Supplement to Petition for Prohibition of Misleading Labeling of Sweeteners; and Supplemental Request for Promulgation of Regulations

Docket No. FDA-2020-P-1478-0001

Submitted by
The Sugar Association
March 8, 2022
Executive Summary

The Sugar Association submitted a Petition for Prohibition of Misleading Labeling of Sweeteners and Request for Enforcement Action to the U.S. Food and Drug Administration (FDA) in June 2020, to increase transparency about the use of alternative sweeteners on food labels and to stop misleading labeling claims about added sugars content. To the best of our knowledge, FDA has not taken any action on this petition since its submission and the problem continues to worsen.

As manufacturers seek alternatives to added sugars, new and reformulated products with misleading, non-transparent ingredient labeling and deceptive claims continue to enter the marketplace. Since the Citizen Petition was filed in June 2020, 2,318 new food and beverage products with alternative sweeteners, including sugar alcohols, have been introduced into the food supply in the United States. The number of new products launched each year containing alternative sweeteners has increased by 832% since 2000, with 300% growth in the prevalence of alternative sweeteners in the food supply in just the last 5 years.

The 2020 petition documents that consumers are being misled by current labeling with regard to the presence of alternative sweeteners and by claims of added sugars content. This issue has worsened as food and beverage companies face increasing pressure to reduce added sugars content, are introducing more products with alternative sweeteners, and are marketing these products to consumers. Approximately 2,733 new and reformulated products with a sugar

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content claim ("sugar free," "no added sugar," or "low/reduced sugar") have been introduced in the U.S. marketplace since the original petition was filed.³

- Many products make express or implied affirmatively misleading claims in violation of Section 403(a)(1) of the Food, Drug, and Cosmetic Act. For example, many product labels make sugar reduction claims, misleadingly implying that the product is free of sweeteners.

- Other products make misleading claims by omitting material facts in violation of Section 201(n) of the Act, such as by failing to provide transparent ingredient lists disclosing that certain ingredients are, in actuality, sweeteners, and/or by failing to provide material disclosures on the front of food packages regarding sweetener content.

Food and beverage packages that make misleading claims are "misbranded" in violation of Section 403 of the Act.

The Petitioner’s concerns have not diminished since the filing of the original petition in June 2020. Manufacturers continue to reduce their use of added sugars by substituting alternative sweeteners that are only disclosed in ingredient lists, under names consumers do not recognize, and manufacturers continue to make misleading claims that obfuscate and mask the use of sugar substitutes. Notwithstanding, to the best of our knowledge, the agency has taken no action to address any of the concerns raised in the original petition.

In support of the Petitioner’s original filing, this supplemental petition:

³ Mintel GNPD (see footnote 1).
• Advises the agency on the continued introduction of new products into the marketplace that contain alternative sweeteners but fail to provide clear and transparent ingredient labeling and front of package sweetener disclosures;

• Presents new consumer research data demonstrating the harm of such misleading labeling to the general public;

• Provides new market research data indicating such problems have worsened; and

• Requests promulgation of regulations (in addition to the individual enforcement actions and issuance of guidance statements requested in the original petition).

In light of the continuing abuses documented here, the Petitioner again requests FDA to bring a halt to misleading claims about sugar content and improve transparency by requiring manufacturers to:

• 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 front of package of food and beverage products consumed by children;

• Disclose the sweetener used on the front of package for products making a sugar content claim, such as “Sweetened with [name of Sweetener(s)]” beneath the claim;

• Disclose gastrointestinal effects of various sweeteners at minimum thresholds of effect;

• Require that no/low/reduced sugars claims be accompanied by the disclosure “not lower in calories” unless such products have 25% fewer calories than the comparison food.
Such measures are essential to ensuring that consumers can make informed purchasing decisions, improve their diets, and protect their health.
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Introduction

On June 3, 2020, The Sugar Association ("the Association" or "Petitioner") submitted a petition pursuant to Section 4(d) of the Administrative Procedure Act, 5 U.S.C. §553, and 21 CFR §§10.25 and 20.30 requesting that the U.S. Food and Drug Administration ("FDA") take action to ensure that consumers are provided truthful and non-misleading information about the presence and potential side effects of alternative sweeteners4 in foods.5 The Petitioner also requested that FDA prevent misleading claims regarding added sugars content by taking enforcement action and issuing regulatory guidance.

FDA acknowledged the submission of the petition on June 4, 2020, and the petition was posted to Regulations.gov on July 9, 2020.6 As of March 7, 2022, 208 public comments have been received. FDA issued an interim response to the Petitioner on November 30, 2020. FDA stated:

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4 This supplemental petition also 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.” See Appendix I of the original petition (https://www.regulations.gov/document/FDA-2020-P-1478-0003).


6 Ibid.
In accordance with Title 21 of the Code of Federal Regulations, section CFR 10.30(e)(2), this letter is to advise you that we have not been able to reach a decision on your petition within the first 180 days of its receipt because of other agency priorities and the limited availability of resources. When we complete our review of your petition, we will notify you of our decision.\(^7\)

**Action Requested**

The Petitioner is submitting this supplement to their original petition (a) to update FDA on new research, new marketplace data, and related developments that add urgency to the actions requested in the original petition and (b) to now request that the agency not only issue regulatory guidance and take enforcement action but also propose and promulgate final regulations to improve transparency and prevent deception around the use of alternative sweeteners and sugar content claims in the marketplace.

