for children under age 3, including infant formula and toddler drinks.ⁱ Using Nielsen advertising data, we identified nine infant formula and toddler milk brands owned by five companies with \$100,000 or more in total advertising spending on baby and toddler food and drink products in 2015. This analysis excluded formula intended for infants or toddlers with specific dietary needs (e.g. pre-term infants or protein allergies). Toddler milk was defined as a powdered milk supplemented with nutrients and that the company indicates is specifically for children older than 12 months and younger than 3 years. Companies typically refer to these products as toddler “formula” or follow-up formula. Given the nature of the Rudd Center analyses, we consider both infant formula and toddler milk data to be relevant to the Proposed Guidance.

Rudd Center researchers coded all marketing messages appearing on 17 infant formula and 5 toddler milk product packages according to the following criteria: nutrition-related (vitamins and nutrients, ingredient and absence) and child development.

The most common child development messages on infant formula packages referenced babies’ brain and cognitive development and digestive health:

- Nutrition-related messages appeared on every drink package examined, averaging 5.6 such messages on each package.
 - Vitamin and nutrient messages were the most frequent type of nutrition message on drink packages, comprising 4.4 of the 5.6 average total number nutrition-related messages appearing on these packages.
 - Six of 10 drink packages had an ingredient message.
 - 77% had an absence message.
- Ninety-four percent of infant formula and 100% of toddler milk packages had child development messages.
 - Infant formula and toddler milk packages averaged 3.1 and 2.6 child development messages per package, respectively.
- A follow-up analysis of claims on the infant formula packages examined found that 100% had structure/function claims.

Infant formula advertisements were similar, but often more detailed, compared to the messages on labels.

In addition to analyzing claims on infant formula labels, Rudd Center researchers evaluated the messages and marketing techniques used in advertisements that appeared on TV, online videos and magazines. Using Kantar Media’s AdScope database, we obtained digital copies of all infant

formula advertisements from three infant formula brands (43 ads) and two toddler milk brand (21 ads) that aired nationally in the United States from January 1, 2012 to December 31, 2015. The majority of advertisements for infant formula brands appeared in magazines, while toddler milk brands advertised primarily on TV.

Nearly all infant formula ads communicated specific product features, averaging 1.8 per ad (2.0 in Spanish language TV), and nutrition was the most common product benefit featured in infant formula and toddler milk ads, appearing in all ads except one for Similac. The nutrients and ingredients DHA, L. Reuteri, probiotics, and lutein were commonly discussed in infant formula advertisements. Furthermore, 73% of infant formula and toddler milk ads communicated benefits to children from consuming the products, primarily physical and cognitive development and digestive health.

Infant formula advertisements often linked product ingredients to developmental outcomes and health of babies.

Approximately one-third of Similac and Enfamil infant formula ads examined associated ingredients in the products with babies' development. For example,

- Enfamil infant formula ads promoted their "Neuro Complete blend that has clinically proven nutrients, like DHA, important for brain growth."
- One Enfamil magazine ad featured a baby sitting on a parent's lap looking at a book with the text, "When you feed your baby Enfamil today, you nourish milestones now and for years to come. In fact, Enfamil Infant is proven to foster learning through age 5."
- Another Enfamil ad featured a newborn and stated, "Enfamil staged nutrition has choline and brain-nourishing DHA. Enfamil's nutrition helps support milestones like grasping and walking."
- Similac advertised its OptiGro and Early Shield blends for enhancing brain and eye development.

All infant formula brands examined also promoted their products' benefits for babies' digestion. These messages were present in 60 of Gerber Good Start ads, and 27 of Gerber Good Start ads claimed that the product reduces crying.

