

August 15, 2005

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Dockets Management Branch  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061 (HFA-305)  
Rockville, MD 20852

Re: Citizen Petition re Nutrition Labeling re Sugar and Other Sweeteners

Dear Sir or Madam:

The Sugar Association submits this petition pursuant to 21 C.F.R. § 10.35.

**A. ACTION REQUESTED**

The Sugar Association (the Association) requests the Commissioner of Food and Drugs to amend its regulations related to sugar and alternative sweeteners as follows:

1. Disallow relative nutrient content claims for sugars.
2. Should the agency find a need to permit claims that distinguish between the calories from sugars and calories from other nutrients, the agency should require that the claims effectively communicate caloric content in the same context and with the same emphasis (e.g., "50% less sugars/syrups<sup>1</sup> and \_\_\_% fewer [or more] calories").
3. Disallow any use of the term "sugar" to refer to any caloric sweetener other than the sweetener defined by FDA as sucrose from sugar cane or sugar beets.
4. Eliminate "sugars" as a mandatory category in the nutrition facts panel (NFP).
5. Should the agency not eliminate the "sugars" category from the NFP, the agency should provide appropriate and nonmisleading information in the NFP on all sweeteners, as follows:
  - Rename the "sugars" category "sugars/syrups."
  - Require the mandatory labeling of polyol sweeteners as a category in the NFP as well as the mandatory labeling of each specific polyol ingredient and its corresponding amount. Require also the mandatory identification each polyol ingredient on the principal display panel (PDP).

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<sup>1</sup> As noted in Part 5, *infra*, the agency should rename the "sugars" category "sugars/syrups."

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- Require the mandatory labeling of artificial sweeteners as a category in the NFP as well as the mandatory labeling of each specific artificial sweetener ingredient and its corresponding amount. Require also the mandatory identification of each artificial sweetener ingredient in the PDP.

## ***B. STATEMENT OF GROUNDS***

FDA's current food labeling regulations have led to consumer confusion about the identities of the sweeteners in their foods and beverages and the calories contributed by these ingredients. Information on caloric content is very important to consumers and is generally well understood. Under the current regulations, however, information on sweeteners is presented in a manner that not only misleads consumers but more importantly undermines important information on caloric content. Specifically, food labeling information related to sugar (sucrose), sugars, and other sweeteners is misleading in two key respects – impact on caloric content and identity of specific sweeteners.

### ***Impact on Caloric Content.***

FDA regulations permit nutrient content claims related to reductions in a specific subcategory of carbohydrates denominated as “sugars” without qualifying information related to the effect on caloric content. Consumers perceive products labeled as having “less sugar” to have health benefits, especially for weight loss or control. In fact, the sugars in these “less sugar” products are often replaced with other caloric ingredients, including dextrins, polyol sweeteners, and/or fats. The net result is that consumers are misled about the significance of caloric content and, indeed, about the actual change in caloric content. They are led to believe that they need not worry about overconsumption of foods bearing “less sugar” and “sugar free” labeling which may, in fact, contain more calories (and more fat) than the reference product.

### ***Identity of Specific Sweeteners.***

FDA regulations permit the use of the term “sugar” in nutrient content claims to refer to any sweetener that falls within the subcategory of “sugars.” Consumers perceive of products labeled as having “less sugar” to contain the specific ingredient sugar, defined by FDA and commonly understood to mean sucrose. Moreover, these types of claims are commonly made for products that contain no sugar whatsoever in either the reference product or the modified product, being actually sweetened with other ingredients. These “less sugar” claims on the PDP obfuscate the expanding use of processed sweeteners that are not natural sugar.

Moreover, while requiring mandatory information on “sugars,” FDA regulations fail to require mandatory information on alternative sweeteners that are commonly substituted for sugars. Scientists are exploring the metabolic differences between sweetening ingredients, which present potential health concerns. Over the past twenty-years there has been an extraordinary proliferation of ingredients designed to replace the

natural ingredient sugar.<sup>2</sup> The NFP, however, by emphasizing “sugars”, suggests that none of today’s alternative formulated sweeteners are present in the product. Polyol sweetener (currently referred to in FDA regulations as “sugar alcohol”) content does not have to be provided in the NFP in the absence of a health claim, and artificial sweeteners are excluded entirely. This leaves consumers misinformed about important modifications to the foods they consume where syrups, polyol sweeteners and artificial sweeteners are being substituted for sugar. Consumers are left unaware that these formulated ingredients are being used in the place of a natural sweetener.

## 1. FDA Should Disallow Relative Nutrient Content Claims for Sugars

FDA’s current regulations governing nutrient content claims for the class of sweeteners denominated as “sugars” authorize relative claims such as “less sugar” to indicate that the sugars content has been reduced from the original product. These claims serve no health-related purpose and are misleading to consumers because they suggest health significance related to the sugars content *per se* and because they often mask more significant information related to caloric content and/or fat content. Because the regulations purport to authorize misleading claims in labeling, they are unlawful and must be modified to disallow these claims.

### (a) Relative Nutrient Content Claims Related to Sugars Content Are Misleading

#### (i) *There Is No Demonstrated Health Significance to Sugars Content Other than Association with Caries.*

Although there is a clear scientific consensus on the health significance of reducing the fat content of diets, there is no such consensus on the health significance of sugars, other than with regard to dental caries. While claims related to the total absence of sugars may communicate useful information regarding the potential for reducing the incidence of caries,<sup>3</sup> relative claims, such as “reduced sugar,” “reduced in sugar,” “sugar reduced,” “less sugar,” “lower sugar” and “lower in sugar,”<sup>4</sup> provide no useful

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<sup>2</sup> These include the following:

- **Polyols (Sugar Alcohol):** Sorbitol, Mannitol, Xylitol, Erythritol, D-Tagatose, Isomalt (Palatinat), Lactitol, Maltitol, HSH (Hydrogenated Starch Hydrolysates), and Maltitol Syrups.
- **Artificial Sweeteners:** Saccharin, Aspartame, Acesulfame-K, Sucralose, Neotame, Stevia (not approved), Alitame (not approved), Cyclamates (not approved), Neohesperidine (not approved), and Thaumatin (not approved).
- **Caloric Sweeteners:** Dextrose, Glucose Syrup, Crystalline Fructose, High Fructose Corn Syrup, Honey, Sugar, Maltodextrin, Trehalose, and Isomaltulose.

<sup>3</sup> The Sugar Association proposes that the currently required terminology for these claims (e.g., “sugar free” and “sugarless,” see 21 C.F.R. § 101.60(c)(1) (2004), is misleading because it suggests sugar is the single ingredient that may cause caries whereas caries is associated with the broader class of carbohydrates. See Part B.3, *infra*.

<sup>4</sup> 21 C.F.R. § 101.60(c)(5) (2005).

information with regard to significant health issues. Concerns regarding a possible association between sugars consumption and diseases such as obesity and diabetes, have been shown to be unfounded.<sup>5</sup>

### *Causation of Disease*

Sugars have been a part of the human diet for over 2,000 years, and their potential impact on health has been intensely studied for the past century. The major, comprehensive reviews of the scientific literature all conclude that, with the exception of dental caries, no direct link can be established between the intake of sugars and lifestyle diseases.