The Petitioner’s original petition calls on FDA to take action to protect consumers by requiring manufacturers to do the following:

- 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 front of package of food and beverage products consumed by children;
- Disclose the sweetener used on the front of package for products making a sugar content claim, such as “Sweetened with [name of Sweetener(s)]” beneath the claim;
- Disclose gastrointestinal effects of various sweeteners at minimum thresholds of effect;

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• Require that no/low/reduced sugar claims be accompanied by the disclosure “not lower in calories” unless such products have 25% fewer calories than the comparison food.

This supplemental filing further calls on FDA to propose and promulgate regulations amending 21 C.F.R. §101. Since 2016, close to 10,000 new products containing alternative sweeteners have been introduced into the U.S. marketplace.8 Over one-third (35%) of new products since 2016 that make a sugar claim, such as “sugar free,” “no sugar added,” or “low/reduced sugar,” contain alternative sweeteners.9 Absent FDA action, new products with alternative sweeteners hidden in indecipherable ingredient lists and obfuscated by misleading claims will continue to enter the marketplace. It is clear that the promulgation of regulations is necessary to prevent instances of misbranding from continuing indefinitely into the future.

Supplementary Statement of Factual Grounds

A. Statement of need.

The addition of the “added sugars” declaration to the Nutrition Facts label10 is a driving force for food and beverage manufacturers to reduce added sugars content. The pursuit of sugar reduction has led manufacturers to reformulate products by replacing added sugars with alternative sweeteners,11 including sugar alcohols and novel sweeteners, in an attempt to mimic the taste and functionality of sugar. Consumer data suggest that while many consumers wish to reduce added sugars intake, they do not wish to do so by increasing their consumption of

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8 Mintel GNPD (see footnote 1).
9 Mintel GNPD (see footnote 1).
11 See Appendix I, Glossary of Terms.
artificial sweeteners. Yet since the petition was filed less than 2 years ago, 2,318 new food and beverage products containing alternative sweeteners have been introduced. As manufacturers continue to decrease their use of added sugars, the use of alternative sweeteners in the U.S. food supply continues to increase as does the use of misleading sugar content claims.

Most consumers believe they are making a lower-calorie and a “healthier” purchase when they choose a product with a no/low/reduced sugar claim. When surveyed, 70% of consumers agreed that products labeled “reduced sugar,” “low sugar,” or “no sugar added” contain fewer calories than the original version. However, products in the marketplace indicate that such widespread impressions are misplaced. For example, Skippy’s “No Sugar Added” peanut butter has 210 calories per 2-tablespoon serving, while the regular version of Skippy peanut butter has just 190 calories. Further, 83% of new products introduced in the United States since 2016 claiming “low/reduced sugar” do not make the claim “low/reduced/no calorie.” The absence of a low/reduced calorie claim is concerning because if the lower-sugar product were lower in calories, the manufacturer would likely make that claim. The fact that many such products making sugar claims are not lower in calories renders such claims misleading, as a reasonable consumer expects “low/reduced sugar” claims to mean that the reformulated product is low or reduced in calories.

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13 Mintel GNPD (see footnote 1).

14 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.

15 See Appendix V, Image 1.

16 Mintel GNPD (see footnote 1).
In addition to implying to consumers that products with sugar content claims are “healthier” and lower in calories through the marketing of a reduction in added sugars, content claims are misleading with regard to the product’s ingredients. When exposed to sugar content claims, consumers do not necessarily assume that a claim of lower sugar content means that alternative sweeteners have replaced the added sugars. When surveyed, only 20% of consumers strongly agree that the claim of “reduced sugar” signals that the product contains sugar substitutes or artificial sweeteners, and 35% of consumers disagree that the claim means the product would have alternative sweeteners.\(^{17}\) However, marketplace data indicate that nearly half (45%) of the 432 products introduced since June 2020 with a “low/reduced sugar” claim do in fact contain alternative sweeteners.\(^{18}\) In addition, over one-third of the approximately 2,733 new products with any sugar claim (“sugar free,” “no added sugar,” or “low/reduced sugar”) introduced since June 2020 contain alternative sweeteners.\(^{19}\)

Further, in a 2020 survey, 67% of consumers agreed that products labeled “reduced sugar” are healthier than the comparison product.\(^{20}\) However, since more than a third of the 2,733 new products since June 2020 making any sugar content claim contain alternative sweeteners and sugar alcohols, many of these can have undesirable dietary qualities such as adverse gastrointestinal effects.\(^{21}\)

\(^{17}\) May 2020 consumer research findings (see footnote 14).  
\(^{18}\) Mintel GNPD (see footnote 1).  
\(^{19}\) Mintel GNPD (see footnote 1).  
\(^{20}\) May 2020 consumer research findings (see footnote 14).  
While FDA regulations requiring the declaration of sugar alcohols when sugar content claims are made is a step in preventing consumers from being misled, it is not sufficient in fully protecting consumers. As noted in our original petition, FDA should provide that foods made with any sugar alcohol, not just sorbitol and mannitol, carry this statement: “Excess consumption, due to use of [name of sugar alcohol] may have a laxative effect.” FDA should set the threshold amount requiring this statement at the lowest observable effect level of 10 grams.

