

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

Petition for Prohibition of)
Misleading Labeling of Sweeteners)
and Request for Enforcement Action)
) Docket No. _____
)

Submitted by

The Sugar Association

June 3, 2020

Executive Summary

The Sugar Association requests FDA to provide consumers with honest information about the use of alternative sweeteners and to stop misleading claims about added sugars content.

Following the addition of “added sugars” to the Nutrition Facts label, food and beverage manufacturers have increased the use of numerous alternative sweeteners. However, the quest for sugar reduction has led manufacturers to reformulate products by replacing sugar with high-intensity sweeteners, non-nutritive sweeteners, sugar alcohols, and novel substances in an attempt to mimic the taste and functionality of sugar. While many consumers wish to reduce added sugars intake, they do not wish to do so by increasing their consumption of unfamiliar substances not clearly identified on the label as sweeteners.

Moreover, recently reformulated brand name products claim, “No Added Sugars,” “Zero Sugar,” or “Reduced Sugars”, and misleadingly imply that the new products are healthier than the traditional versions of the foods. In actuality, the reformulated products are often higher in calories or contain alternative sweeteners that consumers are not familiar with, and may have undesirable dietary qualities such as adverse gastrointestinal effects. The growing use of such alternative sweeteners poses particular concerns in the diets of children, for whom the effects of sweeteners are not well-established.

Petitioner requests FDA to issue industry-wide regulatory guidance so that labels:

- Clearly identify the presence of alternative sweeteners in the ingredient list;
- Indicate the type and quantity of alternative sweeteners, in milligrams per serving, on the fronts of packages of food and beverage products consumed by children; and
- Disclose gastrointestinal effects of various sweeteners at minimum thresholds of effect.

Labels that fail to provide such information are “misleading” because they omit material facts in violation of Section 201(n) of the Food, Drug, and Cosmetic Act.

Petitioner further urges FDA to take enforcement action to stop misleading claims about added sugars content. For example, a leading brand of peanut butter claiming to have less sugar has more calories per serving than the company's regular peanut butter. In another case, a manufacturer attempts to justify a reduced sugar claim by decreasing the portion size of the lower sugar version of its regular product. Such examples abound throughout the marketplace and must be promptly halted.

Further, to prevent misleading claims in the future, FDA should issue industry-wide regulatory guidance providing that:

- No/reduced sugars claims be accompanied by the disclosure "Sweetened with [name of Sweetener(s)]" when alternative sweeteners are present; and
- No/reduced added sugars claims be accompanied by the disclosure "Not lower in calories" unless such products have 25% fewer calories than the comparison food.

Food and beverage packages that make deceptive claims about sweetener content are "misleading" in violation of Section 403(a)(1) of the Act because they imply that the products are free of alternative sweeteners. Despite the requirement that manufacturers disclose the presence of alternative sweeteners in the ingredient list, many consumers are misled because they do not recognize the names of those ingredients and do not identify them as sweeteners. FDA has required similar disclosures in analogous situations and ample precedent indicates that agency action here is both appropriate and necessary.

Increased use of alternative sweeteners is characterized by a shocking lack of transparency and egregiously misleading claims. It is now incumbent upon the agency to take remedial action to protect consumers and ensure honesty in the marketplace.

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- A. Ingredient labels must identify the presence of alternative sweeteners to avoid misleading consumers in violation of Section 201(n) of the Act.
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June 3, 2020

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I. Action Requested

This petition is submitted pursuant to section 4(d) of the Administrative Procedure Act, 5 U.S.C. §553, and 21 C.F.R. §§10.25 and 10.30. The Sugar Association requests that the Food and Drug Administration (“FDA”) take action to ensure that consumers are provided non-misleading information about the presence and potential side effects of alternative sweeteners in foods. The Petitioner also requests FDA to prevent misleading claims regarding added sugars content by taking enforcement action and issuing regulatory guidance.

II. Introduction

Following announced changes to the Nutrition Facts label, food and beverage manufacturers’ approach to reducing the amount of sugars in their products has taken on many forms and often involves the use of numerous alternative sweeteners¹ (defined as all ingredients used to replace caloric sweeteners, i.e. low or no calorie sweeteners, including: high intensity sweeteners, artificial sweeteners, nonnutritive sweeteners, novel sweeteners, and sugar alcohols).

While many consumers are looking to reduce their added sugars intake, the means by which that occurs is important – and yet this is often not obvious with current labeling regulations. Consumers do not desire to reduce their added sugars consumption by increasing

¹ See Appendix I. This petition uses the term ‘alternative sweetener’ to refer to substances that provide sweetness to food and beverage products when caloric sweeteners are reduced or replaced. For the purposes of this petition, both low and non-caloric sweeteners, including sugar alcohols, are referred to as ‘alternative sweeteners.’

their consumption of artificial sweeteners.² However, the quest for sugar reduction has led food and beverage manufacturers to reformulate products by replacing added sugars with a combination of high-intensity sweeteners, novel sweeteners, and sugar alcohols to mimic the taste and functionality of sugar without the consumer's knowledge.

The use of alternative sweeteners in the food supply is pervasive. Over the last 5 years, the number of food products that contain at least one high-intensity sweetener has tripled. High-intensity sweeteners and sugar alcohols, such as Luo Han Guo Extract (Monk Fruit), certain forms of Stevia Extract, and Erythritol have seen over 100% growth in new product launches from 2016 to 2018.³

This rising increase in the use of alternative sweeteners, including high-intensity sweeteners and sugar alcohols, has been characterized by a troubling lack of transparency in the marketing and labeling of foods and beverages containing these ingredients. Leading brand name products bear prominent front of package (also referred to as the Principal Display Panel or PDP) claims such as “No Added Sugars,” “Zero Sugar,” “Less Sugar,” and “Reduced Sugars” (hereinafter no/reduced sugar). The claims imply that the reformulated product is healthier or lower in calories than the comparison food due to the reduction in sugar without disclosing how the sugar has been reduced. It has also become common practice for food manufacturers to manipulate nutritional values reported on the Nutrition Facts label by reducing the serving size in order to market products with a reduced sugar claim. Even when qualified, no/reduced sugar claims are misleading because they imply that the products are free of alternative sweeteners.

² Innova Market Insights: Consumers more interested in reducing sugar than replacing it, yet use of sweeteners surges, November 19, 2019. Retrieved from <https://www.foodnavigator-usa.com/Article/2019/11/19/Innova-Market-Insights-Consumers-more-interested-in-reducing-sugar-than-replacing-it-yet-use-of-sweeteners-surges>. Three in five consumers would rather cut back on sugar than consume alternative sweeteners.

³ See Appendix II and III [Mintel Report (2019). Sugar and Sweeteners Landscape-August 2019].

Despite the requirement that manufacturers must disclose the presence of high-intensity sweeteners, novel sweeteners, and sugar alcohols in the ingredient list, many consumers do not associate those as sweeteners or even recognize the names of these ingredients.

Changes to the Nutrition Facts label were introduced, in part, to create greater transparency and provide consumers with information to make informed decisions. The new Nutrition Facts label helps consumers detect the presence and amount of added sugars in the foods and beverages they purchase and consume. However, this level of transparency provided by FDA's regulatory framework is incomplete; it should be extended to the growing range of high intensity sweeteners, sugar alcohols, and novel sweeteners that are being used in America's food supply and go undetected.

The failure to ensure such transparency was an oversight in FDA's efforts to update the Nutrition Facts label.⁴ The clear disclosure of all sweeteners is particularly appropriate given that FDA's disclosure requirements for added sugars has provided an incentive for manufacturers to increase their use of alternative sweeteners.