- In 1986, the FDA Sugars Task Force, following review of over 1000 scientific papers and reported that, “[o]ther than the contribution to dental caries, there is no conclusive evidence that demonstrates a hazard to the general public when sugars are consumed at the levels that are now current and in the manner now practiced.”<sup>6</sup>
- The 1989 National Academy of Sciences Report on Diet and Health stated: “Sugar consumption (by those with an adequate diet) has not been established as a risk factor for any chronic disease other than dental caries in humans.”<sup>7</sup>

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<sup>5</sup> Although there have been questions raised regarding the possibility that sugars may displace certain nutrients in the diets of certain American subpopulations, *see, e.g.*, Food & Nutrition Bd., Nat’l Acad. of Sciences, *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients) 6-42* (2002) [hereinafter *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients)*] (Tab 1), a unilateral relationship is not established and the interrelated nature of macronutrient and micronutrient consumption is complex. Today’s foods are so commonly fortified with micronutrients that questions of the balance between health benefits and concerns over potential toxicity are becoming more widespread. Cutberto Garza, *Moving Beyond the RDAs to Dietary Reference Intakes (DRIs)* (2002), available at <http://www.cce.cornell.edu/food/expfiles/topics/garza/garzaoverview.html> (Tab 2). Data from the *USDA Nutrient Content of the US Food Supply, 1909-2000* show that daily per capita levels of important vitamins and minerals have increased in the U.S. food supply during this period. Ctr. for Nutrition Policy and Promotion, USDA, Home Econ. Research Report No. 56, *Nutrient Content of the U.S. Food Supply, 1909-2000: A Summary Report 68-69* (2004) [hereinafter Ctr. for Nutrition Policy and Promotion, USDA, Home Econ. Research Report No. 56], available at [www.cnpp.usda.gov/Pubs/Food%20Supply/FoodSupply2003Rpt/FoodSupply1909-2000.pdf](http://www.cnpp.usda.gov/Pubs/Food%20Supply/FoodSupply2003Rpt/FoodSupply1909-2000.pdf) (Tab 3). It has also been established that calories from food components other than sugars are more clearly associated with micronutrient intakes. Richard A. Forshee & Maureen L. Story, *Controversy and Statistical Issues in the Use of Nutrient Densities in Assessing Diet Quality*, 134 *J. Nutrition* 2733 (2004) (Tab 4). To the extent there is a health policy concern over intake of micronutrients, it should not be addressed through labeling of sugars content. Clearly it would be irrational to institute a policy designed to encourage greater consumption of certain micronutrients for certain subpopulations by misleading consumers into thinking that they are making a healthy choice when they buy “less sugar” products that may have more calories and more fat than the original products. Such an approach would turn rational health policy on its head.

<sup>6</sup> Walter H. Glinsmann, et al., *Evaluation of Health Aspects of Sugars Contained In Carbohydrate Sweeteners*, 116 *J. Nutrition* S1, S15 (Supp. 11 1986) (Tab 5).

<sup>7</sup> Comm. on Diet and Health, Nat’l Research Council, *Diet and Health: Implications of Reducing Chronic Disease Risk 1-11* (1989) (Tab 6).

- In 1997, a joint FAO/WHO report concurred that “there is no evidence of direct involvement of sucrose, other sugars and starch in the etiology of lifestyle diseases.”<sup>8</sup>

During the 2000 Dietary Guidelines debate, it was widely recommended that the National Academy of Sciences (NAS) conduct an independent, comprehensive scientific review of the health implications of sugars consumption. The Sugar Association publicly stated its support of this recommendation. Following its three-year review of the scientific literature, and based on 279 scientific references, the NAS panel concluded in 2002:

Based on the data available on dental caries, behavior, cancer, risk of obesity, and risk of hyperlipidemia, there is insufficient evidence to set a UL (upper level) for total or added sugars.<sup>9</sup>

The NAS report also stated unequivocally: “There is *no* clear and consistent association between *increased intakes of added sugars* and BMI.”<sup>10</sup>

### *Management of Diabetes*

While total carbohydrate content of a food is an important consideration for management of diabetes, sugars content is of no particular relevance. The American Diabetes Association provides diabetics with practical, science-based recommendations on carbohydrates (starch and sweeteners) and on the glycemic index.<sup>11</sup> The Diabetes Association recommends as follows:

In persons with type 1 or type 2 diabetes, ingestion of a variety of starches or sucrose, both acutely and for up to 6 weeks, produced no significant differences in glycemic response if the amount of carbohydrate is similar. Therefore, the total amount of carbohydrate in meals and snacks will be more important than the source or type.<sup>12</sup>

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<sup>8</sup> World Health Organization & Food and Agric. Org. of the United Nations, FAO Food and Nutrition Paper 66, Carbohydrates In Human Nutrition: Report of a Joint FAO/WHO Consultation 36 (1998) (Tab 7).

<sup>9</sup> Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients), *supra* note 5, at 6-42.

<sup>10</sup> Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients), *supra* note 5, at 6-37 (emphasis added).

<sup>11</sup> Am. Diabetes Ass’n, *Evidence-Based Nutrition Principles and Recommendations for the Treatment and Prevention of Diabetes and Related Complications*, 25 Diabetes Care S50 (Supp. 1 2002) (Tab 8).

<sup>12</sup> *Id.* at S51.

The Diabetes Association further advises diabetics that sugar (sucrose) can be included in their diets when consumed within their suggested carbohydrate allowance.<sup>13</sup> Monitoring total carbohydrate intake is a more important aspect of the diet of a diabetic than tracking the specific sources of carbohydrates.<sup>14</sup> The Diabetes Association also notes that the use of sugar alcohols (polyol sweeteners) in food items does not offer significant assistance for improving glucose response or energy reduction. While polyol sweeteners produce a lower post-prandial glucose response than sucrose or glucose and have lower available energy values, there is no evidence that the amounts likely to be consumed in a meal or day result in significant reduction in total daily energy intake or improvement of long-term glycemia.<sup>15</sup> Based on the totality of the scientific evidence, the fundamental message of the American Diabetes Association for diabetics is the total carbohydrate content of a food or diet is the most important consideration.

### *The Glycemic Index*

Consistent with the statement that total carbohydrate content is more important than specific source or type of carbohydrate, the Diabetes Association further advises that the glycemic response of a food ingredient is not as important as its total carbohydrate content.<sup>16</sup> Even if glycemic response or glycemic index were to be deemed relevant for diabetics, however, it would not suggest greater concern over sugar or sugars than over other carbohydrates.

As indicated in the International Table of Glycemic Index,<sup>17</sup> potatoes, white bread, wheat bread, and carrots have a higher glycemic index than sugars other than dextrose/glucose. This compilation shows that sugar (sucrose) is not a high glycemic food. It is also important to note that glycemic response can be affected by factors such as accompanying fat and/or protein content.