In addition to sugar alcohols, FDA should thoroughly examine the gastrointestinal impact of novel sweeteners, some not yet characterized with respect to labeling, with reported adverse effects and warn consumers accordingly. Such novel alternative sweeteners are only disclosed to consumers in ingredient lists under names that consumers are not familiar with and do not recognize as an alternative sweetener. FDA has recognized that ingredient lists are not always sufficient to inform consumers about the substances in food and beverage products. This consideration was an impetus behind one of the agency’s rationales for requiring the disclosure of added sugars on the Nutrition Facts label. The agency believed that the previous disclosure of added sugars on the ingredient list was insufficient to inform consumers what was in the food they were eating. FDA stated:

Consumers [are not] . . . able to determine the relative amount of added sugars in a serving of a product from the ingredient list for several reasons. There are many different types and forms of sugar that may be added to a food during processing and preparation. Consumers also may not recognize the names of some types of sugars to be a sugar (e.g., trehalose).

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22 May 2020 consumer research findings (see footnote 14).

Research has shown the same to be true for alternative sweeteners. There are many different types and forms of alternative sweeteners that may be added to a food during processing. Consumers may not recognize the names of some types of alternative sweeteners to be a sugar substitute (e.g., neotame). In fact, research confirms that when presented with a list of food additives, fewer than 4 in 10 consumers correctly identified those that might be used as sweetening ingredients.24

**B. Studies conducted since the filing of the original petition confirm that consumers want improved labeling of alternative sweeteners and that such labeling is necessary to prevent deception and ensure transparency.**

1. **Consumers desire greater transparency in the use of alternative sweeteners.**

New data since the original petition was filed indicate that 81% of consumers believe that transparency—i.e., the provision of material information about what is in a food product and how it is made—is important. In addition, 76% think it is important to know when their food contains sugar substitutes.25 Further, 66% of consumers agree that sugar substitutes should be clearly identified as sweeteners on food labels.26 A 2021 study found that when purchasing a food and/or beverage product for the first time, 50% of consumers surveyed look to the Nutrition Facts label to determine if they will purchase the product.27 Yet the Nutrition Facts label does not provide clear information regarding the presence of artificial and other alternative sweeteners. Plainly, clearer ingredient labeling is necessary to avoid deception.

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24 May 2020 consumer research findings (see footnote 14).
25 Ibid.
26 Ibid.
27 FONA International (2021), page 6.
2. Consumers are being misled by sugar content claims.

In its original filing, the Petitioner asserted that “most consumers have little idea that when they purchase a product with a no/low/reduced sugar claim, they are often simply buying a product that contains alternative sweeteners.” Based on current labeling practices, 54% of respondents would not expect to find sugar substitutes in products containing them. A 2022 study assessing the most prevalent macronutrient front of package claims on fruit-flavored beverages purchased by U.S. households with children aged 0 to 5 years found that sugar absent claims (e.g., “no added sugars”) appeared the most frequently, on 31% of fruit drinks, 39% of 100% fruit juice, and 48% of flavored waters. While only 3% of these beverages disclosed the presence of non-caloric sweeteners on the front of package, non-caloric sweeteners were present in nearly half of all fruit drinks (47%) and in the majority of flavored waters (80%).

A December 2021 study found that overall, products containing claims related to sugar content were rated as healthier and less caloric than their regular alternatives, supporting data presented in the original petition. As the study states, “food packaging usually includes multiple cues, including claims about nutrients that may modulate how the consumer perceives (and behaves towards) the product.” Sugar reduction claims such as “no sugar” or “low/reduced sugar” can mislead consumers to believe that the product is better for them.

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29 May 2020 consumer research findings (see footnote 14).


32 See Prada et al. (2021).
Such claims have a significant impact on purchasing decisions. According to research conducted by Innova Market Insights, 91% of consumers are influenced by sugar reduction claims. In the United States, 82% of shoppers report actively looking for at least one front of package claim. And “low sugar” is the top product claim shoppers seek out when purchasing food products, with 34% of consumers reporting that they look for it on packages.

Notably, the impact of the “no added sugar” claim has a similar impact on consumer behavior to claims that refer to the absence of sugar (i.e., “0% sugar,” “sugar-free”). For example, 74% of consumers stated that the “no sugar added” claim is important.

The original petition provided numerous misleading product examples that still exist in the marketplace, such as these:

- **Quaker Instant Oatmeal Apples & Cinnamon** claims “Lower Sugar” on the principal display panel but is sweetened with monk fruit extract.
- **Welch’s Fruit Snacks** claim “Reduced Sugar” on the principal display panel but are sweetened with chicory root fiber and maltitol syrup.
- **Del Monte Diced Peaches** claim “No Sugar Added” and “No Artificial Sweeteners” on the principal display panel but are sweetened with stevia leaf extract.

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33 FONA (2021), page 5.
35 Ibid.
36 FONA (2021), page 6.
37 See Appendix V, Image 4.
3. **The expected proliferation of alternative sweeteners is concerning.**

As noted in the original petition, more than 70% of consumers say it is a priority to avoid artificial sweeteners in products like yogurt, peanut butter, bread, and canned fruit.\(^{40}\) However, sweeteners are even more ubiquitous now—found in places consumers would not expect them, like in children’s products.\(^{41}\) Consumers are interested in consuming less sugar, but the reformulations involved in reducing sugar content are causing confusion and concern. Consumer skepticism is well founded.

New data demonstrate that the artificial sweetener market is increasing and further growth is projected.\(^{42}\) The trends in the use of artificial sweeteners and projected revenue for the artificial sweetener market in the United States through 2025, based on data since 2012, demonstrate that revenue has consistently risen over time from nearly $500 million in 2012 to a projected nearly $700 million in 2025.\(^{43}\) The volume of the artificial sweetener market in the United States shows consistent growth each year, starting with 26.21 million kilograms in 2012 and projected to reach 35.42 million kilograms in 2025.\(^{44}\)

Despite consumer concerns over artificial sweeteners, their use is increasing and expected to continue to grow at a consistent rate. Absent action from FDA requiring more transparent sweetener disclosure, this problem will continue unabated.