In addition, many of the ads with nutrition and child development messages specifically compared their products' formulations with breast milk. For example,

- One Gerber Good Start Gentle ad featured a smiling, giggling baby in the center with the text, "Comfort for baby means giggles for all," and in smaller text below, "*Inspired by breast milk*, Gerber Good Start Gentle formula has Comfort Proteins that are easy for tiny tummies to digest. Our complete nutrition with DHA is uniquely designed to bring comfort to babies and happiness for all."
- One Similac ad stated, "Similac has LUTEIN to *help you nourish more like breast milk*. This is a critical time for your newborn's developing brain and eyes. That's why, in addition to DHA, we have lutein, an important nutrient found in breast milk."
- Advertisements for Similac Advance focused on nutrients associated with brain and eye development, "Now is the time when your baby's brain and eyes develop the most, which

is why Similac has an exclusive brain and eye blend. In addition to having DHA, Similac has Lutein. *Babies can get Lutein from breast milk and Similac formulas.*"

- One ad for Enfamil for Supplementing and Enfamil Newborn claimed these products, "*have DHA and choline, nutrients found in breast milk and important vitamin D.*"

Furthermore, these advertisements often implied that advertised claims about infant formulas were supported by strong scientific evidence. For example,

- Enfamil advertised its scientific formula in more than one-half of ads. One ad proclaimed "Big News," "in an independent clinical study, children fed Enfamil Infant during the first 12 months of life exhibited: An increased ability to pay attention and stay on task and a 16% higher score on an early measure of IQ."
- In addition, 100% of Enfamil ads stated that "Enfamil is the #1 brand recommended by pediatricians."
- Gerber Good Start promoted its scientific formula in 35% of ads, including one TV advertisement that stated, "it is the only formula to have the probiotic [L.Reuteri] clinically shown to reduce crying time by 50%."

The Rudd Center report findings also support the CFSAN statement that claims should be analyzed "in the context of the labeling as a whole," and that consumer testing is needed to determine "consumer understanding of each claim in context ... when all the statements and graphics in the labeling are considered together."

Although not all messages found on infant formula product packages might qualify as structure/function claims by themselves, when considered together with other messages and visuals on the product package, they are likely to convey implicit structure/function claims. For example, messages about added nutrients or ingredients (e.g., lutein, DHA, ARA) commonly promoted on product packages might imply structure/function advantages over other formulas and even breastmilk. There is evidence that these nutrients are not essential since they can be synthesized by babies,ⁱⁱ and such additions might even be detrimental given certain nutrient interactions, their bioavailability and shelf life.ⁱⁱⁱ However, a consumer might reasonably assume that these nutrients are essential for babies and that they might not be getting them from other formulas.

Frequent messages on infant formula packages about the absence of certain ingredients, such as "gluten-free," "milk-free," and "lactose-free," may also take advantage of parents' mistaken beliefs about the prevalence of metabolic diseases such as lactose intolerance or milk protein allergy. Although there is a lack of evidence to support an effect of minor formula changes in protein content, lactose reduction, or use of soy or hydrolyzed proteins, probiotics and prebiotics,^{iv} these types of claims may lead consumers to infer that these products will address normal babies' gastrointestinal symptoms, even if the label doesn't explicitly state it.

Moreover, some product names themselves and their taglines could imply that different varieties are designed to provide structure/function benefits. The leading infant formula brands devoted the majority of their advertising spending from 2011 to 2015 on their specialty formulas:

- Nestle’s Gerber Good Start advertised its Soothe variety for “colicky” infants, its Gentle variety for “easy digestion,” and its Protect variety for “advance immune support.”
- Abbott’s Similac advertised its Sensitive variety for “gas and fussiness” and its Advance variety “formulated to be closest to breastmilk.”
- Mead Johnson’s Enfamil advertised its Reguline variety for “comfortable stools” and its Newborn variety “closest formula to early breast milk” (in 2011 only).

Increasing emphasis on specialty formulas, such as these, may also increase parents’ perceptions that a typically fussy or crying baby would benefit from a specialty formula instead of breastmilk or regular formulas.^v

Furthermore, previous Rudd Center research on nutrition-related messages used in sugary drink and children’s cereal marketing demonstrated that these messages often lead parents to believe that unhealthy products that contain nutrition-related claims are healthier and provide additional benefits for children than other products that do not feature such messages.^{vi,vii}

The Rudd Center research provides additional recommendations and revisions to the Proposed Guidance to adequately protect the public from untruthful or misleading structure/function claims.