This Petition calls on FDA to take actions to protect consumers by A) improving the labeling of alternative sweeteners in the ingredients list on food labels, B) taking steps to address the particular difficulties raised by the unquantified presence of nonnutritive sweeteners in the diets of children, C) requiring disclosures of potential gastrointestinal effects of various sweeteners at meaningful quantities, D) taking action against misleading or otherwise unlawful added sugars claims, and E) issuing guidance to industry specifying that no/reduced added sugars claims be accompanied by appropriate disclosures. The actions requested here are called for by

⁴ [81 Fed Reg. 33742](#), May 27, 2016.

law, will help fulfill the agency's mandate to ensure clear and honest food labeling, and advance recent agency consumer-focused initiatives, such as FDA's Nutrition Innovation Strategy.⁵

III. Statement of Factual Grounds

A. Ingredient labels should clearly disclose the presence of all alternative sweeteners not already declared on the Nutrition Facts label.

In order to make claims and present their products as more attractive to consumers, food and beverage manufacturers are using a range of alternative sweeteners and novel ingredients that are not commonly recognized by consumers as sweeteners.

High-intensity sweeteners, also known as artificial sweeteners or non-nutritive sweeteners, are several hundreds to thousands of times sweeter than sucrose and used to sweeten and enhance the flavor of foods. Currently, six high-intensity sweeteners are FDA-approved as food additives for use in foods and beverages:

- Advantame
- Aspartame
- Saccharin
- Acesulfame Potassium (Ace-K)
- Neotame
- Sucratose

Two additional high-intensity sweeteners have received GRAS (Generally Regarded as Safe) authorizations from the FDA to be used as sweeteners:

- Steviol Glycosides: Rebaudioside A (also known as Reb A), Stevioside, and Rebaudioside D
- Luo Han Guo Extract (also known as Monk Fruit)⁶

⁵ See, <https://www.fda.gov/food/food-labeling-nutrition/fda-nutrition-innovation-strategy>.

⁶ See, <https://www.fda.gov/food/food-additives-petitions/high-intensity-sweeteners>.

Polyols, often referred to as sugar alcohols, are considered bulk sweeteners that can be used to replace added sugars in foods. The caloric value of sugar alcohols ranges between 0 kcal/g to 2.4 kcal/g. Sugar alcohols are less sweet than sugar and often used in combination with high-intensity sweeteners to increase a product's sweetness profile and mimic some of sugar's functional properties. Sugar alcohols commonly found in products include:

- Erythritol
- Isomalt
- Glycerin (Vegetable Glycerol)
- Lactitol
- Maltitol
- Maltitol Syrup
- Mannitol
- Sorbitol
- Xylitol

In addition to the sugar substitutes listed above, food and beverage manufacturers are seeking out novel ingredients to reformulate products with sweetening agents that do not require being disclosed under total or added sugars on the Nutrition Facts label. These ingredients include:

- Allulose
- Chicory Root Fiber
- Polydextrose

The lack of transparency that surrounds the use of alternative sweeteners in foods and beverages is confounded by claims on the PDP that misleadingly imply that the product does not contain sweetening agents. Examples currently seen in the marketplace include:

- Oikos Greek Yogurt claims on the PDP "No Added Sugar and No Artificial Sweeteners" but contains Stevia and Chicory Root Fiber;
- Quest Nutrition's Hero Blueberry Cobbler Bar claims "1 g" of sugar on the PDP but is sweetened with Allulose, Erythritol, Sucratose, and Steviol Glycosides (Stevia);

- Quaker Instant Oatmeal Apples & Cinnamon claims “Lower Sugar” on the PDP but is sweetened with Monk Fruit Extract;
- Welch’s Fruit Snacks claim “Reduced Sugar” on the PDP but are sweetened with Chicory Root Fiber and Maltitol Syrup;
- Del Monte Diced Peaches claim, “No Sugar Added” and “No Artificial Sweeteners” on the PDP but are sweetened with Stevia Leaf Extract;
- Hapi Water claims, “0 Grams of Sugar” and “Naturally Sweetened, Nothing Artificial” on the PDP but is sweetened with Erythritol and Stevia Leaf Extract;
- Rebel Ice Cream claims, “No Sugar Added” on the PDP but is sweetened with Erythritol, Chicory Root Fiber, Vegetable Glycerin, and Monk Fruit;
- Kool-Aid Jammers claim, “Zero Sugar” on the PDP but are sweetened with Sucralose and Acesulfame Potassium;
- Snack Pack Chocolate Pudding Cups claim, “Sugar Free” on the PDP but are sweetened with 4 sweeteners: Sorbitol, Maltitol, Sucralose, and Acesulfame Potassium.

The use of prominent front-of-package claims regarding sugar content has proliferated throughout the aisles of grocery stores. Innova Market Insights found that eight percent of all new food and beverage launches in 2018 featured a sugar reduction claim. No added sugar claims were the most prominent, making up 42% of all sugar-related claims, followed by sugar-free claims (36%) and lower sugar claims (27%).⁷ Such claims have become increasingly important to consumers. In the U.S., 82% of shoppers report actively looking for at least one front-of-package claim. Low sugar is the top product claim shoppers seek out when purchasing

⁷ See Innova Market Insights, footnote 2.

food products, with 34% of consumers reporting that they look for it on packages.⁸ When making purchasing decisions, 22% of consumers report that their purchases are influenced by the presence of a low/no sugar claim.⁹

Consumer research demonstrates there is a need for FDA to ensure that the presence of alternative sweeteners is effectively communicated to consumers. The ingredient list and product packaging are key sources of information about a product. According to a survey conducted by Label Insight, 75% of consumers look to avoid specific ingredients when shopping for food products. In order to ensure a product meets their dietary needs, three-fourths of consumers review the ingredient list. However, consumers report that food labels make it difficult to shop within their nutritional wants and needs. Sixty-seven percent of consumers find it challenging to determine whether a product meets their dietary needs by reviewing the product label and nearly half of consumers consider themselves to be “not informed at all about a product” even after reading the product’s label.¹⁰

Consumers desire greater information about the presence of sweeteners in the foods they purchase. In a study conducted by Mintel, 72% of consumers stated that food and beverage products should show more clearly if they contain sweeteners.¹¹ Research has found that a large percentage of consumers do not recognize non-nutritive sweeteners and sugar alcohols in the products they purchase. In fact, 52% percent of consumers were unfamiliar with Acesulfame-Potassium (Ace-K). Forty-nine percent of consumers were unfamiliar with Monk Fruit, while

⁸ FMI US Grocery Shopper Trends, 2019. Retrieved from: https://www.fmi.org/docs/default-source/webinars/trends-a-look-at-today%27s-grocery-shopper-slides-pdf.pdf?sfvrsn=9d01576e_0.

⁹ Innova Market Insights Consumer Lifestyle Survey, 2019.

¹⁰ Label Insight Shopper Trends Survey 2017.

¹¹ Mintel Report - Sugar and Alternative Sweeteners, U.S. – December 2018.

47% had never heard of Xylitol.¹² Consumers want to know how the foods they purchase are sweetened and support greater transparency in labeling, with 66% of consumers agreeing that it is important for food companies to clearly identify sugar substitutes as sweeteners in the ingredients list.¹³

Consumers have shown a heightened concern with regard to artificial sweeteners. Forty-four percent of consumers report that when shopping for food products the specific ingredient they look to avoid is artificial sweeteners.¹⁴ This finding is further supported by survey data from Pew Research Center that found 44% of consumers limit their consumption of artificial sweeteners, while 38% reported they limit sugar.¹⁵ Among consumers who reported avoiding artificial sweeteners, more than four in ten do so largely because of concerns about health rather than taste or functionality.¹⁶ In the 2018 Global Sweetener Report, consumers in the U.S. were asked to rate different types of sweeteners as good, bad or neutral. Consumers showed a clearly negative view of artificial sweeteners with only 18% of consumers reporting that they believe artificial sweeteners are safe.¹⁷

¹² Research was funded by The Sugar Association and conducted by Marriner Marketing in December 2018, among a national survey of 1,500 U.S. consumers.