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\(^{40}\) May 2020 consumer research findings (see footnote 14).

\(^{41}\) Mintel GNPD (see footnote 1).


\(^{43}\) Ibid.

\(^{44}\) Ibid.
C. Special concerns are increasingly being raised about the growing use of alternative sweeteners in foods and beverages consumed by children.

Since the filing of the original petition, new research has emerged that sheds additional light on the subject of children and alternative sweetener consumption, calling for targeted action by FDA. New marketplace data show that since 2016, 217 new products classified by Mintel as “children’s products” containing alternative sweeteners have been introduced in the United States.\(^{45}\) Compared to households without children, households with children buy more beverages and food products that contain non-nutritive sweeteners.\(^{46}\) The growing use of such alternative sweeteners poses particular concerns in the diets of children, for whom the effects of alternative sweeteners are not well established.\(^{47}\)

The lack of transparency in the amount of alternative sweetener(s) used is particularly acute with respect to food products consumed by children. In a new study that assessed the prevalence of front of package claims on fruit-flavored beverages purchased by U.S. households with children aged 0 to 5 years between 2012 to 2017, non-caloric sweeteners were present in nearly half of all fruit drinks (47%) and the majority of flavored waters (80%), but only 3% of these beverages disclosed the presence of these non-caloric sweeteners on the front of package. Further, a “no artificial sweeteners” front of package claim was present on 10% of fruit drinks and 6% of flavored waters that contained non-caloric sweeteners.\(^{48}\) According to another study published in April 2021, significant misperceptions about the content of added sugars, non-

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\(^{45}\) Mintel, GNPD (see footnote 1).


\(^{47}\) Shum B, Georgia S. The effects of non-nutritive sweetener consumption in the pediatric populations: what we know, what we don’t, and what we need to learn. *Frontiers in Endocrinology.* 2021;12:272.

\(^{48}\) See Muscius et al. (2022).
nutritive sweeteners, and juice in popular children’s drinks were demonstrated among parents with young children (1–5 years). The majority of parents (53%–58%) could not identify drinks with non-nutritive sweeteners, many (38%–43%) incorrectly believed that unsweetened juices contained added sugars, and a quarter (24%–25%) believed that sweetened flavored waters had no added sugars. These findings led the authors to suggest, “Misperceptions about product ingredients under current labelling practices indicate that updated regulations are necessary, including clear disclosures of sweetener and juice content on package fronts.”

Despite the current lack of transparency and ubiquity of alternative sweeteners in children’s products, 73% of parents think it is important to know the amount of sugar substitutes in their children’s food. Parents of children younger than 18 spent an average of 27.2 minutes per week reading food labels and considering the ingredients in the food and drinks they feed their children, with 87% of the 626 parents polled saying they were concerned about the ingredients in their children’s food.

The long-term health implications of chronic non-nutritive sweetener exposure, starting from infancy through adolescence and into adulthood, are poorly understood. Prospective studies are clearly needed in the pediatric population to understand the physiological mechanisms that lead to obesity and metabolic dysregulation, including their impact on pancreatic, neuronal, and microbiome physiology.

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50 May 2020 consumer research findings (see footnote 14).

51 Whole Foods Market online survey conducted by The Harris Poll (August 2021).

52 See Shum et al. (2021).
Although children’s intake of the common non-nutritive sweeteners appears to be within international recommendations worldwide, it is difficult to capture actual intakes and study exposure of children and adults because the amount of sweeteners added to products do not require disclosure. The children’s age group seems to be particularly vulnerable to exceed acceptable daily intakes. In addition, it should be highlighted that consumption of non-nutritive sweeteners among children is expected to increase, as sugar reduction programs continue to prioritize partial or total substitution of sugar while maintaining sweetness.

In a recent review on sugar reduction for children, the authors concluded:

[F]ood scientists should take into account the best interests of children when engaging in the regulation of products targeted at them, avoiding high content of sugar, as well as the use of any ingredient with potential negative effects on their health and wellbeing. In this sense, emerging evidence stresses the need to avoid the use of non-nutritive sweeteners as part of the efforts to reduce the sugar content of products targeted at children.53

Lessons on the impact on children’s diets from sugar reduction policies can be learned from examining such efforts globally. Internationally, alternative sweeteners have permeated the food supply and their use continues to grow. Since 2016, 33,423 new food and beverage products containing alternative sweeteners, including sugar alcohols, have been introduced across the globe.54 One reason for this increase may be sugar-reduction policies. In a study across four countries, Mexico was found to have the highest proportion of products containing non-nutritive sweeteners, potentially due to regulations imposed in 2011 on foods and beverages allowed to be

54 Mintel GNPD (see footnote 1).
sold in schools and to a sugar-sweetened beverage and junk food tax implemented in 2014.\textsuperscript{55} Due to these recent policy initiatives, the Mexican food and beverage industry likely replaced added sugars ingredients with non-nutritive sweeteners to avoid taxation and to be allowed to sell their products in schools.\textsuperscript{56}