### *(ii) Nutrient Content Claims Related to Sugars Detract from Important Information Related to Calories*

“Less sugar” claims are not only of no value to consumers; they are *misleading* because they distract consumers from the importance of monitoring total caloric intake.

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<sup>13</sup> Am. Diabetes Ass’n, *The Scoop on Sugar*, available at <http://www.diabetes.org/youthzone/the-scoop-on-sugar.jsp> (last visited June 17, 2005) (Tab 9).

<sup>14</sup> Am. Diabetes Ass’n, *supra* note 11, at S51.

<sup>15</sup> *Id.*

<sup>16</sup> It is also significant to note that both the Institute of Medicine and the 2005 Dietary Guidelines Advisory Committee pronounced that neither the glycemic index nor the glycemic load of foods was a useful measure of diet quality. See USDA, HHS, Nutrition for Your Health: Dietary Guidelines for Americans: 2005 Dietary Guidelines Advisory Comm. Report § 5 (Carbohydrates), available at [http://www.health.gov/dietaryguidelines/dga2005/report/HTML/D5\\_Carbs.htm](http://www.health.gov/dietaryguidelines/dga2005/report/HTML/D5_Carbs.htm) (Tab 10).

<sup>17</sup> Kaye Foster Powell et al., *International Table of Glycemic Index and Glycemic Load Values: 2002*, 76 *A m. J. Clinical Nutrition* 5, 14-15, 95, tbl. 1 (2002), available at <http://www.ajcn.org/cgi/content/full/76/1/5#SEC4> (Tab 11).

FDA and the Departments of Health and Human Services [HHS] and Agriculture (USDA) have acknowledged the importance of total caloric intake in achieving long-term weight loss. Both FDA's "Calories Count: Report of the Working Group on Obesity"<sup>18</sup> and the joint HHS-USDA 2005 report, "Dietary Guidelines for Americans,"<sup>19</sup> emphasize that total caloric consumption is a more significant component of a weight-loss program than the relative proportion of macronutrients such as fats, carbohydrates, and protein.

FDA's "Calories Count" report describes "an action plan to cover critical dimensions of the obesity problem from the FDA's perspective and authorities."<sup>20</sup> The report provides in relevant part as follows:

Although there is much discussion about (1) the appropriate makeup of the diet in terms of relative proportions of macronutrients (fats [lipids], carbohydrates, and protein) that provide calories and (2) the foods that provide these macronutrients, for maintenance of a healthy body weight it is the consumption and expenditure of calories that is most important. In other words, "calories count."<sup>21</sup>

Consistent with this analysis, the report makes no specific recommendations as to dietary proportions of macronutrients.<sup>22</sup>

The report of the 2005 Dietary Guidelines Advisory Committee, promulgated as a source of dietary health information for policymakers, nutrition educators, and health providers, seeks to "encourage most Americans to eat fewer calories, be more active, and

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<sup>18</sup> CFSAN, FDA, Calories Count: Report of the Working Group on Obesity (Mar. 12, 2004) [hereinafter CFSAN, FDA, Calories Count], available at <http://www.cfsan.fda.gov/~dms/owg-toc.html>.

<sup>19</sup> USDA, HHS, Nutrition for Your Health: Dietary Guidelines for Americans: 2005 Dietary Guidelines Advisory Comm. Report, available at <http://www.health.gov/dietaryguidelines/dga2005/report/default.htm>

<sup>20</sup> CFSAN, FDA, Calories Count, *supra* note 18, at Executive Summary.

<sup>21</sup> *Id.*

<sup>22</sup> The Report did include a discussion of the recent interest in low-carbohydrate diets and the common usage of labels regarding the level of carbohydrates in various foods. The report notes that these labels appear to "vary widely" and proposed the following:

In order to ensure that terms are consistently defined and that carbohydrate claims are not false or misleading, the OWG recommends that the FDA file these petitions and publish a proposed rule to provide for nutrient content claims related to the carbohydrate content of foods, including guidance for use of the term "net" in relation to the carbohydrate content of foods.

CFSAN, FDA, Calories Count, *supra* note 18, at § V.A. Although this recommendation concerns macronutrient labeling, its inclusion in the report does not stem from a conclusion that reduced carbohydrate consumption is useful in achieving weight loss. In fact, the report discusses some of the difficulties associated with achieving long-term weight-loss through such a diet. *Id.* at app. B. The recommendation appears to reflect an acknowledgment of popular interest in low-carbohydrate dieting and a need to standardize some of the promotional claims being made as a result of this trend.

make wiser food choices.<sup>23</sup> The Guidelines emphasize: “When it comes to body weight control, it is calories that count—not the proportions of fat, carbohydrates, and protein in the diet.”<sup>24</sup>

Because they emphasize sugars content over caloric content, the current regulations permitting “less sugar” claims on the PDP are at odds with the principles expressed in the “Calories Count” and the 2005 Dietary Guidelines Advisory Committee reports. The current regulations permit “less sugar” claims on the PDP without any accompanying information on the net effect of the sugars modification on caloric content. The only mention of calories is provided in the nutritional facts panel, and that information is limited to total caloric content rather than relative caloric content (except for fat). The clear message from this format is that sugars are to be avoided and that calories are less significant.

Reducing sugars or any other caloric ingredients without a concomitant reduction in total calories provides no health benefit for consumers focused on weight reduction or weight maintenance. This has been amply demonstrated by the marketing of foods based on “low fat” claims for products that do not have corresponding reductions in caloric content because of increased carbohydrate content.<sup>25</sup> Now “less sugar” products are replacing “low fat” products as the current marketing fad. As with the “low fat” marketing stratagem, the new line of “less sugar” products misleads consumers regarding actual caloric intake [suggesting there are necessarily fewer calories] or regarding the importance of total caloric intake [suggesting that total caloric intake is less important than sugars intake].

Of course, when sugars are removed from foods, other ingredients must be added to preserve as much functionality, bulk, and taste as possible. Thus, food manufacturers include bulking sweeteners, such as polyols or maltodextrins, and/or increase fat content to maintain functionality and/or taste. Such practices permit foods bearing “less sugar” labels to have increased fat content and similar, or even increased, caloric content that cannot be discerned readily from the labels of single, stand-alone food products.<sup>26</sup>

As one might expect, consumers are clearly confused. In a recent survey of 437 females aged 25 to 65, forty percent of those surveyed stated that they “believe a product has fewer calories if the food label says ‘sugar free’ or makes a claim that the product contains less sugar.”<sup>27</sup> In consumer research conducted in 2001, 800 respondents were asked whether “no added sugar” meant (1) better for you, (2) better value, (3) less

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<sup>23</sup> USDA, HHS, *supra* note 19, at i, vi.

<sup>24</sup> *Id.* at 15. The report also states that “diets that provide very low or very high amounts of protein, carbohydrates, or fat are likely to provide low amounts of some nutrients and are not advisable for long-term use.” *Id.*

<sup>25</sup> See exhibits attached at Tab 12.