¹³ Preliminary findings from consumer research funded by The Sugar Association and conducted by Quadrant Strategies in May 2020, among a national survey of 1,002 U.S. consumers. See Appendix IV.

¹⁴ See Label Insight Shopper Trends Survey 2017, footnote 10.

¹⁵ Pew Research Center, November 2018, “Public Perspectives on Food Risks”
<https://www.pewresearch.org/science/2018/11/19/public-perspectives-on-food-risks/>

¹⁶ See Mintel Report, footnote 11.

¹⁷ Health Focus International 2018 Global Sweetener Report, Neutral opinions are likely due to low awareness of the many different sweetener options available and a lack of understanding of specific types of sweeteners. See Appendix V and VI.

To prevent consumers from being misled, FDA should provide that the term “(Sweetener)” follow the name of each sweetening ingredient in the ingredients list that is not already disclosed on the Nutrition Facts label.

Increasing labeling transparency around the use of alternative sweeteners in food and beverage products would further FDA’s Nutrition Innovation Strategy.¹⁸ A key component of the strategy is to modernize ingredient labels to help people better understand what is in their food. The agency states: “FDA plans to re-evaluate the ingredient list on food packages to see what changes could make ingredient information more consumer-friendly. Consumers want . . . labels that are readable and understandable. . . In addition to readability, this includes considering whether simpler names for certain ingredients are appropriate.”¹⁹ The action requested here is consistent with and would advance such objectives.

B. Awareness of the presence and quantities of alternative sweeteners are of particular importance in the diets of children.

1. Health organizations advise against the consumption of nonnutritive sweeteners by children.

Experts have cautioned against the inclusion of non-nutritive sweeteners in food and beverage products consumed by children.²⁰ Questions regarding the long-term safety of non-nutritive sweetener consumption among the pediatric population remain.²¹ Conclusive evidence

¹⁸ <https://www.fda.gov/food/food-labeling-nutrition/fda-nutrition-innovation-strategy>.

¹⁹ See footnote 18.

²⁰ Institutes of Medicine (IOM). 2007. Nutrition Standards for Foods in Schools: Leading the Way Toward Healthier Youth. Washington, DC: The National Academies Press.

²¹ Sylvetsky AC, Jin Y, Clark EJ, Welsh JA, Rother KI, Talegawkar SA. Consumption of Low-Calorie Sweeteners among Children and Adults in the United States. *J Acad Nutr Diet.* 2017;117(3):441–448.e2. doi:10.1016/j.jand.2016.11.004

demonstrating the safety and potential benefit of non-nutritive sweetener use in food for children is lacking and has not been systemically reviewed.²²

Despite concerns around the use of non-nutritive sweeteners in food for children, consumption has increased.²³ Analysis of dietary recall data from the National Health and Nutrition Examination Survey (NHANES) from 2009 to 2012 found a 200% increase in nonnutritive sweetener consumption among children in comparison to data published from 1999-2000.²⁴ The growing number and variety of food and beverage products that contain non-nutritive sweeteners as ingredients and the blending of several non-nutritive sweeteners together to improve the palatability of products containing alternative sweeteners may be responsible for the increased consumption seen among children.²⁵ Due to the ubiquitous presence of non-nutritive sweeteners in the food supply, the ability to determine the quantity of non-nutritive sweeteners that children are consuming is very limited.²⁶

2. Labels do not adequately disclose the presence of non-nutritive sweeteners in products consumed by children.

A recent analysis assessing the sales, nutrition, and marketing of children's beverages found that the majority of children's products that contain non-nutritive sweeteners feature reduced sugar claims on the PDP, but do not indicate that the product contains other types of

²² Baker-Smith CM, de Ferranti SD, Cochran WJ. AAP Committee on Nutrition, Section on Gastroenterology, Hepatology, and Nutrition. The Use of Non-nutritive Sweeteners in Children. Pediatrics. 2019; 144(5): e20192765.

²³ See footnote 22.

²⁴ See footnote 21.

²⁵ See footnote 21.

²⁶ See footnote 22.

sweeteners.²⁷ Fifty-three percent of parents stated that they seek out products labeled reduced sugar, but most did not realize that the product was instead sweetened with a non-nutritive sweetener.²⁸

For example, Snack Pack Chocolate Pudding cups claim “Sugar Free” on the PDP but contain two sugar alcohols (Sorbitol and Maltitol) and two non-nutritive sweeteners (Sucralose and Acesulfame Potassium).



Figure 1: Snack Pack Chocolate Pudding cups contain a “Sugar Free” claim on the front of package. The product is sweetened with 2 sugar alcohols and 2 non-nutritive sweeteners. The product contains Sorbitol, Maltitol, Sucralose, and Acesulfame Potassium.

²⁷ Harris, J., Romo-Palafox, M., Choi, Y., Kibwana, A. Children’s Drink FACTS 2019. Sales, Nutrition, and Marketing of Children’s Drinks. UConn Rudd Center for Food Policy and Obesity, October 2019. Accessed from: <http://uconnruddcenter.org/files/Pdfs/FAC TS2019.pdf>.

²⁸ See footnote 22.

To be able to recognize that the products they purchase for their children contain non-nutritive sweeteners, parents would need to know the chemical names of these ingredients. However, name recognition of non-nutritive sweeteners and knowledge on how to identify products containing these ingredients is low.²⁹ Only twenty-three percent of parents are able to correctly identify products that contain non-nutritive sweeteners.³⁰

In another example, Kool-Aid Jammers makes a bold “Zero Sugar” claim on the PDP but is sweetened with both Sucralose and Acesulfame Potassium (Ace-K).



Figure 2: Kool-Aid Jammers, which is marketed for children, contains a “Zero Sugar” claim on the front of package with no indication the product contains other sweeteners. The product is sweetened with Sucralose and Acesulfame Potassium.

²⁹ Wilson T, Murray B, Price T, Atherton D, Hooks T. Non-Nutritive (Artificial) Sweetener Knowledge among University Students. *Nutrients*. 2019;11(9):2201. Published 2019 Sep 12. doi:10.3390/nu11092201

³⁰ Sylvetsky AC, Greenberg M, Zhao X, Rother KI. What parents think about giving nonnutritive sweeteners to their children: A pilot study. *Int J Pediatr*. 2014;2014:819872

The current trend of featuring no/reduced sugar claims on children's products that contain non-nutritive sweeteners is an effort to market these products to parents as a healthier option for their children and these claims could be an additional factor driving the increase in non-nutritive sweetener intake seen among children.³¹ In the same way, the use of "No Artificial Sweeteners" claims found on products that contain Stevia Extract may mislead consumers to believe that these products do not contain non-nutritive sweeteners.³²



Figure 3: Del Monte Diced Peaches product, which is marketed as a lunchbox favorite, features "No Sugar Added" and "No Artificial Sweeteners" claims on the front of package with no indication the product contains non-nutritive sweeteners. The product is sweetened with Stevia Leaf Extract.

³¹ See footnote 21.

³² Pomeranz JL, Harris JL. Children's Fruit "Juice" Drinks and FDA Regulations: Opportunities to Increase Transparency and Support Public Health", American Journal of Public Health. 2020 pp. e1-e10. <https://doi.org/10.2105/AJPH.2020.305621>.



Figure 4: Project 7 Gummy Bears clearly disclose the amount of sugar in the product, but feature a “No Artificial Sweeteners” claim on the PDP despite being sweetened with Allulose and Stevia.