According to a recent study conducted in Chile, 55.5\% of processed products contain at least one alternative sweetener as a consequence of the food industry’s response to the implementation of nutritional warnings highlighting products with high sugar content.\textsuperscript{57} The objective of this study was to evaluate the intake levels of non-nutritive sweeteners in Chilean school children after the enactment of the aforementioned law. A total of 250 Chilean children aged 6–12 years were surveyed. All school children (100\%) reported consumption of food or beverages that contained some type of non-nutritive sweetener in their formulation as a sugar substitute. The non-nutritive sweetener with the highest consumption frequency was sucralose (99.2\%), followed by acesulfame-K (92.8\%), stevia (86.0\%), and aspartame (85.2\%).\textsuperscript{58}

Importantly, the Pan American Health Organization (PAHO) Nutrient Profile Model, which is intended for use as a tool for governments to identify unhealthy products and to implement public policies to discourage their consumption, lists “other sweeteners” as a criterion for consideration to add to the PAHO model identifying processed and ultra-processed foods.\textsuperscript{59} The criteria include sodium, free sugars, other sweeteners (any amount of other sweeteners),

\textsuperscript{56} Ibid.
\textsuperscript{57} Martinez X et al. 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. 2020;12(6):1594.
\textsuperscript{58} Ibid.
saturated fat, and \textit{trans}-fat.\textsuperscript{60} As countries base front of package labeling and other policies on the PAHO Nutrient Profile Model, it is important to note that the PAHO model guides that foods with any amount of other sweeteners should be disclosed and factored into labeling claims.\textsuperscript{61}

“Other sweeteners” are defined by PAHO as “food additives that impart a sweet taste to a food, including artificial non-caloric sweeteners (e.g., aspartame, sucralose, saccharin, and acesulfame potassium); natural non-caloric sweeteners (e.g., stevia); and caloric sweeteners such as polyols (e.g., sorbitol, mannitol, lactitol, and isomalt).”\textsuperscript{62}

\textbf{D. Products with misleading claims named in the original petition are still being offered for sale.}

The Association’s original petition named a dozen brand-named products making misleading labeling claims.\textsuperscript{63} All but one of these examples are still available in the marketplace. A few examples mentioned previously are as follows:

- The reduced-sugar version of Skippy peanut butter has one-third less sugar than its traditional counterpart but has more calories per serving than the regular version. Despite having 1 gram less added sugars, the reformulated product provides 20 more calories per 2-tablespoon serving. The claim on the principal display panel 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.\textsuperscript{64}

\textsuperscript{60} Ibid.
\textsuperscript{61} Ibid.
\textsuperscript{62} Ibid.
\textsuperscript{63} See docket number FDA-2020-P-1-1478-0001.
\textsuperscript{64} See Appendix V, Image 2.
• 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. Parents also may be surprised to learn that sugar alcohols and novel sweeteners are used in both the regular product as well as the less sugar version.65

FDA should take immediate action to stop such misleading claims.

E. Numerous new products are making misleading claims.

New products making sugar reduction claims continue to enter the market. Since the June 2020 filing of the original petition, 2,733 new products with a sugar content claim were introduced in the United States.66 The number of new products launched each year containing alternative sweeteners has increased by 832% since 2000, with 300% growth in the prevalence of alternative sweeteners in the food supply in just the last 5 years.67

Many of these products containing alternative sweeteners that enter the marketplace are accompanied by misleading claims. A few examples follow:

• Pop Secret Kettle Corn claims “no artificial…” but is made with sucralose.68

• Reese’s Miniature Cups claim “zero sugar” and “aspartame free” yet contain maltitol, lactitol, and sucralose. Further, the aspartame-free claim misleadingly implies that the product does not contain other artificial sweeteners.69

65 See Appendix V, Image 3.
66 Mintel GNPD (see footnote 1).
67 Mintel GNPD and Baker-Smith et al. (2019) (see footnote 2).
68 The label was submitted as a consumer complaint to FDA. See citizen comment and see Appendix V, Image 5.
69 See Appendix V, Image 7.
• Ensure Max Protein Café Mocha Nutrition Shake claims 1 gram of sugar yet contains multiple alternative sweeteners, including sucralose and acesulfame potassium.70

• Wegmans “Lower Sugar” Instant Oatmeal is sold in a smaller portion size (34 grams per packet versus 43 grams in the regular version).71 The lower-sugar version is also made with sucralose.

• Capri Sun Roarin’ Waters claims “50% less sugar” and “all natural ingredients” but is sweetened with stevia leaf extract. Additionally, this product is marketed for children.72

• Danone’s Light & Fit yogurt is sweetened with sucralose and acesulfame potassium. This product is available in schools.73

Support for FDA Enforcement and Regulatory Action Is Growing Among Leading Members of Congress, the Public Health Community, Consumer Organizations, and the General Public

A. Congressional leaders call for action.

Since the filing of this petition, senior members of Congress have introduced the Food Labeling Modernization Act of 2021 H.R. 4971/S. 2594 (FLMA). It is noted that sections of the bill would mandate some of the label disclosures requested in the original petition and reiterated in this supplemental petition.

The FLMA has only rather recently been introduced but represents the thinking of a group of senior Democratic members of the House with jurisdiction over the agency, including

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71 It is noteworthy that the product’s ingredient list discloses “*Sweetened with Nutritive and Nonnutritive Sweeteners,” a practice supported by the Petitioner. See the product label (https://shop.wegmans.com/product/150628/wegmans-instant-oatmeal-lower-sugar-maple-brown-sugar).

72 See Appendix V, Image 8.

Representatives Frank Pallone, Chairman of the House Energy and Commerce Committee, and Rosa DeLauro, Chair of the House Appropriations Committee. In the Senate, the bill is cosponsored by senior Senators Richard Blumenthal, Ed Markey, and Sheldon Whitehouse.