- a) Recommend that the CFSAN hold toddler milk, including WIC (federally) approved formulas for >12 months, under that same guidance as infant formula.**

The majority of infant formula brands also offer toddler milk products. Toddler milk product packages carry similar nutrition and child development claims and messages as infant formula packages. For example:

- Enfagrow Toddler Next Step promotes “brain Nourishing DHA and iron to help support your toddler’s brain development” and “prebiotics designed to help support digestive health.”
- Similac Go & Grow toddler milk claims to contain “DHA like that found in fish for brain,” “Lutein like that found in spinach for eyes,” and “Vitamin E like that found in broccoli for development.”
- Gerber Good start toddler milk includes claims of “DHA and iron to help support brain development” and “probiotics to help support digestive health.”

Additional marketing practices used to promote toddler milk products indicate that consumers may confuse them with infant formula and thus warrant similar oversight. Notably, packaging for these products commonly refer to them as “formula,” although they are not required to meet the same standards as infant formulas. For example, toddler milks are not required to contain

minimum amounts of certain nutrients per 100 calories, with maximum levels when appropriate, as required by the FDA for infant formula.^{viii}

However, these products contain different ingredient formulations than infant formula. Babies' nutrient requirements differ from toddlers in that they do not require fiber, and should receive smaller amounts of protein and larger amount of simple carbohydrates. In addition, infant formula packages are required to carry disclaimers that breastfeeding is best for babies and that caregivers should consult with a pediatrician before use. Not one toddler milk package examined carried the disclaimer that breastfeeding is best for babies, including Enfagrow Toddler Transitions which is promoted for babies 9 to 18 months.

In TV advertising for Enfagrow toddler milk, nutrition was the most common product feature mentioned. These ads emphasized how toddler milk provides vitamins to supplement young children's diets. Approximately three-quarters of Enfagrow toddler milk ads implied that the product helps children's physical development, particularly brain growth. For instance, one ad featured a toddler looking at shapes in a picture book as he consumes Enfagrow. The ad claims that this is an important time for learning "since 85% of brain growth is complete by age 3 and now is the time to nourish them. Enfagrow has DHA, an important building block of the brain." The brand also advertised its benefits for children's mental performance and digestive health.

There is also evidence that marketing of toddler milk products intended for children older than 12 months may mislead and confuse parents about the differences between toddler milk and infant formula. One study found that companies market infant formula (i.e., for babies younger than 12 months) and toddler milk as part of the same line of products, with similar labels, colors, and logos.^{ix} Companies also present toddler milk line extensions (i.e., use of an already existing brand name for a new product in the same product category) in larger text than the text that identifies the correct product category (i.e., infant formula, toddler milk). For example, Enfagrow toddler milk packages included the message "continue to give your toddler the brain-nourishing DHA and nutrition he may still need with great-tasting Enfagrow Toddler Next Step." This marketing practice may encourage consumers to transfer what they already know about an existing product (i.e., infant formula) to the new product line extension (i.e., toddler milk).

Another study demonstrated that mothers had difficulty differentiating between infant formula, supplementary formula (i.e., formula designed for ages 6 months and up to complement weaning), and toddler milk, which are collectively referred to as "formula" in advertisements.^x Similarly, in focus groups with mothers, 12 of the 15 participants used the terms "formula," "infant formula," or "baby formula" to describe toddler milk products.^{xi} In addition, toddler milk is less expensive than infant formula and more readily available, as it is typically stocked on store shelves whereas infant formula may be stocked in a locked display case or behind the counter. These practices all raise concerns that parents may be serving toddler milk to their babies younger than 12 months.

Finally, companies appear to be increasing their promotion of toddler milk at the same time they have reduced advertising spending on infant formula. For example, toddler milk brands (Enfagrow and Nido) spent almost \$17 million in 2015, an increase of 74% compared with 2011.