As research discussed above suggests, parents preferentially select products with sugar-related nutrient content claims in order to provide what they see as a healthier alternative for their children without realizing that these products often contain non-nutritive sweeteners. The same parents who preferred reduced sugar products also reported that they do not believe non-nutritive sweeteners are safe for children.³³ Food labeling is intended to help consumers make informed decisions about the products they purchase for their families, yet current FDA labeling regulations may be promoting parental confusion rather than preventing it. Parents’ selection of products containing ingredients that they report avoiding indicates that labeling may be misleading to consumers.³⁴ Current labeling practices shown in the examples provided demonstrate that it is not possible to identify from the PDP when products marketed for children contain non-nutritive sweeteners.

³³ Sylvetsky AC, Dietx WH. Nutrient-content claims – Guidance or cause for confusion? N Engl J Med. 2014; 317(3): 195-198.

³⁴ See footnote 33.

Given that non-nutritive sweeteners are currently only required to be identified by their chemical name on the ingredients list, parents are not provided with enough information to recognize if the products they purchase for their children contain non-nutritive sweeteners or how much of these sweeteners their children are consuming in their diet.³⁵ Amending the ingredient list to include the term “(Sweetener)” after the chemical name of all nonnutritive sweeteners will ensure that non-nutritive sweeteners are recognizable in the ingredient list and help parents accurately identify the ingredients as the source of sweetness in the product.

While once limited to use as a tabletop sweetener and in diet soft drinks, non-nutritive sweeteners can now be found in a variety of children’s products including breads, cereals, granola bars, and dairy products including yogurt, ice cream, and flavored milk.³⁶ For parents concerned with their child’s intake of non-nutritive sweeteners, the acceptable daily intake (ADI) of specific non-nutritive sweeteners provides the amount of sweetener that can be ingested on a daily basis over a lifetime without appreciable health risk.³⁷ However, the amount of a non-nutritive sweeteners added to a product remains proprietary, which prevents parents from being able to determine how much of a food or beverage that contains a non-nutritive sweetener is safe for their child to consume.³⁸

3. The type and quantity of each non-nutritive sweetener used should be disclosed in milligrams per serving on products consumed by children.

³⁵ See footnote 21.

³⁶ Sylvetsky, A. C., & Rother, K. I. (2016). Trends in the consumption of low-calorie sweeteners. *Physiology & behavior*, 164(Pt B), 446–450. doi:10.1016/j.physbeh.2016.03.030.

³⁷ See footnote 33 and Appendix VII.

³⁸ See footnote 33.

In order to better understand pediatric exposure to non-nutritive sweeteners, the American Academy of Pediatrics (AAP) has recommended that the FDA require products marketed in the United States to include labels that list the type and quantity of any non-nutritive sweetener contained in a serving of a product.³⁹ The AAP's recommendation is similar to Canada's current regulatory requirement that food and beverage products containing an alternative sweetener (artificial and high intensity sweeteners, including those obtained from natural sources) include a statement on the front of the package as well as disclose the amount of the sweetener or sweeteners in milligrams per serving.⁴⁰ Without clear and transparent labeling, it will remain difficult for parents to accurately determine the amount and type of non-nutritive sweeteners being consumed within their child's overall diet.⁴¹ Requiring the disclosure of the type and quantity of non-nutritive sweeteners that have been added to food and beverage products marketed for children would further help parents understand and make informed decisions about what they feed their children.⁴² The disclosure of non-nutritive sweeteners is especially warranted now that the Nutrition Facts label is required to disclose added sugars, which may encourage manufacturers to replace added sugars with nonnutritive sweeteners.⁴³ A recent study on the consequences of Chile's new added sugars labeling requirement found that manufacturers were reformulating many of their products with non-nutritive sweeteners to avoid

³⁹ See footnote 22.

⁴⁰ See footnote 33.

⁴¹ Serra-Majem, L., Raposo, A., Aranceta-Bartrina, J, et al. (2018). Ibero-American Consensus on Low- and No-Calorie Sweeteners: Safety, Nutritional Aspects and Benefits in Food and Beverages. *Nutrients*, 10(7), 818. doi:10.3390/nu1007081.

⁴² See footnote 33.

⁴³ See footnote 32.

labeling sugar on products, many of which are marketed directly toward children. These actions have in turn increased the availability, exposure, and consumption of non-nutritive sweeteners.⁴⁴

C. Some alternative sweeteners are associated with gastrointestinal disturbances that should be disclosed to consumers at the minimum threshold of effect.

1. Sugar Alcohols

Many foods claiming on the PDP to be reduced in sugar have simply replaced sugars with sugar alcohols including erythritol, isomalt, lactitol, mannitol, sorbitol, xylitol, and others that have about half as many calories as sugar.⁴⁵ FDA has recognized that the consumption of sugar alcohols can cause gastrointestinal distress.⁴⁶

FDA requires as a condition of use that the labels of food products containing sorbitol state “Excess consumption may have a laxative effect, 21 CFR 184.1835 when reasonably foreseeable consumption of the food may result in daily ingestion of 50 g or more of sorbitol.

FDA requires as a condition of use that the labels of food products containing mannitol state “Excess consumption may have a laxative effect, 21 CFR 180.25 when reasonably foreseeable consumption of the food may result in daily ingestion of 20 g or more of mannitol.

⁴⁴ Martínez et al. (2020). Intake of Non-Nutritive Sweeteners in Chilean Children after Enforcement of a New Food Labeling Law that Regulates Added Sugar Content in Processed Foods. *Nutrients*, 12(6), 1594. doi.org/10.3390/nu12061594

⁴⁵ Erythritol has one-twentieth as many calories as sugar.

⁴⁶ Food and Drug Administration. Nutrition Facts Label: Fact Sheet – Sugar Alcohols. Accessed from https://www.accessdata.fda.gov/scripts/InteractiveNutritionFactsLabel/factsheets/Sugar_Alcohols.pdf.

FDA's regulations are not sufficient to protect consumers.⁴⁷ First, FDA should provide that foods made with any sugar alcohol, not just sorbitol and mannitol, carry the statement "Excessive consumption, due to use of [name of sugar alcohol], may have a laxative effect."

Second, FDA should set the threshold amount of sugar alcohols at the lowest observable effect level of 10 grams. The malabsorption of sugar alcohols has been proven to induce laxative effects as well as lead to flatulence, bloating and abdominal discomfort in sensitive individuals.⁴⁸ However, the threshold amount of sugar alcohol consumption that induces gastrointestinal symptoms is subject to a great deal of variability. The onset of symptoms from consumption appears to be largely dose dependent but has been shown to increase when sugar alcohols are consumed with other carbohydrates.⁴⁹

⁴⁷ FDA's Nutrition Facts panel regulations are inadequate to protect consumers. They merely require the disclosure of the number of grams of sugar alcohols when a claim is made about sugars. FDA's regulation states, states:

"Sugar alcohol" (VOLUNTARY): A statement of the number of grams of sugar alcohols in a serving may be declared voluntarily on the label, except that when a claim is made on the label or in labeling about sugar alcohol or total sugars, or added sugars when sugar alcohols are present in the food, sugar alcohol content shall be declared. For nutrition labeling purposes, sugar alcohols are defined as the sum of saccharide derivatives in which a hydroxyl group replaces a ketone or aldehyde group and whose use in the food is listed by FDA (e.g., mannitol or xylitol) or is generally recognized as safe (e.g., sorbitol). In lieu of the term "sugar alcohol," the name of the specific sugar alcohol (e.g., "xylitol") present in the food may be used in the nutrition label provided that only one sugar alcohol is present in the food. Sugar alcohol content shall be indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero. 21 CFR 101.9(6)(iv). Such disclosures are not adequate to alert consumers to the undesirable gastrointestinal effects from consuming sugar alcohols.