Section 2 of the bill, “Additional requirements for front-of-package labeling for foods,” sub-paragraph (d) “Sweeteners,” states that a food that contains any added artificial or natural non-caloric sweetener is misbranded unless the presence of such ingredients is prominently disclosed on the principal display panel.74

Section 13 of the bill, “Sugar alcohols and isolated fibers,” states that a food which contains allulose, polydextrose, sugar alcohols, or isolated fibers is misbranded unless the presence of such ingredients is prominently disclosed on the principal display panel. Section 13 also states that such disclosures must include a warning if the amount of such ingredients per serving exceed levels (established by the FDA by regulation) above which the agency considers to cause deleterious health effects.75

The chief sponsor of the legislation, Representative Frank Pallone, stated that “American consumers have a right to know what’s in the food they and their families eat, but that isn’t

74 The exact wording of the bill is as follows:
“Section 403 of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (c), is further amended by adding at the end the following:

(ff) Sweeteners – If in the case of food other than a dietary supplement, it bears or contains any added artificial or natural non-caloric sweetener, unless such fact is prominently stated on the principal display panel of the packaging of the food.”

75 The exact wording of the bill is as follows:
“(hh) If it is a food intended for human consumption that is offered for sale and contains allulose, polydextrose, sugar alcohols, or isolated fibers, unless such fact is prominently stated on the principal display panel of the packaging of the food. The Secretary shall by regulation establish quantities above which such labeling shall include a warning that the food contains a level of allulose, polydextrose, sugar alcohols, or isolated fibers per serving determined by the Secretary to cause deleterious health effects.”
always easy with today’s opaque food labels and marketing claims… The FLMA will give food labeling requirements an important and long-overdue overhaul.”

Representative Rosa De Lauro stated, “Food labels should give a clear, accurate, and fair representation of the product, and that is just not the case right now.” The other sponsors of the legislation echoed similar support for the transparency required by the legislation.

B. Consumer advocacy organizations voice support for Petitioner’s requests.

Since the Petitioner’s initial filing, consumer advocacy organizations have also voiced support for some of the actions requested in the petition. The Center for Science in the Public Interest (CSPI) issued a comprehensive fact sheet entitled “Trends in Low Calorie Sweetener Consumption in the United States.” The fact sheet surveys the literature on low- and no-calorie sweeteners, citing concerns voiced here and in Petitioner’s original filing. The CSPI fact sheet includes several policy recommendations:

- FDA should require all LCS to be affirmatively disclosed in the list of ingredients on the food label, and not permit LCS to be included under the terms “natural flavors” or “artificial flavors.”

...
FDA should require disclosure of information on the label that overconsumption of certain sweeteners (sugar alcohols, allulose) may cause gastrointestinal distress. This is especially pressing in light of current trends showing an increase in the use of allulose, and the widespread use of chemically related sugar alcohols. In the interim, food and beverage manufacturers should voluntarily disclose this information.  

CSPI also supports provisions of the FLMA that require more transparent disclosure of low- and no-calorie sweeteners. While noting that its support for some of the disclosures required in the FLMA is tied to its support for other portions of the bill not supported by the Petitioner, CSPI stated: “Food labels can play an important role in promoting healthy eating and preventing chronic diseases. Yet today’s food labels do not provide the simple, straightforward information that consumers need to evaluate products and make healthy choices.”

CSPI has especially cautioned against policies that would encourage the use of artificial sweeteners in foods directed to children. In its School Meals Corporate Report Card, CSPI

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80 The CSPI Fact Sheet also calls for the following actions:

“Congress should ensure that FDA has the authority to collect data on the production and use of LCS and other food additives. Meanwhile, food and beverage manufacturers should voluntarily disclose the amounts of different LCS used in their products in a public database.

Congress should fund a National Academies of Sciences, Engineering, and Medicine (NASEM) study that examines key changes in exposure to specific LCS among children and adults, reviews the scientific evidence regarding LCS safety for children, and develops recommendations to protect children and other consumers.

FDA should conduct an exposure assessment on LCS for the U.S. population, for children in different age groups, and for pregnant women.

Food and beverage manufacturers as well as consumers should especially avoid the use of aspartame because of compelling evidence that it causes cancer, and should favor safer LCS such as erythritol, stevia leaf extract, and advantame...”

See footnote 79.

proposes that the U.S. Department of Agriculture (USDA) establish an added sugars standard for the school meal program but states concerns that if USDA were to establish limits on an added sugars standard, food manufacturers would substitute “harmful” artificial sweeteners. The report thus proposes that USDA also establish a standard that school meals must contain “no harmful artificial sweeteners,” which, according to the consumer group, includes aspartame, acesulfame-K, saccharin, and sucralose.82

CSPI, together with the American Heart Association and the American Public Health Association, filed a petition to USDA asking the agency to disallow aspartame, saccharin, acesulfame-k, and sucralose from school foods, again citing concern that “if FNS [USDA Food and Nutrition Service] were to establish an added sugars standard, food manufacturers would substitute low-calorie sweeteners (LCS) for added sugars.” Adding credence to CSPI’s concern, Chile saw an increase in intake of non-nutritive sweeteners in preschoolers after the first phase of a national policy that promoted sugar reformulation.83

In a letter to FDA, the National Consumers League (NCL), the nation’s oldest consumer advocacy group stated, “We urge the FDA to prohibit misleading labeling of alternative sweeteners in processed foods and beverages and to grant the citizens’ petition for greater transparency in food labeling when it comes to these artificial sweeteners.”84

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83 Rebolledo N et al. Changes in nonnutritive sweetener intake in a cohort of preschoolers after the implementation of Chile’s Law of Food Labelling and Advertising. Pediatric Obesity. 2022;e12895 [Epub ahead of print 27 January 2022].