At the same time that Mead Johnson reduced advertising spending on its Enfamil infant formula by 92%, it more than doubled advertising for Enfagrow toddler milk.

Notably, the American Academy of Pediatrics (AAP) and American Academy of Family Physicians do not recommend serving toddler “formula” to young children, citing the additional cost and no proven advantages over whole milk for 1- to 2-year-olds.^{xii} Furthermore, these products contain added sugar, and the American Heart Association does not recommend serving products with added sugar to children under age 2^{xiii}.

b) Remove the blanket exclusion of breast milk comparison claims.

The Proposed Guidance currently states: “We are aware that infant formula products may also bear labeling claims that suggest that the product contains constituents found in breast milk or that the product is ‘closer’ to breast milk than other formulas. These are not structure/function claims and are not addressed in this guidance.” This statement should be stricken from the final guidance as it is overly broad and does not reflect the use of breast milk comparison claims on formula. As demonstrated by previously cited examples, comparison to breast milk on infant formula labels and in advertising often links ingredients contained in formulas and breast milk to development and health outcomes for babies.

c) Clarify that claims related to human milk supplementation and replacement are structure/function claims.

Supplementation and replacement claims directly relate to the bodily function of lactation and are for a food that is statutorily defined to include products that act as a complete or partial substitute for a lactating woman’s human milk. The guidance should make clear that supplementation claims on infant formula will be analyzed as structure/function claims and require substantiation with competent and reliable scientific evidence.

d) Include full disclosure of study funding, author conflicts of interest and other industry engagement in the study evaluation process and as a critical element and quality standard for intervention studies and systematic reviews.

Funder bias and conflicts of interest by study authors greatly undermine study quality and can greatly compromise study findings. The proposed guidance should be revised to include the following additional steps in the “Recommended Process for Evaluating Scientific Evidence”^{xiv}:

- Eliminating studies with inadequate author conflict of interest disclosures.
- Eliminating studies that do not provide full disclosure of funding sources.

“Critical Elements for Intervention Studies”^{xv} should be revised to include an “Industry Engagement” section that references specific criteria for adequate ethical safeguards for nutrition research such as the International Life Sciences Institute (ILSI) North America Working Group on Guiding Principles’ *Conflict of Interest Guidelines*.^{xvixvii}

“Quality Considerations for Intervention Studies” should include a quality measure for full transparency of funding sources and require conflict of interest disclosures by study authors.^{xviii} When not met, these quality measures should be used to exclude studies from systematic reviews. Disclosed conflicts of interest and steps taken to limit funder bias should be evaluated to determine the strengths and weaknesses of studies included in systematic reviews.

e) Engage in formal rulemaking to adequately address infant formula and toddler milk labeling.

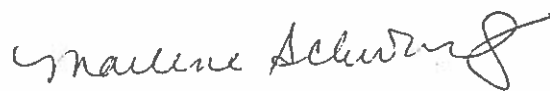
Non-binding guidance documents are an important step in the process towards robust oversight of infant formula labeling claims. We applaud the current effort and fully support the Proposed Guidance as a useful step forward in the near term. We respectfully request that the FDA also pursue formal rulemaking on the issue of structure/function claims on infant formula. The FD&C Act grants the agency broad authority to efficiently administer the Act through regulations, 21 U.S.C. 371(a). Infant formula is a highly specialized product that is the sole source of nutrition for many infants. Infant formula labels are barred by the FD&C Act from containing false and misleading claims, and have been subject to the FTC Act’s prohibition on false, deceptive and unfair trade practices and its Policy Statement for Advertising Substantiation, yet a recent analysis of structure/function claims on infant formula labels found widespread use of unsubstantiated claims.^{xix}

Thank you again for the opportunity to submit these comments on the Proposed Guidance. We look forward to continuing to working with the FDA on this most important and timely issue.