⁴⁸ Grabitske, Hollie & Slavin, Joanne. (2009). Gastrointestinal Effects of Low-Digestible Carbohydrates. Critical reviews in food science and nutrition. 49. 327-60. 10.1080/10408390802067126.

⁴⁹ Lenhart, A., & Chey, W. D. (2017). A Systematic Review of the Effects of Polyols on Gastrointestinal Health and Irritable Bowel Syndrome. Advances in nutrition (Bethesda, Md.), 8(4), 587–596. doi:10.3945/an.117.015560.

Large amounts of sorbitol, defined as doses between 20 to 50 grams, are known to produce osmotic diarrhea.⁵⁰ The current regulatory framework for disclosure dismisses research that indicates smaller amounts of ingested sorbitol are associated with symptoms characteristic of carbohydrate malabsorption.⁵¹ Within the general healthy population, most individuals experience mild gastrointestinal discomfort (gas and bloating) after the consumption of 10 grams of sorbitol.⁵² Doses of 20 grams of sorbitol have been shown to induce more severe gastrointestinal symptoms such as cramps, abdominal pain, and diarrhea.⁵³ This research shows that malabsorption and intolerance of sorbitol can result from ingestion of doses commonly found in many foods.⁵⁴ The same dose-dependent relationship between sorbitol consumption and the onset of gastrointestinal symptoms has also been seen with isomalt, lactitol, and maltitol.⁵⁵

Given the potential of sugar alcohols to reduce added sugars content, the prevalence of these sweeteners in processed foods is increasing.⁵⁶ The perceived benefit of using sugar alcohols as a substitute for sugar in foods is related to individuals' inability to completely breakdown and digest the carbohydrates into absorbable saccharides. The unabsorbed carbohydrates are subsequently fermented in the colon, which leads to the laxative effect and gastrointestinal distress associated with their consumption. The responses experienced with

⁵⁰ Hyams, J. (1983). Sorbitol Intolerance: An Unappreciated Cause of Functional Gastrointestinal Complaints. *Gastroenterology*, Volume 84, Issue 1, 30 – 33.

⁵¹ Corazza, G. R., Strocchi, A., Rossi, R., Sirola, D., & Gasbarrini, G. (1988). Sorbitol malabsorption in normal volunteers and in patients with coeliac disease. *Gut*, 29(1), 44–48. doi:10.1136/gut.29.1.44

⁵² See footnotes 48 and 51.

⁵³ See footnotes 48 and 51.

⁵⁴ See footnotes 48.

⁵⁵ See footnote 51.

⁵⁶ See footnote 48.

consumption impact consumers' acceptance of food and beverage products that contain sugar alcohols.⁵⁷

It is important that consumers are informed that sugar alcohols are added to a variety of foods, are able to recognize the names of these compounds, and are aware that the consumption of foods containing sugar alcohols at levels as low as 10 grams may lead to gastrointestinal discomfort and laxative effects.⁵⁸ A uniform approach to the disclosure of sugar alcohols in foods and the potential for gastrointestinal discomfort will ensure that food labels disclose material facts.

2. Allulose

Allulose is a sugar substitute that appears to result in only negligible increases in blood glucose or insulin levels and has fewer calories than sugar because it is poorly absorbed by the body. FDA intends to exclude allulose from the amount declared in the total and added sugars declarations, and to use 0.4 calories per gram of allulose when calculating the calories from allulose in a serving of product.⁵⁹

However, because it is a poorly digested carbohydrate, consumption of allulose can have gastrointestinal effects such as nausea, bloating, diarrhea, and abdominal pain.⁶⁰ Studies

⁵⁷ Mäkinen KK. Gastrointestinal Disturbances Associated with the Consumption of Sugar Alcohols with Special Consideration of Xylitol: Scientific Review and Instructions for Dentists and Other Health-Care Professionals. *Int J Dent.* 2016;2016:5967907. doi:10.1155/2016/5967907.

⁵⁸ Government of Canada. Health Canada. (2005). Sugar Alcohols (Polyols) and Polydextrose Used as Sweeteners in Foods - Food Safety. Retrieved from <https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/sugar-substitutes/sugar-alcohols-polyols-polydextrose-used-sweeteners-foods-food-safety.html>

⁵⁹ Docket No. FDA-2019-D-0725, The Declaration of Allulose and Calories from Allulose on Nutrition and Supplement Facts Labels, Draft Guidance for Industry.

⁶⁰ See, comments of the Center for Science in the Public Interest, <https://cspinet.org/sites/default/files/attachment/allulose%20final%20from%20CSPI.pdf>

conducted on allulose tolerance in healthy adults have reported gastrointestinal distress at varying levels of intake. A study conducted in ten healthy adults found that gastrointestinal symptoms ranging from diarrhea, abdominal pain, nausea, and distension were experienced at doses of allulose above 0.5g/kg of body weight.⁶¹

To date, the single largest clinical trial conducted on gastrointestinal tolerance of allulose was completed with 30 adults to determine the maximum single dose for occasional ingestion and the maximum daily intake of allulose for regular ingestion. The study suggested setting a maximum single dose at 0.4 g/kg of body weight (24g for 60 kg) and a maximum total daily intake of 0.9mg/kg of body weight (54g for a 60kg person).⁶² The suggested doses were based on the development of severe gastrointestinal symptoms experienced by study participants at the next highest dose. In the first experiment to determine the maximum single dose of allulose, 29 adults completed the trial. At a single dose of 0.5g/kg of body weight, 13 participants (44.8%) reported diarrhea while four (13.7%) reported more severe symptoms.⁶³

Similar to what has been observed in studies conducted on sugar alcohol tolerance, there appears to be a level of variability related to the onset of gastrointestinal distress with consumption of allulose. At the lowest tested dose of allulose (0.1g/kg of body weight), five study participants reported nausea while four participants reported bloating, diarrhea, and headache.⁶⁴ The human studies evaluating the gastrointestinal effects of allulose in healthy

⁶¹ See footnote 60.

⁶² Han, Y., Choi, B. R., Kim, S. Y., Kim, S. B., Kim, Y. H., Kwon, E. Y., & Choi, M. S. (2018). Gastrointestinal Tolerance of D-Allulose in Healthy and Young Adults. A Non-Randomized Controlled Trial. *Nutrients*, 10(12), 2010. doi:10.3390/nu10122010.

⁶³ See footnote 62.

⁶⁴ See footnote 60.

adults are not sufficient to determine safe levels of consumption for the general population, and in particular children.

FDA's intention to exclude allulose in total and added sugars declarations has increased the food industry's interest in using allulose in significant quantities and a greater variety of products.⁶⁵ The level of patent activity around allulose is indicative of the current interest in its use, with an increase of 42% in 2018 over 2017. New product development in food and beverages featuring allulose had an average annual growth of 45% over the time period from 2014 to 2018.⁶⁶ If individuals, including children, consume more allulose due to the expansion in its use, consumers are likely to reach levels of consumption known to have adverse effects.⁶⁷



Figure 5: Quest Hero Bar prominently declares that it contains 1 g sugar despite containing four different sweeteners: Allulose, Erythritol, Sucralose, and Steviol Glycosides. A single bar contains 12 grams of Allulose, a dose high enough to induce adverse gastrointestinal effect.

The gastrointestinal disturbances caused by allulose are similar to the effects seen with other poorly digested carbohydrates.⁶⁸ Allulose is a novel substance that is unfamiliar to

⁶⁵ See Innova Market Insights, footnote 2.

⁶⁶ See Innova Market Insights, footnote 2.

⁶⁷ See footnote 61.

⁶⁸ See footnote 61.

consumers. Findings from the Sugar Association's 2018 survey on consumer awareness of sweeteners confirms consumers are unaware of allulose, with 68% reporting that they have never heard of the sweetener.⁶⁹ Consumers should be informed of allulose's potential to induce gastrointestinal distress. A label statement regarding the gastrointestinal disturbances associated with allulose consumption would alert consumers who may be sensitive to allulose.