NCL also stated that one of its top 10 priorities for 2021 was “supporting a Citizen’s Petition to FDA to ensure transparent labeling of novel sweeteners.” NCL says it has “joined with other consumer groups in urging FDA to stop misleading claims, such as ‘no added sugars,’ ‘zero sugar,’ and ‘reduced sugars,’ that imply a new product is healthier than the original without disclosing that the sugar reduction resulted from reformulation with artificial substances and sugar alcohols.”

The Environmental Working Group summarized the problem as follows: “Parents often don’t know they’re consuming these sweeteners or giving them to their kids. Consumers who read labels may see an artificial sweetener listed as an ingredient, but because information about quantities isn’t required on the label, they can’t know how much of it a food product contains.”

C. Public health experts support greater transparency on food labels.

Similar support has been voiced by the public health community. For example, Dr. Elizabeth Dunford, a researcher at the University of North Carolina Gillings School of Global Public Health and co-author of a study in the *Journal of the Academy of Nutrition and Dietetics*, stated: “There is a need to be able to track our exposure to specific types of sweeteners in order to properly understand their health implications . . . The change to the food supply shown in our study documents and reinforces the need to develop and maintain data systems to monitor what companies are putting in their foods.”

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87 Elizabeth Dunford, PhD, postdoctoral fellow in nutrition with the Gillings School and the Carolina Population Center. Also see Dunford et al. (2020).
Dr. Shu Wen Ng, Distinguished Scholar in Public Health Nutrition at the Gillings School, said, “Further improvements to the Nutrition Facts label, including the amounts of non-nutritive sweeteners present in products, would allow for monitoring our exposure to these additives so we can better assess their potential harms or benefits to health.” \(^8^8\)

**D. Consumer support for original petition.**

The positions of consumer organizations and public health experts are reflected by comments submitted to FDA by the general public. At the time of filing this supplement, 208 public comments have been received on the Petitioner’s original submission, and all but three have been supportive of FDA taking the action requested. \(^8^9\) Additionally, 15,445 consumers and counting have signed their names to a petition in support of sweetener transparency and an end to misleading sugar claims. \(^9^0\)

The docket for the Petitioner’s original filing contains comments such as these:

- **Comment from Joyce Turley:** The latest product, *Pop Secret Kettle Corn*, presents its ‘Classic Sweet and Salty Recipe’ with a prominent ‘No Artificial’ banner. Why would I ever think this *product contains Sucralose*. This has happened to me with oatmeal, cold cereal, other microwave popcorn (with monk fruit, an equally awful taste), rice crisp snacks, applesauce, canned fruit, the list goes on and on. And I am a careful shopper! ‘No Sugar Added’ is the only warning I get, but it is easy to overlook and always misunderstood.

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\(^8^8\) Shu Wen Ng, PhD, Distinguished Scholar in Public Health Nutrition at the Gillings School.

\(^8^9\) See https://www.regulations.gov/document/FDA-2020-P-1478-0001/comment.

• **Comment from Destiny Moody:** I am registered dietitian and board-certified specialist in sports nutrition who works with college athletes and NBA athletes. With it being my personal responsibility to procure food products for my athletes, I have to express my personal input on the need to more clearly label nutritive sweeteners, especially with them becoming more and more ubiquitous in products geared toward athletes. I feel the depth of my concern specifically as it pertains to sugar alcohols can be more succinctly expressed through the Amazon reviews on sugar free gummi bears.

The general public and athletes alike are tempted by anything labeled “sugar free” as it is more common now than ever before for people to avoid sugar either due to media messaging about its harmful effects on health or simply efforts to drop weight. Either way, people are tempted to consume these products, usually in excess, to a degree that causes GI discomfort or other side effects simply because they are not aware of what is actually sweetening what they are eating. As a sports RD, this is deeply concerning to me because I have all too often had athletes come to be devastated about their performance on the field, court or pool because they experienced painful and embarrassing GI symptoms due to consuming a sports product high in sugar alcohols. Furthermore, it’s hardly productive for me as an RD to educate athletes on the side effects of sugar alcohols if they are not aware that foods or drinks they are consuming even contain them due to lack of labeling.
Statement of Legal Grounds

A. Labels omit material facts and make affirmatively misleading claims and hence are misbranded.

Section 403(a)(1) of the Federal Food, Drug, and Cosmetic 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 make intelligent choices, and, to that end, misbranding was one of the chief misdeeds Congress sought to stop in

_U.S. v. Watkins_, 278 F.3d 961 (9th Cir. 2002).

Section 201(n) of the Federal Food, Drug, and Cosmetic Act further provides the following:

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.91

The food labels discussed in this petition fail to reveal material facts, and/or make affirmatively misleading claims, and are hence misbranded. A full statement of legal grounds is supplied in the Petitioner’s original filing.92

B. The agency should take interim action and then proceed by rulemaking.

The Petitioner’s original filing requested that FDA take the action requested and require the specified disclosures under its authority to issue statements of enforcement discretion and

91 21 USCA §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.)

guidance documents. The Petitioner continues to support such steps as an initial response to the current marketplace chaos.