<sup>26</sup> See *id.*

<sup>27</sup> Marriner Mktg. Communications, SAI Sugar Free Omnibus 1, 3 (2005) (Question 1) (Tab 13).

fattening, or (4) fewer calories. Twenty percent responded that “no added sugar” meant less fattening and thirty percent believed it meant a food product had fewer calories.<sup>28</sup>

Academic institutions<sup>29</sup> and the media<sup>30</sup> are now expressing alarm about the misleading nature of nutrient content claims for sugars.

The unavoidable conclusion is that “less sugar” claims not only fail to assist consumers in planning healthful diets, but actually deceive consumers into purchasing products that are not reduced in calories, and are sometimes higher in both calories and fat, than the original products.

### *The Sugar/Fat Seesaw*

Labeling that encourages consumers to consume “less sugar” foods with greater fat content serves only to undermine the public health. Fat intake is consistently linked with numerous serious health problems including obesity, which ironically is the condition consumers are led to believe they can avoid by consuming foods labeled as having “less sugar.”

This can only exacerbate the troubling growth in fat consumption in the United States. The most recent USDA report on the nutrient content of the U.S. food supply, indicates that total daily per capita fat grams escalated from 161 grams in 1999 to 170 grams in 2000, the largest single increase since 1909.<sup>31</sup> Moreover, the USDA also reports that, since 1970, total per capita consumption of added fats and oils has risen 63 percent.<sup>32</sup>

We know that there is an inverse relationship between fat and sugars intake when expressed as percent of energy in both the United States and the European Union.<sup>33</sup>

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<sup>28</sup> Am. Viewpoint, Inc., National Sugar Survey: The Sugar Association Survey tbl. 30-1 (2001) (Tab 14).

<sup>29</sup> A recent issue of the Tufts University “Health & Nutrition Letter” points out that sugar-free cookies have a similar number of grams of carbohydrates and calories as sugar-containing cookies. *Sugar-Free Shortcomings*, Health & Nutrition Letter (Tufts Univ., Medford, MA), June 2003, at 1 (Tab 15).

<sup>30</sup> *Lower-Sugar Foods: Some are Diet Traps*, Consumer Reports, Feb. 2005, at 49; Bonnie S. Benwicj, *Are Reduced-Sugar Cereals Worth It?*, Wash. Post, Feb. 23, 2005, at F1; Bonnie S. Benwicj, *How Big Is Your Cereal Bowl?*, Wash. Post, Feb. 23, 2005, at F2; ABC News, *Experts Question Reduced-Sugar Cereals* (Mar. 22, 2005), available at [http://abclocal.go.com/kabc/health/032205\\_hs\\_reduced\\_sugar\\_cereals.html](http://abclocal.go.com/kabc/health/032205_hs_reduced_sugar_cereals.html) (Tab 16).

<sup>31</sup> Ctr. for Nutrition Policy and Promotion, USDA, Home Econ. Research Report No. 56, *supra* note 5, at 64.

<sup>32</sup> Jean Buzby et al., Econ. Research Serv., USDA, *Will 2005 Be The Year of the Whole Grain?*, Amber Waves, Jun. 2005, at 13, 14 (Tab 17).

<sup>33</sup> Michael Gibney et al., *Consumption of Sugars*, 62 Am. J. Clinical Nutrition 178S (Supp. 1995). This relationship was reflected in a more recent study that examined the impact of low fat interventions in school lunches, where it was noted that “[a]s percent of calories from fat or saturated fat in lunches decreased, that from sugars increased.” Johanna T. Dwyer et al., *Fat-Sugar See-Saw in School Lunches*:

Concerns over the inverse fat-sugar relationship in the diet prompted the 2002 NAS panel to recommend research “to determine whether there is a metabolic effect of sugars in enhancing energy expenditure and/or in suppressing fat intake at a fixed level of energy.”<sup>34</sup>

Federal labeling policies that exacerbate this unhealthy trend by encouraging food manufacturers to market increasing numbers of “less sugar” products that often contain more calories and/or fat are simply irrational. In the final analysis, FDA must address the fact that its current regulations effectively permit food manufacturers to defeat the primary goals of its Calories Count initiative and of the 2005 Dietary Guidelines for Americans advice to consume fewer calories.<sup>35</sup>

**(b) Because the Regulations Authorize Misleading Labeling, They Are Unlawful.**

As described above, the regulations authorizing relative nutrient content claims for sugars permit claims that are misleading because they suggest that sugars content has a significant impact on health and because they mask the significance of total caloric content and/or fat content.

Labeling that is false or misleading in any particular is prohibited under the misbranding provisions of the Food, Drug, and Cosmetic Act (FDCA).<sup>36</sup> A claim of “less sugar” suggests that a product may be useful in weight control because consumers will naturally associate claims of reductions in sugars content with reductions in calories. FDA discussed this association in the preamble to the proposed regulation<sup>37</sup> and, because of the association, required that “sugar free” claims be accompanied by disclaimers that the product is not low calorie or calorie reduced unless the food so qualifies.<sup>38</sup> Although, as suggested by the Association’s consumer research and by common sense, consumers associate claims about relative sugars content with weight control and caloric content, the present regulations governing “less sugar” foods require no accompanying disclaimer where “less sugar” foods are not lower in calories and may in fact be higher in calories and/or fat.

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*Impact of a Low Fat Intervention*, 32 J. Adolescent Health 428 (Supp. 6 2003). See also Rosanne P. Farris, *Nutrient Intake and Food Group Consumption of 10-Year-Olds by Sugar Intake Level: The Bogalusa Heart Study*, 17 J. Am. College Nutrition 579 (1998); James O. Hill & Andrew M. Prentice, *Sugar and Body Weight Regulation*, 62 Am. J. Clinical Nutrition 262S (Supp. 1995) (Tab 18).

<sup>34</sup> Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients), *supra* note 5, at 6-42.

<sup>35</sup> CFSAN, FDA, Calories Count, *supra* note 18; USDA, HHS, *supra* note 19, at vi.

<sup>36</sup> FDCA § 403(a).

<sup>37</sup> Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms, 56 Fed. Reg. 60,421, 60,435 ( Nov. 27, 1991) (proposed rule).

<sup>38</sup> 21 C.F.R. § 101.60(c).

These facts are highly material and are necessary to understand the health significance or, more precisely, the absence of any health significance associated with the reduction in sugars content. Under the FDCA, labeling may be deemed misleading based on the failure to reveal a fact that is material in light of other labeling representations.<sup>39</sup> In determining whether labeling is misleading, the agency must consider not only the impressions made by labeling terminology on sophisticated consumers but also on “the ignorant, the unthinking and the credulous consumer.”<sup>40</sup> Indeed, the agency expressly relied upon these statutory provisions in promulgating the regulation on nutrient content claims.<sup>41</sup>

The presence of information on total caloric content in the nutrition facts panel cannot cure this legal defect. That information provides no comparison to the caloric (or fat) content of the original product. Moreover, as noted above in the nutrient labeling rulemaking, the presence of caloric information in the nutrition facts panel is not adequate to prevent consumers from being misled about caloric content in products based on claims on the PDP that the product is “low sugar.”