Allulose will likely be used in combination with other ingredients, some of which are known to cause gastrointestinal disturbances on their own. Some allulose manufacturers are recommending a sweetener system comprising allulose, at least one bulking agent, and at least one high intensity sweetener as a solution for foods and beverages where regulatory requirements will not allow the use of high levels of allulose in products.⁷⁰ Examples of bulking agents suggested for use with allulose include polydextrose, maltodextrin, and sugar alcohols such as maltitol, xylitol, and erythritol.⁷¹

Bulking fibers, such as polydextrose and chicory root fiber belong in the same class of poorly absorbed carbohydrates as sugar alcohols and allulose. They can provide sweetness to products, yet they are captured on the Nutrition Facts label as fibers instead of added sugars. Despite their association with gastrointestinal disturbances, food manufacturers can use these substances to reduce the amount of added sugars disclosed on the Nutrition Facts panel without disclosing the undesirable potential effects.

The FDA should consider the safety and cumulative effect of using allulose in combination with sugar alcohols and bulking agents with regard to gastrointestinal disturbances.⁷² Additionally,

⁶⁹ See footnote 12.

⁷⁰ United States Patent Application. US 2016/0302463 A1. Retrieved from <https://patentimages.storage.googleapis.com/46/81/4c/1debb28728ce62/US20160302463A1.pdf>.

⁷¹ See footnote 70.

⁷² See footnote 60.

more research on the level of allulose that induces gastrointestinal disturbances is needed, with special evaluation in children. Due to consumers' lack of awareness of allulose, and the gastrointestinal disturbances associated with its consumption at varying doses, the FDA should ensure that the following label statement is provided on foods containing Allulose: "Excess consumption of Allulose may cause laxative and/or other adverse gastrointestinal effects."

D. FDA needs to take enforcement action to stop misleading claims about added sugars content.

Consumer welfare is further harmed by misleading claims regarding added sugars content. Consumer research has demonstrated that, in general, the use of nutrient content claims leads consumers to believe that a product is more healthful than a comparable product marketed without such a claim.⁷³ In a recent survey, 67% of consumers agreed that products labeled "reduced sugar" are healthier than the comparison product.⁷⁴ When used as ingredients, alternative sweeteners can facilitate no/reduced sugar labeling claims that may make a product more appealing to a consumer, however the labeling claims may not be associated with improved dietary health or nutritional value.⁷⁵

Most consumers have little idea that when they purchase a product with a no/reduced sugar claim, they are often simply buying a product that contains alternative sweeteners. Consumers have been led to believe that a no/reduced added sugar claim means a product contains fewer calories. When surveyed, 70% of consumers agreed that products labeled "reduced sugar" contain

⁷³ See, KIND Healthy Snacks (KIND) Citizen Petition: <https://s3.amazonaws.com/kind-docs/nutrient-content-claim-citizen-petition.pdf>.

⁷⁴ See footnote 13 and Appendix IV.

⁷⁵ See footnote 29.

fewer calories than the original version.⁷⁶ However, products currently in the marketplace suggest such impressions are misplaced.

FDA should take immediate action to stop these claims. Further, the agency should issue guidance to ensure that food manufacturers avoid making misleading claims in the future.

1. Misleading no/reduced added sugars claims are common and increasingly prevalent among brand name food products.

The reduced sugar version of Skippy peanut butter has 1/3 less sugar than its traditional counterpart but has more calories per serving than the regular version. Despite having 1 g less added sugars, the reformulated product provides 20 more calories per 2 tablespoon serving. The claim on the PDP is misleading because it implies that the reformulated version is healthier and lower in calories due to the reduction in added sugars when the reformulated version is, in fact, higher in calories.



Figure 6: Skippy 1/3 less sugar peanut butter has more calories per serving than regular Skippy Peanut Butter

⁷⁶ See footnote 13 and Appendix IV.

Quaker's "25% less sugar" version of its regular chocolate chip Chewy granola bars implies that the product is also lower in calories. However, the new product has the same number of calories (100) per serving as the regular version.



Nutrition Facts	
8 servings per container	
Serving size	1 bar (24g)
<hr/>	
Amount per serving	
Calories	100
<hr/>	
% Daily Value*	
Total Fat 4g	5%
Saturated Fat 1g	6%
Trans Fat 0g	
Polyunsaturated Fat 1g	
Monounsaturated Fat 1.5g	
Cholesterol 0mg	0%
Sodium 75mg	3%
Total Carbohydrate 17g	6%
Dietary Fiber 3g	10%
Total Sugars 5g	
Includes 5g Added Sugars 10%	
Sugar Alcohol 0g	
<hr/>	
Protein 1g	
<hr/>	
Vitamin D 0mcg	0%
Calcium 110mg	8%
Iron 0.6mg	2%
Potassium 50mg	0%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.



Figure 7: Quaker 25% less sugar Chewy snack bars compared to regular Quaker Chewy snack bar.

Oikos Triple Zero blended Greek Yogurt makes a “0 Added Sugar” claim but has more calories per serving than the company’s regular Greek Yogurt. The zero added sugars product, which is sweetened with Stevia Leaf Extract, has 120 calories per serving while the company’s original version has 110 calories per serving.



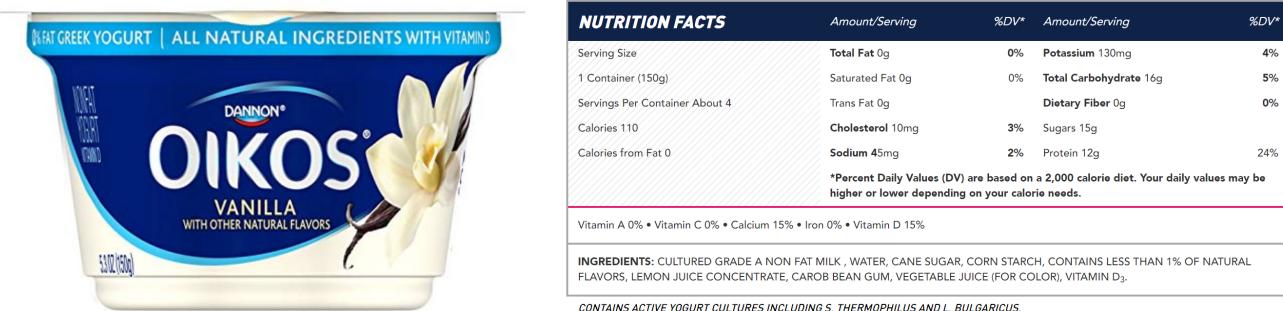


Figure 8: Oikos “0” added sugar yogurt compared to Oikos regular yogurt.

Quaker’s reformulated “Apples & Cinnamon Lower Sugar” instant oatmeal claims “35% less sugar.” However, the claim is achieved by decreasing the portion size of the lower sugar version. The lower sugar claim, despite being qualified, is misleading to consumers. Studies indicate that food companies vary serving sizes as a marketing strategy to stimulate sales by reporting lower values of certain nutrients on nutrition information labels.⁷⁷ The serving size of the regular version is 43 grams and contains 11 grams of sugar while the serving size of the lower sugar version has been reduced to 31 grams and contains 5 grams of sugars. If the serving size of the reformulated version was standardized to a 43 gram serving, the lower sugar product would have 152 calories and contain 7 grams of sugar. A 43 gram serving of the regular version contains 160 calories and 11 grams of sugars. While the sugar has been reduced by 35%, the calories have only gone down by 4.8%.