Sincerely,



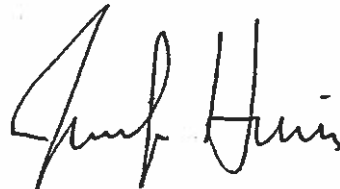
Maria Romo-Palafox, PhD, RD
Post-doctoral Fellow



Marlene Schwartz, PhD
Director



Sally Mancini, MPH
Director of Advocacy Resources



Jennifer Harris, PhD, MBA
Director of Food Marketing Initiatives

-
- ⁱ Harris J, et. al (2016). Baby Food FACTS: Nutrition and Marketing of Infant and Toddler Food and Drinks. Available at: http://www.uconnruddcenter.org/files/Pdfs/BabyFoodFACTS_2016_FINAL_103116.pdf
- ⁱⁱ Institute of Medicine (US) Committee on the Evaluation of the Addition of Ingredients New to Infant Formula. Washington (DC): National Academies Press (US); 2004.
- ⁱⁱⁱ Institute of Medicine (US) Committee on the Evaluation of the Addition of Ingredients New to Infant Formula. Washington (DC): National Academies Press (US); 2004.
- ^{iv} Belamarich PF, Bochner RE, Racine AD. A Critical Review of the Marketing Claims of Infant Formula Products in the United States. *Clin Pediatr (Phila)*. 2016 May;55(5):437-42.
- ^v Belamarich PF, Bochner RE, Racine AD. A Critical Review of the Marketing Claims of Infant Formula Products in the United States. *Clin Pediatr (Phila)*. 2016 May;55(5):437-42.
- ^{vi} Munsell CR, Harris JL, Sarda V, Schwartz MB. Parents' beliefs about the healthfulness of sugary drink options: opportunities to address misperceptions. *Public Health Nutr*. 2016 Jan;19(1):46-54.
- ^{vii} LoDolce ME, Harris JL, Schwartz MB. Sugar as part of a balanced breakfast? What cereal advertisements teach children about healthy eating. *J Health Commun*. 2013;18(11):1293-309. doi: 10.1080/10810730.2013.778366. Epub 2013 Jul 26.
- ^{viii} FDA (1988). Code of Federal Regulations [CFR] Title 21, section 107.100. www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=107
- ^{ix} Berry NJ, Jones S, Iverson D (2010). It's all formula to me: women's understandings of toddler milk ads. *Breastfeeding Review*, 18, 21-30.
- ^x Berry NJ, Jones SC, Iverson D (2012). Circumventing the WHO Code? An observational study. *Archives of Disease in Childhood*. 97, 320-325.
- ^{xi} Berry et al. (2010).
- ^{xii} O'Connor NR (2009). Infant Formula. *American Family Physician*, 79(7):565-570.
- ^{xiii} Vos MB, Kaar JL, Welsh JA, Van Horn LV, Feig DL, et al. (2016). Added sugars and cardiovascular disease risk in children. A scientific statement from the American Heart Associations. *Circulation*, 134(15). circ.ahajournals.org/content/early/2016/08/22/CIR.0000000000000439
- ^{xiv} Proposed Guidance at 6.
- ^{xv} Id. at 8.
- ^{xvi} Alexander N., Rowe S., Brackett R.E., Burton-Freeman B., Hentges E.J., Kretser A., ... Mukherjea R. (2015). Achieving a transparent, actionable framework for public-private partnerships for food and nutrition research. *American Journal Of Clinical Nutrition*, 101(6), 1359-1363;
- ^{xvii} Rowe, S., Alexander, N., Kretser, A., Steele, R., Kretsch, M., Applebaum, R., Falci, K. (2013). Principles for building public-private partnerships to benefit food safety, nutrition, and health research. *Nutrition Reviews*, 71(10), 682-691.
- ^{xviii} Proposed Guidance at 10.
- ^{xix} Belamarich PF, Bochner RE, Racine AD. A Critical Review of the Marketing Claims of Infant Formula Products in the United States. *Clin Pediatr (Phila)*. 2016 May; 55(5):437-42.