The regulation thus purports to authorize labeling that is misleading and that would render the labeled product misbranded. As such, the regulation is contrary to law because the agency cannot authorize, by regulation or otherwise, conduct that is expressly prohibited under the statute. As the United States Court of Appeals for the District of Columbia has held, “a regulation which operates to create a rule out of harmony with the statute, is a mere nullity.”<sup>42</sup>

## **2. Should Nutrient Content Claims Specific to Caloric Sweeteners Be Deemed Necessary, Such Claims Should Emphasize Caloric Content.**

As discussed above, there is no demonstrated health significance to sugars content, as distinct from total caloric content. There is thus no health-related need for a nutrient content claim related to sugars, and such claims should be disallowed because they are misleading and unlawful. If the agency nevertheless determines that nutrient content claims should distinguish caloric sweeteners<sup>43</sup> from other sources of calories, the

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<sup>39</sup> FDCA § 201(n).

<sup>40</sup> *United States v. Manischewitz . . . Diet Thins*, 377 F. Supp. 746, 749 (E.D.N.Y. 1974) (citing *United States v. An Article—Sudden Change*, 409 F.2d 734, 740 (2d Cir. 1969)).

<sup>41</sup> Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2,302, 2,303 (Jan. 6, 1993).

<sup>42</sup> *Social Sec. Admin., Baltimore, MD. v. Fed. Labor Relations Auth.*, 201 F.3d 465, 471 (D.C. Cir. 2000) (citing *Manhattan Gen. Equip. Co. v. Comm’r of Internal Revenue*, 297 U.S. 129, 134 (1936)). See also *Caldera v. J.S. Alberici Constr. Co.*, 153 F.3d 1381, 1383 n.\*\* (Fed. Cir. 1998) (“Statutes trump conflicting regulations”).

<sup>43</sup> As discussed below, the “sugars” category is not rational from a health perspective because it fails to include polyols and other carbohydrates that contribute to caloric content. If caloric sweeteners as a class are deemed relevant, they must include polyols [See Part 5(b), *infra*] and other carbohydrate bulking agents, and must be identified in a manner that is not misleading.

nutrient content claim should always qualify the information on caloric sweeteners by including information on total caloric content. Any such claim must communicate caloric content in the same context and with the same emphasis (e.g., “50% less sugars/syrups and \_\_\_% fewer [or more] calories”). The term “sugars/syrups” should be used rather than the term “sugar” or “sugars” as discussed in Parts 3 and 5 below.

In the absence of this type of equally prominent qualifying information related to caloric content, “less sugar” claims will be misleading because they will mask more important information regarding modifications to total caloric content and/or fat content. FDA has acknowledged that the presence of caloric information in the nutrition facts panel cannot in and of itself counterbalance misleading information regarding caloric content presented in nutrient content claims on the PDP. As discussed above, FDA cannot authorize misleading claims in labeling that will render a product misbranded under the FDCA.

### **3. FDA Should Disallow any Use of the Term “Sugar” to Refer to any Ingredient other than Sucrose.**

#### **(a) The Paradox of the Current Regulations**

The regulations governing nutrient content claims for the class of ingredients denominated as “sugars” authorize food companies to use the term “sugar” when referring to any sweetener in the class. This means that products can be labeled as containing “less sugar” when, in fact, the products contain no sugar and are manufactured with other “sugars” such as corn syrup.<sup>44</sup> The regulations also require use of the term “sugar” in claims that a product contains no sweetener that falls within the “sugars”

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<sup>44</sup> 21 C.F.R. § 101.60(c)(5) provides as follows:

The terms “reduced sugar,” “reduced in sugar,” “sugar reduced,” “less sugar,” “lower sugar,” or “lower in sugar” may be used on the label or in labeling of foods, except meal products as defined in § 101.13(l), main dish products as defined in § 101.13(m), and dietary supplements of vitamins or minerals, provided that:

(i) The food contains at least 25 percent less sugar per reference amount customarily consumed than an appropriate reference food as described in § 101.13(j)(1); and

(ii) As required in § 101.13(j)(2) for relative claims:

(A) The identity of the reference food and the percent (or fraction) that the sugar differs between the two foods are declared in immediate proximity to the most prominent such claim (e.g., “these corn flakes contain 25 percent less sugar than our sugar coated corn flakes”); and

(B) Quantitative information comparing the level of the sugar in the product per labeled serving with that of the reference food that it replaces (e.g., “Sugar content has been lowered from 8g to 6g per serving.”) is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with § 101.2.

Although the wording of the regulation is somewhat ambiguous, the agency made clear in the preamble to the final regulation that a claim of “less sugar” is authorized for any ingredient falling into the category of “sugars.” See 58 Fed. Reg. at 2,350.

category.<sup>45</sup> This terminology is directly contrary to the agency's regulations that define the category of "sugars" to include "all free mono- and disaccharides (such as glucose, fructose, lactose, and sucrose),"<sup>46</sup> and define "sugar" as "sucrose, which is obtained from sugar cane or sugar beets . . . ."<sup>47</sup>

The agency should thus require that nutrient content claims clearly identify the specific ingredient or the class of ingredients that are the subject of the claim. In the case of "less sugar" claims, the regulation might be modified to permit "less sugars/syrups" claims to more correctly identify the class.<sup>48</sup> In the case of "sugar free" claims, the regulation might be modified to permit claims that the product "contains no sugars/syrups."

**(b) Use of the Term "Sugar" to Refer to other Sweeteners Is Misleading.**

Consumers generally understand the term "sugar" to refer to sucrose products, such as table sugar. FDA acknowledged this fact when it proposed the current statement made by the agency in the same rulemaking:

[T]he agency believes that sucrose is the only sweetener that has traditionally been referred to as 'sugar' by industry and consumers . . . .<sup>49</sup>

A statement in labeling that a product has less of a particular ingredient indicates that both the reference product and the modified product actually contain the particular ingredient. Where a product contains no sucrose, it by definition cannot have less sugar. Thus the "less sugar" claim is literally false if the term "sugar" is to be given its common and usual meaning. It is also literally false if "sugar" is to be given the meaning assigned in FDA's regulation, where it is defined as "sucrose, which is obtained from sugar cane or sugar beets . . . ."<sup>50</sup>

There is no question that consumers are being misled. In a recent National Quorum Survey of 1000 adult Americans age 18 and older, participants were asked whether "a product that promotes on its package that it contains '50% less sugar' when it contains no sugar but is actually sweetened with HFCS is misleading."<sup>51</sup> Eighty-six percent of the respondents indicated they found the '50% less sugar' labeling to be misleading.<sup>52</sup>

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<sup>45</sup> 21 C.F.R. § 101.60(c)(1)-(2).

<sup>46</sup> *Id.* § 101.9(c)(6)(ii).

<sup>47</sup> *Id.* § 101.4(b)(20).