⁷⁷ Kliemann, N., Kraemer, M., Scapin, T., Rodrigues, V. M., Fernandes, A. C., Bernardo, G. L., ... Proen  a, R. (2018). Serving Size and Nutrition Labelling: Implications for Nutrition Information and Nutrition Claims on Packaged Foods. *Nutrients*, 10(7), 891. doi:10.3390/nu10070891



Nutrition Facts	
10 servings per container	
Serving Size	1 Packet (31g)
Calories	
110	% Daily Value*
Total Fat 1.5g	2%
Saturated Fat 0.5g	3%
Trans Fat 0g	
Polyunsaturated Fat 0.5g	
Monounsaturated Fat 0.5g	
Cholesterol 0mg	0%
Sodium 150mg	6%
Total Carbohydrate 23g	8%
Dietary Fiber 3g	11%
Soluble Fiber 1g	
Total Sugars 5g	
Includes 2g Added Sugars	5%
Protein 3g	
Vitamin D 0mcg	0%
Calcium 20mg	0%
Iron 0.9mg	4%
Potassium 120mg	2%
Thiamine 0.1mg	10%
*The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.	
Ingredients: Whole grain oats, dried apples, sugar, salt, cinnamon, monk fruit extract, natural flavor.	



Nutrition Facts	
10 servings per container	
Serving Size	1 Packet (43g)
Calories	
160	% Daily Value*
Total Fat 2g	3%
Saturated Fat 0.5g	2%
Trans Fat 0g	
Polyunsaturated Fat 0.5g	
Monounsaturated Fat 1g	
Cholesterol 0mg	0%
Sodium 160mg	7%
Total Carbohydrate 33g	12%
Dietary Fiber 4g	13%
Soluble Fiber 1g	
Total Sugars 11g	
Includes 8g Added Sugars	16%
Protein 4g	
Vitamin D 0mcg	0%
Calcium 20mg	0%
Iron 1.2mg	6%
Potassium 150mg	2%
*The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.	
Ingredients: Whole grain oats, sugar, dried apples, natural flavor, salt, cinnamon.	

Figure 9: Quaker's reformulated "Apples & Cinnamon Lower Sugar" instant oatmeal claims "35% less sugar" but the claim and calorie reduction is achieved in part by reducing the portion size of the lower sugar version.

Welch's Fruit Snacks Reduced Sugar version claims 25% less sugar than their original version. The claim, while qualified, is misleading to parents and children. The Reduced Sugar version contains Maltitol Syrup as a sugar substitute. If a parent were unfamiliar with this ingredient, they would assume there were no alternative sweeteners in the product. Moreover, the claim is predicated upon also reducing the serving size of the reformulated version of the product. The original version has a serving size of 25.5 g while the Reduced Sugar version has decreased to 22.7g.



Figure 10: Welch's reduced sugar fruit snacks compared to Welch's regular fruit snacks.

2. FDA should issue guidance to industry.

Food processors find themselves under increasing pressure to lower sugar content as consumers seek out foods with less added sugar. In the process, some companies are promoting no/reduced added sugars foods as implicitly healthier. As these examples illustrate, no/reduced added sugar claims misleadingly imply that the reformulated product is lower in calories and is overall healthier than the original counterpart. FDA has an obligation to protect consumers from such misleading claims.

The problem is industry-wide and calls for FDA to issue guidance. FDA should put companies on notice that the agency considers no/reduced added sugars claims to be misleading unless such claims are accompanied by the statement “Sweetened with “[name of Sweetener(s)].” In addition, FDA guidance should provide that no/reduced sugar claims are misleading in situations where the food is not significantly lower in calories (i.e. 25% lower) than the food to which it is being compared, *unless* the claims are accompanied by the disclosure “Not lower in calories” for products that indeed have 25% fewer calories than the comparison food. The issuance of such guidance will help level the competitive playing field and protect consumers from being misled.⁷⁸

IV. Statement of Legal Grounds

Section 403 (a)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) prohibits labeling that is “false or misleading in any particular.” Foods with false or misleading claims are considered misbranded in violation of the Act. The Act was enacted to enable purchasers to

⁷⁸ FDA should also consider whether no/reduced added sugars claims should be prohibited for foods high in total sugars. This matter, however, is beyond the scope of this petition.

make intelligent choices, and, to that end, misbranding was one of the chief evils Congress sought to stop. *U.S. v. Watkins*, 278 F.3d 961 (9th Cir. 2002).

Section 201(n) of the FD&C Act further provides “If an article is alleged to be misbranded because the labeling … is misleading, then in determining whether the labeling … is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word… but also the extent to which the labeling … fails to reveal facts material in the light of such representations.”⁷⁹

The labels discussed in this petition fail to reveal material facts, and are affirmatively misleading, and hence misbranded.⁸⁰

A. Ingredient labels should identify the presence of alternative sweeteners to avoid misleading consumers in violation of Section 201(n) of the Act.

FDA has recognized that the nature of ingredients must at times be stated in the ingredient list when such disclosures are necessary to prevent misbranding.

The agency has stated:

“The agency . . . has authority to require information on the label when the information is a material fact with regard to other representations made on the label. . . 21 USC 321(n). . . FDA will . . . consider any suggestion for declaration of the function of a particular ingredient or group of ingredients that is supported by appropriate evidence and that can be justified under . . .the relevant statutory standards.”⁸¹

⁷⁹ 21 U.S.C.A. § 321(m) provides: "(m) The term 'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." (June 25, 1938, c 675, § 201, 52 Stat 1041.

⁸⁰ The Act does not preclude a private party from bringing a Lanham Act claim challenging as misleading a food label that is regulated by the FDCA. Lanham Act, § 43(a), 15 U.S.C.A. § 1125(a); Federal Food, Drug, and Cosmetic Act, § 1 et seq., 21 U.S.C.A. § 301 et seq. *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228 (2014).

⁸¹ Food Labeling, Declaration of Ingredients, Proposed Rule, 56 Fed. Reg. 28592, at 28615 (June 21, 1991).

In 21 C.F.R. §101.22 (j), FDA states:

A food to which a chemical preservative(s) is added shall, except when exempt pursuant to §101.100 bear a label declaration stating both the common or usual name of the ingredient(s) and a separate description of its function, e.g., “preservative”, “to retard spoilage”, “a mold inhibitor”, “to help protect flavor” or “to promote color retention.”⁸²

These function descriptors typically appear parenthetically following the common or usual name of a preservative in an ingredient listing.

Similarly, FDA requires in 21 C.F.R. § [101.4](#)(d):

“When foods characterized on the label as “nondairy” contain a caseinate ingredient, the caseinate ingredient shall be followed by a parenthetical statement identifying its source. For example, if the manufacturer uses the term “nondairy” on a creamer that contains sodium caseinate, it shall include a parenthetical term such as “a milk derivative” after the listing of sodium caseinate in the ingredient list.⁸³

FDA has also recognized the need to require food manufacturers to elaborate on the source of particular ingredients. For example, ingredients such as “soy lecithin” and “hydrolyzed wheat gluten” must disclose their origin (soy and wheat) in the ingredient listing.⁸⁴

FDA has recognized that in such cases, consumers lack familiarity with chemical names and manufacturers should disclose additional information to prevent the public from being misled. Consumers lack familiarity with the names of many sugar substitutes. FDA should thus issue guidance providing that the parenthetical term “(Sweetener)” be disclosed after the common or usual name of each sweetener used in a food that is not

⁸² The Act recognizes the need for ingredients to disclose their purpose in the food. Section 401 (k) states that when a food contains any artificial flavoring, artificial coloring, or chemical preservative, the label must state that fact.

⁸³ See also, 21 C.F.R. § [101.4](#)(b)(14); labeling of “hydrogenated vegetable oil (soybean, cottonseed, and palm oils)”

⁸⁴ See, FDA Compliance Policy Guide § 578.100.

already required to be identified as a sweetener or is required to be disclosed on the Nutrition Facts label.