Considering the growing severity of the problem, the Petitioner now urges the agency to follow up such interim actions with the promulgation of regulations. FDA has authority to issue such regulations, under Section 701 of the Food, Drug, and Cosmetic Act, 21 U.S.C. §371. That section of the Act provides the agency with authority to issue regulations for “efficient enforcement” of the section of the Act that prevents misbranding. See 403(a) of the Act, 21 U.S.C. §343. Given the pervasiveness of the problem, it is now clear the promulgation of regulations is necessary to bring order to the marketplace and protect consumers from misbranding.

**Conclusion**

As demonstrated here, the problems identified in the original 2020 petition have grown. Consumers are increasingly being deprived of essential information about the use of alternative sweeteners, which they need to make informed dietary decisions and protect their health. The deception created by the lack of transparent alternative sweetener labeling is exacerbated by misleading claims about added sugars content. This trend is fueled by increasing pressure on food and beverage companies to reduce added sugars content, creating unintended consequences.

There is a growing consensus that FDA should take the regulatory and enforcement actions requested here. Public health experts, consumer groups, leading members of Congress, and members of the general public all agree: The agency should act.

The Petitioner respectfully submits that it is incumbent upon FDA to fulfill its statutory mandate to prevent misbranding and to assist consumers in maintaining healthy dietary practices by taking the actions requested in the original petition and this supplementary filing.
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.

Economic Impact

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

Certification

The undersigned party certifies that, to the best of their knowledge and belief, 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,

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Appendix I. Glossary of Terms

**Alternative Sweeteners:** Substances used as substitutes for sucrose and other mono- and disaccharides in food and beverage products to provide sweetness. Alternative sweeteners provide less than 4 calories per gram and include all low and non-calorie sweeteners, including high-intensity sweeteners, artificial sweeteners, and sweeteners used for bulking purposes such as sugar alcohols.

**Low- and No-Calorie Sweeteners (LNCS):** Substances of low or no energy value that provide sweet taste but do not contain the calories of carbohydrates or their glycemic effects. Based on their sweetness level compared to sucrose, LNCS are divided into two classes: high-intensity and bulk sweeteners.

**High-Intensity Sweeteners:** Also known as non-nutritive or artificial sweeteners. Substances that are several hundreds to thousands of times sweeter than sucrose and added to food and beverage products to provide sweetness.

**Bulk Sweeteners:** Also known as sugar alcohols or polyols. Substances of lower energy value than sucrose that in addition to providing sweetness contribute to the bulk, texture, and viscosity of foods.
Appendix II. Proposed Product Disclaimer and Ingredient List

**Ingredients:** Enriched Bleached Flour (Wheat Flour, Niacin, Iron, Thiamin Mononitrate, Riboflavin, Folic Acid), Maltitol, Leavening (Baking Soda, Calcium Phosphate, Sodium Aluminum Phosphate), Contains 2% Or Less of: Canola Oil, Salt, Cellulose, Propylene Glycol Esters of Fatty Acids, Artificial Flavor, Monoglycerides, Xanthan Gum, Cellulose Gum, Sodium Stearoyl-2-Lactylate, Acesulfame Potassium (Sweetener), Sucralose (Sweetener), Red 40, Yellow 5.

**Product Disclaimers**
Excess Consumption May Cause Laxative Effect (Due To Maltitol)

The Petitioner asks that the following changes be made: (1) add product disclaimer for all sugar alcohols (as depicted on the left) at a minimal threshold of adverse effect and (2) add “Sweetener” behind alternative sweeteners in the ingredient list (as depicted and highlighted on the right).
Appendix III. Proposed Front of Pack Sweetener Disclosure

Add the disclosure “Sweetened with (name of Sweetener)” on products that feature a No/Reduced Sugars claim to identify the alternative sweeteners used in place of sugar.

Add “Sweetened with (name of Sweetener)” on the front of package where sugar claims are made so that it is clear to consumers that alternative sweeteners are used in place of sugar.
Appendix IV. Proposed Labeling for Principal Display Panel—Children’s Products

For children’s products, it should be clear from the front of package that sweeteners were used in place of sugar when sugar claims are made.
Appendix V. Marketplace Examples

Image 1

Skippy’s “No Sugar Added” peanut butter has 210 calories per 2 tablespoons, while the regular version of Skippy peanut butter has just 190 calories.
Skippy’s “1/3 Less Sodium & Sugar” has one-third less sugar than its traditional counterpart but more calories per serving than the regular version. Despite having 1 gram less added sugars, the reformulated product provides 20 more calories per 2-tablespoon serving.
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 “less sugar” product has the same number of calories (100) per serving as the regular version. Parents also may be surprised to learn that sugar alcohols and novel sweeteners are used in both the regular product as well as the less sugar version.
Quaker Instant Oatmeal Apples & Cinnamon claims “Lower Sugar” on the principal display panel but is sweetened with monk fruit extract. Additionally, the “35% Less Sugar” claim was achieved by decreasing the serving size and adding a sugar substitute.
Pop Secret Kettle Corn claims “No Artificial” but is made with sucralose.
Snack Pack chocolate pudding claims “Sugar Free” yet there are four sweeteners in the product.
Reese’s Miniature Cups claim “Zero Sugar” and “Aspartame Free” yet contain maltitol, lactitol, and sucralose. Further, the aspartame-free claim misleadingly implies that the product does not contain other artificial sweeteners.
Capri Sun Roarin’ Waters advertises “50% less sugar” on the front of package, yet an alternative sweetener was used in the product.