<sup>48</sup> As discussed in Part 5, *infra*, the category for "sugars" should be renamed "sugars/syrups."

<sup>49</sup> Food Labeling; Declaration of Ingredients, 58 Fed. Reg. 2,850, 2,857 (Jan. 6, 1993).

<sup>50</sup> 21 C.F.R. § 101.4(b)(20).

<sup>51</sup> Wirthlin Worldwide, Quorum 2004, at 2, tbl. 2 (Apr. 2-5, 2004) (Tab 19).

<sup>52</sup> *Id.*

A similar question was asked in a 2004 telephone poll of 1024 participants conducted by the Gallup Organization: “If a soft drink is sweetened using high fructose corns syrup and an artificial sweetener but says on the front of the can 50 percent Less Sugar, do you feel it is okay or not, or doesn’t it matter?”<sup>53</sup> Forty-nine percent of respondents answered that it was “not okay.”<sup>54</sup>

It is clear that under the current nutrient content claim regulations, consumers are led to believe that sugar is the sweetener in foods labeled as having “less sugar.” These sorts of claims further mislead consumers into believing that sugar is ubiquitous in the food supply when, in fact, sugar accounts for less than half of the nutritive sweeteners available for use by the U.S. food and beverage industries.<sup>55</sup> It is important to note that “less sugar” claims are commonly used by major soft drink manufacturers who sweeten their products exclusively with HFCS. This results in consumers being ignorant of the fact that they are consuming HFCS, not sucrose.<sup>56</sup>

**(c) Confusion over the Term “Sugar” Is Detrimental to Consumers.**

**(i) *The Changing Nature of the Sweetener Industry***

Since commercialization of starch hydrolysis in the 1960s, food manufacturers have steadily shifted from sucrose to sweeteners manufactured through this process. These ingredients include the following:

Dextrose  
Glucose Syrup  
Corn Syrup  
Corn Syrup Solids  
Isomaltose  
Maltodextrin  
Maltose  
High Fructose Corn Syrup  
Crystalline Fructose  
Erythritol  
Maltitol

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<sup>53</sup> The Gallup Org., Sugar Association Poll 35 (Aug. 2004) (excerpts provided at Tab 20).

<sup>54</sup> *Id.*

<sup>55</sup> Econ. Research Serv., USDA, Briefing Room, Sugars and Sweeteners: Data Tables 49, 50, 51, 52 (U.S. consumption of caloric sweeteners) [hereinafter ERS, USDA, Sugars and Sweeteners: Data Tables], available at <http://www.ers.usda.gov/briefing/sugar/Data/data.htm> (last visited June 17, 2005) (Tab 21).

<sup>56</sup> In the August 2004 Gallup poll, participants were asked to “name some of the ingredients that can be added to food and beverages to make them sweeter?” Fifty percent of the respondents named sugar, 30% named Splenda, 17% named Sweet ‘N Low, 16% named honey, 15% named Equal, 13% named NutraSweet, and 8% named Aspartame. Fewer than 8% identified HFCS as a sweetener that is added to food and beverages. The Gallup Org., *supra* note 53, at 11.

Mannitol  
Sorbitol  
Hydrogenated Starch Hydrolysate

Today, products derived from starch hydrolysis constitute the majority of sweetening ingredients consumed by Americans.<sup>57</sup> This dramatic change has occurred not only because starch-hydrolysis ingredients are cheaper but also because FDA labeling regulations have permitted food manufacturers to use multiple sweeteners to camouflage the true level of caloric sweeteners (the regulations require that the primary ingredient, rather than the primary ingredient class, be listed first in the ingredient statement).

**(ii) *The Need for Consumers to Distinguish between Sweeteners***

Although, as discussed above, sugars as a class of ingredients have no overarching negative health significance, individual sweetening ingredients appear to differ in their metabolic effects. Sweeteners produced through starch hydrolysis have raised particular health concerns because of the potential to specifically elevate fructose and polyol intakes. The American Dietetic Association has expressed concern that high intakes of fructose and polyol sweeteners may have consequences for gastrointestinal health, and that elevated intakes of fructose may create unintended consequences for blood glucose control and lipid metabolism.<sup>58</sup>

It has long been known that individual sugars differ in the manner in which they are absorbed by the human body, and that some are associated with gastrointestinal problems. The Dietetic Association reports:

Fructose is better absorbed when consumed as sucrose, than in products where the amount of free fructose exceeds the amount of glucose . . . .<sup>59</sup> It should be noted that adults vary in their abilities to absorb fructose, with some also experiencing symptoms of malabsorption with a 20 to 50 g load.<sup>60</sup>

The Dietetic Association cites HFCS as an example of a product in which the amount of free fructose exceeds the amount of glucose. It is significant to note that HFCS has essentially replaced sugar as the sweetener in many beverages, particularly soft drinks.<sup>61</sup>

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<sup>57</sup> ERS, USDA, Sugars and Sweeteners: Data Tables, *supra* note 55, tbl. 50.

<sup>58</sup> *Position of the American Dietetic Association: Use of Nutrition and Nonnutritive Sweeteners*, 104 J. Am. Dietetic Ass'n 255 (2004); see also Sharon S. Elliott et al, *Fructose, Weight Gain, and the Insulin Resistance Syndrome*, 76 A m. J. Clinical Nutrition 911 (2002) (Tab 22).

<sup>59</sup> *Position of the American Dietetic Association*, *supra* note 58, at 259.

<sup>60</sup> *Id.* at 266.

<sup>61</sup> *Id.*

HFCS is one of the many newer sweeteners produced through the starch hydrolysis process.<sup>62</sup> A recent review of the science on the metabolism of starch hydrolysis products reports:

Considerable individual variation was observed in humans and in many cases the absorption of fructose was not complete. On the other hand, it was observed that fructose formed from sucrose cleavage was completely absorbed and that glucose enhanced fructose absorption.

It has been observed that sorbitol and fructose each have inhibitory effects on the absorption of the other.

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As noted above, the abdominal distress noted in humans fed sorbitol appeared to be enhanced by the simultaneous presence of fructose and vice versa.<sup>63</sup>

Experts have expressed concern about the increasing consumption of free (chemically unbonded) fructose from increased intakes of fructose-enriched corn syrups. A 2002 IOM report notes:<sup>64</sup> "Because of the introduction of high fructose corn sweeteners in 1967, the amount of free fructose in the diet of Americans has increased substantially. . . ."<sup>65</sup> The situation has been exacerbated by the expanding use of crystalline fructose (a purer form that is up to 95% fructose),<sup>66</sup> and by the increased use of sorbitol and mannitol, which are oxidized to fructose.<sup>67</sup>

Available data, while limited, generally supports the view that the fructose molecularly bonded in sucrose generates physiologic effects distinct from those established by molecularly free fructose.<sup>68</sup> It is important to distinguish different health

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<sup>62</sup> The category of "sugars" has been expanded beyond its original meaning. This class was intended to include naturally occurring, water-soluble crystalline carbohydrates with glucose, fructose, maltose, galactose, sucrose and lactose being identified as the major constituents. Many of today's sweeteners should not be included under the traditional "sugars" definition because they are man-made formulations developed solely for the purpose of replacing natural sugars. Man-made sweeteners like fructose-enriched syrups and hydrogenated disaccharides (e.g., lactitol and maltitol) do not exist in nature.