B. The type and quantity of non-nutritive sweeteners should be disclosed on food and beverage labels of products consumed by children in accordance with Section 201 (n) of the Act.

There is a pressing need to better assess the exposure of children to non-nutritive sweeteners. FDA should follow the recommendations of the AAP and provide that food labels of foods and beverages consumed by children, disclose the type and quantity of any non-nutritive sweeteners used in the product. Such action would be consistent with Health Canada's regulatory requirement that foods and beverages containing a non-nutritive sweetener include a statement on the PDP and disclose the amount of the sweetener or sweeteners in milligrams per serving.⁸⁵

The failure to disclose such information is an omission of a material fact in violation of Section 201 (n) of the Act. In the absence of such information, it will remain difficult if not impossible for the pediatric medical community to assess the impact of non-nutritive sweeteners on children's health and for parents to accurately determine the amount and type of non-nutritive sweeteners being consumed within their child's overall diet.

C. The failure to disclose potential gastrointestinal effects of various alternative sweeteners at minimum thresholds of effect constitutes an omission of a material fact, in violation of Section 201(n) of the FD&C Act.

⁸⁵ Retrieved from https://laws-lois.justice.gc.ca/eng/regulations/c.r.c._c._870/page-10.html.

FDA has acknowledged that the gastrointestinal effects of various sweeteners should be disclosed to consumers. The label of a food whose reasonably foreseeable consumption may result in a daily ingestion of exceeding 20 g of mannitol or 50 g of sorbitol must bear the statement "Excess consumption may have a laxative effect."⁸⁶ As demonstrated here, studies indicate that the same requirement should apply to foods with lesser amounts of mannitol or sorbitol, and should be expanded to cover all sugar alcohols.

The need for clear disclosure of potential gastrointestinal effects is augmented by the increasing trend of food processors using sugar substitutes that are unfamiliar to consumers. The need for clear disclosure is also needed in light of the growing tendency of manufacturers to combine the use of several sugar substitutes. The need to disclose gastrointestinal effects is particularly acute in the case of children.

FDA has recognized the need to require disclosures for ingredients that may have unexpected health effects. For example, the label of any food containing aspartame must bear, either on the PDP or on the information panel, the statement:

"PHENYLKETONURICS: CONTAINS PHENYLALANINE"⁸⁷ In another instance, the agency is considering expanding the list of major food allergens (that require special disclosure in or immediately following the ingredient list) to include sesame.⁸⁸

The need to alert consumers to the gastrointestinal effects of sugar alcohols and other sugar substitutes is consistent with other agency efforts to alert consumers to the nature of

⁸⁶ 21 C.F.R. § [180.25](#)

⁸⁷ 21 C.F.R. § [172.804](#).

⁸⁸ Docket No. FDA-2018-N-3809, <https://www.fda.gov/food/cfsan-constituent-updates/fda-asks-input-sesame-allergies-and-food-labeling>.

specific ingredients when there is a need to do so. The failure to provide such information is an omission of a material fact in violation of Section 201(n) of the Act

D. Food and beverage packages that make deceptive claims about sweetener content are “false and misleading” in violation of section 403(a)(1) of the Act.

The marketplace is rife with misleading claims concerning no/reduced added sugars claims. As discussed,

- A reformulated peanut butter boasts 1/3 less sugar than its traditional counterpart, but has more calories per serving than the original product;
- A yogurt sweetened with stevia and chicory root fiber boasts “No Added Sugars” but contains more calories per serving than the company’s traditional yogurt product;
- A reduced sugar snack bar has as many calories per serving as the company’s regular version of the snack bar;

Misbranding under the Act does not require proof of falsity; misleading labels are prohibited as well. *U.S. v. Watkins*, 278 F.3d 961 (9th Cir. 2002). Further, to prove a violation of the Act, it is unnecessary to show that any consumer was actually misled or that there was an intent to deceive. *U.S. v. 45/194 Kg. Drums of Pure Vegetable Oil*, 961 F.2d 808 (9th Cir. 1992) (referring to 21 U.S.C.A. § 343(i)).

Consumer perception studies demonstrate that these and the other products identified in this petition mislead consumers and hence are misbranded in violation of Section 403(a) of the Act, 21 USC § 343(a).

E. Claims such as “No Added Sugars” or “Reduced Sugars” must be accompanied by disclosures to avoid being false or misleading in violation of section 403(a)(1) of the Act.

Both no added sugar and reduced sugar label statements are nutrient content claims.

Section § 403(r) of the FD&C Act recognizes that disclosures must in various instances be required in conjunction with nutrient content claims to prevent consumer deception.

Added sugars nutrient content claims are not yet authorized and, therefore, illegal. 21 C.F.R. § 101.13(b). When FDA has authorized nutrient content claims, the Agency has recognized that steps need to be taken to protect consumers from misleading half-truths. Accordingly, FDA often requires nutrient content claims to be accompanied by disclosures that ensure that consumers are told the whole story about the composition of a food product. For example:

- Products that claim to be low in saturated fat must disclose the total fat and cholesterol content of the food in immediately proximate to the claim (unless the product is low in fat or cholesterol free).⁸⁹
- Cholesterol content claims must typically be accompanied by total fat and saturated fat disclosures⁹⁰
- Dietary fiber content claims, such as “Good source” or “High” need to be accompanied by a disclosure of the amount of total fat per serving (when the food is not low in fat).⁹¹
- In addition, if a nutrient content claim is made on a food label and the product exceeds prescribed levels for fat, saturated fat, cholesterol or sodium, the amount of those

⁸⁹ 21 CFR §101.62(c).

⁹⁰ 21 CFR §101.62(d)(1)(ii)(D).

⁹¹ 21 CFR §101.54(d).

nutrients must be specified in a disclosure on the principle display panel accompanied by the statement “See nutrition information for [name of nutrient(s)] ____ content.”⁹²

In these circumstances, FDA has recognized that touting the level of a specific nutrient in a food product is misleading unless qualified in a manner that places the claim in its proper context. For the same reasons, no/reduced added sugar claims should be accompanied by the disclosure “Sweetened with ____” if a sweetener has been added to replace the added sugars.

In addition, FDA guidance should provide that no/reduced sugar claims should be accompanied by the disclosure “Not lower in calories” where the food is not significantly lower (25%) in calories than the food to which it is being compared.

FDA’s existing regulation on “No Added Sugar” claims,⁹³ incorporates a similar requirement. Under that regulation, a food may not make a no added sugar claim unless *inter alia*, the product bears a qualifying statement that it is not low or reduced in calories and directs the consumer’s attention to the Nutrition Facts panel for further information on sugar and calorie content.⁹⁴ The same reasoning should be applied here.

V. Environmental Impact

The action requested is subject to a categorical exclusion under 21 C.F.R. § 25.30 and therefore does not require the preparation of an environmental assessment.

VI. Economic Impact

No statement of the economic impact of the requested action is presented because none has been requested by the Commissioner.⁹⁵

⁹² 21 C.F.R. § [101.13\(h\)](#).

⁹³ 21 CFR 101.60 (c)(2).

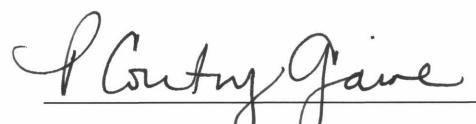
⁹⁴ 21 CFR 101.60(c).

⁹⁵ 21 C.F.R. § 10.30(b).

VII. Certification

The undersigned party certifies that, to the best knowledge and belief of their knowledge, that 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 is unfavorable to the petition.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "P. Courtney Gaine". The signature is fluid and cursive, with a horizontal line underneath the name.

P. Courtney Gaine, Ph.D., R.D.
The Sugar Association