<sup>63</sup> William L. Dillis, Jr., *Metabolism, in Starch Hydrolysis Products: Worldwide Technology, Production, and Applications* 395 (Fred W. Schenck, Ronald E. Hebeda eds., 1992) (Tab 23).

<sup>64</sup> Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients), *supra* note 5, at 6-23.

<sup>65</sup> Judith Hallfrisch, *Metabolic Effects of Dietary Fructose*, 4 FASEB J. 2652 (1990) (Tab 24).

<sup>66</sup> L. Mark Hanover & John S. White, *Manufacturing, Composition, and Applications of Fructose*, 58 Am. J. Clinical Nutrition 724S, 727S (Supp. 58 1993) (Tab 25).

<sup>67</sup> *See id.* at 726S & 727S, tbl. 2.

<sup>68</sup> G. Harvey Anderson, et al., *Inverse Association Between the Effect of Carbohydrates on Blood Glucose and Subsequent Short-Term Food Intake in Young Men*, 76 Am. J. Clinical Nutrition 1023, 1029

outcomes associated with different sugars just as we differentiate health outcomes of individual dietary fatty acids. As discussed above, it is inappropriate from a health perspective to continue the practice of assigning dietary sugars into a single generic, nonspecific class.

**(d) The Regulations Are Unlawful.**

**(i) *The Regulations Are Contrary to the Misbranding Provisions of the FDCA***

As discussed above, products are deemed misbranded under the FDCA if their labeling is false or misleading in any particular<sup>69</sup> and in determining whether labeling is misleading, FDA must consider not only the impressions made by labeling terminology on sophisticated consumers but also on “the ignorant, the unthinking and the credulous consumer.”<sup>70</sup> The use in labeling of the term “sugar” to refer to the broader class of “sugars” is clearly misleading to even the most rational consumer.

Moreover, the FDCA expressly requires that terms used in food labeling be given their ordinary and customary meaning if they have one.<sup>71</sup> This statutory command cannot be squared with the agency’s statement in the preamble to the final rule that “the agency believes that sucrose is the only sweetener that has traditionally been referred to as ‘sugar’ by industry and consumers . . . .”<sup>72</sup>

As discussed above, FDA cannot authorize, by regulation or otherwise, labeling or any other conduct that is prohibited under the statute.<sup>73</sup>

**(ii) *The Regulations Are Not Supported by the Rulemaking Record***

In addition to being unlawful because they purport to authorize misleading labeling, the regulations are unlawful because they were not promulgated in accordance with the notice and comment requirements of the Administrative Procedure Act (APA).

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(Supp. 5 2002); Hella Jurgens et al., *Consuming Fructose-sweetened Beverages Increases Body Adiposity in Mice*, 13 *Obesity Research* 1146, 1156 (2005) (Tab 26).

<sup>69</sup> FDCA § 403(a).

<sup>70</sup> *United States v. Manischewitz . . . Diet Thins*, 377 F. Supp. 746, 749 (E.D.N.Y. 1974).

<sup>71</sup> See, e.g., *Brina v. United States*, 179 F. 373-74 (2d Cir. 1910) (use of term “salad oil” [*olio per insalata*] contrary to accepted meaning); *United States v. Seventy-Five Boxes of Alleged Pepper*, 198 F. 934, 936-37 (D.N.J. 1912) (use of term “pure pepper” contrary to accepted meaning in trade and in market).

<sup>72</sup> Food Labeling; Declaration of Ingredients, 58 Fed. Reg. 2,850, 2,857 (Jan. 6, 1993).

<sup>73</sup> See discussion at Part B(b), *supra*.

### *The Originally Proposed Regulations*

In its original proposed rule in 1991, FDA recognized the distinction between “sugar” and the category of “sugars.” The agency noted that “FDA has traditionally held that the term “sugar” in an ingredient list means “sucrose” and does not include other sugars.”<sup>74</sup> The agency thus proposed that those terms not be confused in the context of “sugar free” and “sugarless” claims. The agency stated:

The agency considers it important for nutrient content claims to be consistent with the nutrition label, which serves as a source of specific information for consumers concerning the nutritional value of the food. As stated above, the agency has proposed to require that the nutrition label contain information on the sugars content. FDA is concerned that there would be potential for confusion if the nutrient content claim were to use the term “sugar,” and the nutrition label were to specify information using the term “sugars.” Such a discrepancy could make it more difficult to implement education efforts pertaining to label information.<sup>75</sup>

The agency further discussed the need to distinguish “sugar” from “sugars” in the context of “no sugar added” claims:

Dietary Guidelines stipulate that Americans should ‘consume sugars only in moderation’ and indicate that sugars other than sucrose should be consumed in moderation.

Therefore, given current dietary recommendations, FDA has tentatively concluded that the use of a descriptive term that implies that the product has been made without adding sugars would be more helpful to consumers in implementing such recommendations than would a term that is limited only to sucrose (i.e., ‘sugar’).<sup>76</sup>

Although the preamble to the proposed regulation did not discuss use of the term “sugar” in the context of “less sugar” claims,<sup>77</sup> the proposed regulation provided for claims of “less sugars” rather than “less sugar.”<sup>78</sup>

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<sup>74</sup> Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms, 56 Fed. Reg. 60,421, 60,435 ( Nov. 27, 1991) (proposed rule).

<sup>75</sup> *Id.* at 60,436. The agency further stated:

The need for consistency is supported by the IOM report on nutrition labeling. The report highlights the importance of the content claims on the PDP being supported by the quantitative values listed in the nutrition information panel. Furthermore, ‘sugars free’ is consistent with the terminology used in government dietary recommendations, specifically ‘Nutrition and Your Health, Dietary Guidelines for Americans’ which advise that sugars should be consumed in moderation.

<sup>76</sup> *Id.* at 60,438.

<sup>77</sup> *Id.* at 60,452-53.

### ***The Reversal in the Final Regulation***

Despite the compelling logic of its proposed regulation, the agency reversed itself in its final regulation, allowing use of the term “sugar” for all nutrient content claims, including “less sugar.” In the case of “less sugar” claims, the agency explained its policy reversal as follows:

Only a few comments addressed the term. Some supported defining the claim “less sugars,” while a few others suggested that the term “less sugars” is not useful to consumers, is misleading, and should not be used. However, those objecting did not provide information as to why this was so.

As discussed in comment 80 of this document, the agency has determined that the term “sugars free” may be confusing to consumers and therefore is providing for use of the term “sugar free.” The agency believes that “less sugars” would also be confusing. Therefore, for consistency the agency has determined that “less sugar” is the more appropriate term to describe reductions in the sugars content. Further, *because the comments provided no arguments why the term should be eliminated*, and because the term would provide certain useful information to consumers in comparing the sugars content of one food to another, *the agency is not persuaded that the definition for “less sugar” should be eliminated*. Accordingly, the agency has retained this definition.<sup>79</sup>

Of course, there were no comments on why the term “less sugar” or its definition should be eliminated because the term did not appear in the proposed regulation and FDA never suggested the use of such a term.

Although one comment from the Grocery Manufacturers of America (GMA) did express doubt that consumers would understand or care about the distinction between “sugar” and “sugars,”<sup>80</sup> it provided no evidence in support of this notion. This comment was in contrast to the comments of the American Diabetes Association, which stated that it “strongly support[ed] the proposal defining “sugars free.”<sup>81</sup> The American Dietetic

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<sup>78</sup> See *id.* at 60,473 (proposed 21 C.F.R. § 101.60(c)(4)(ii)).

<sup>79</sup> Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2,302, 2,350 (Jan. 6, 1993) (emphasis added).

<sup>80</sup> Nutrient Claims, Definitions of Terms, General Principles, FDA Docket No. 91N-0384, C1587, at 26. In its discussion of “sugar free” claims, the agency stated that “a couple of comments requested that the term “sugar free” be used instead of the term “sugars free.” 58 Fed. Reg. at 2,325. In addition to the one comment suggesting that the term might confuse consumers, the agency noted that one comment said that the term “sugar free” would be in harmony with the terminology used in Canada and other countries. *Id.*

<sup>81</sup> Nutrient Claims, Definitions of Terms, General Principles, FDA Docket No. 91N-0384, C871.

Association also supported the proposed definition of “sugars free,”<sup>82</sup> and suggested use of the term “sugars free” as an alternative to the term “unsweetened” for nutrient content claims related to dietary supplements, vitamins, and minerals.<sup>83</sup> The Sugar Association also submitted comments in support of the proposed terminology as did General Mills, Inc.

Compounding the confusion, the agency reaffirmed in the preamble to the final regulation that “the agency believes that sucrose is the only sweetener that has traditionally been referred to as ‘sugar’ by industry and consumers . . . .”<sup>84</sup>

### ***The Failure to Provide Adequate Notice and an Opportunity for Comment***

Rulemaking under the APA requires both notice and an opportunity to comment. Indeed, the statutory right to comment depends initially on the notice and is meaningless in the absence of notice that the agency is considering a particular regulatory outcome. In the case of the final regulation on “less sugar” claims,<sup>85</sup> there was no notice that the agency might consider requiring that sweeteners other than sugar (sucrose) be referred to as “sugar.” Although the agency relied on the fact that “the comments provided no arguments why the term [“less sugar”] should be eliminated,”<sup>85</sup> the term “less sugar” had never been proposed for comment in any manner.

The agency also relied on its separate decision to require use of the term “sugar free” rather than “sugars free,” and stated that the term “less sugar” should be required “for consistency.”<sup>86</sup> Again there was no opportunity to comment on this proposition. Had the Association been allowed to comment on the issue, it would have commented that the term “less sugar” carries a greater potential for confusion than does the term “sugar free.” In the case of a “sugar free” product, it is literally true that the product does not contain sugar (sucrose). In the case of a product bearing a “less sugar” claim, there may be no sugar in the product, or in the reference product, even though the claim suggests a residual level of sugar. Indeed, a majority of products on the market that bear “less sugar” claims are products that are sweetened not with sucrose but solely with corn-based syrups, or a combination of corn-based syrups and sucrose.

The courts do not permit an agency to adopt a position in a final regulation that is radically different from the position originally proposed for comment in the absence of notice that the agency is considering both positions. In *Chocolate Manufacturers Ass’n v. Block*,<sup>87</sup> the United States Court of Appeals for the Fourth Circuit overturned a USDA regulation deleting chocolate flavored milk from the list of supplemental foods approved

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<sup>82</sup> *Id.* C1087.

<sup>83</sup> *Id.* C1377.

<sup>84</sup> 58 Fed. Reg. at 2,857.

<sup>85</sup> *Id.* at 2,350.

<sup>86</sup> *Id.*

<sup>87</sup> 755 F.2d 1098 (4th Cir. 1985).

for the WIC program. The proposed rule had specifically authorized flavored milk as part of a permissible diet. The court stated:

An agency . . . does not have carte blanche to establish a rule contrary to its original proposal simply because it receives suggestions to alter it during the comment period. An interested party must have been alerted by the notice to the possibility of the changes eventually adopted from the comments.<sup>88</sup>

Similarly, in *Small Refiner Lead Phase-Down Task Force v. EPA*, the United States Court of Appeals for the D.C. Circuit held:

If the final rule deviates too sharply from the proposal, affected parties will be deprived of notice and an opportunity to respond to the proposal.

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Agency notice must describe the range of alternatives being considered with reasonable specificity. Otherwise, interested parties will not know what to comment on, and notice will not lead to better-informed agency decisionmaking.<sup>89</sup>

It is also important to note that, although one of the comments proposed the change adopted by the agency in the regulations, a comment to the regulation cannot be deemed to provide notice to the public that the agency is considering a change in the regulation. As the D.C. Circuit stated in *Small Refiner*:

As a general rule, [an agency] must *itself* provide notice of a regulatory proposal. Having failed to do so, it cannot bootstrap notice from a comment.<sup>90</sup>

### ***The Failure to Address Comments***

The APA requires that the agency conducting a rulemaking address relevant comments and provide a detailed explanation of its decision that will permit judicial review.<sup>91</sup> The agency failed to do so in the context of its distinction between use of the terms “sugar” and “sugars” in food labeling. With regard to “less sugar” claims, the agency states only that the use of the term “sugars” would be misleading for the same reasons that “sugar free” claims would be misleading. There was no discussion of the

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<sup>88</sup> *Id.* at 1104 (citing *Wagner Elec. Corp. v. Volpe*, 466 F.2d 1013, 1019 (3d Cir. 1972)).

<sup>89</sup> 705 F.2d 506, 546-9 (D.C. Cir. 1983). *See also* *AFL-CIO v. Donovan*, 757 F.2d 330, 338 (D.C. Cir. 1985); *Wagner Elec Corp*, 466 F.2d at 1019-20.

<sup>90</sup> *Small Refiner*, 705 F.2d at 549.

<sup>91</sup> *Nat'l Nutritional Foods Ass'n v. Weinberger*, 512 F.2d 688, 701 (2d Cir. 1975), *cert. denied*, 423 U.S. 827 (1975). *See also* *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Automobile Ins. Co.*, 463 U.S. 29, 57 (1983); *Chemical Mfrs. Ass'n v. EPA*, 885 F.2d 253 (5th Cir. 1989), *cert. denied*, 495 U.S. 910 (1990); *United States v. Nova Scotia Food Products*, 568 F.2d 240 (2d Cir. 1977).

differences between these two types of claims in terms of how consumers would be misled (in the case of “sugar free” products there actually is no sugar in the product, whereas in the case of “less sugar” products sugar may or may not be present). More significantly, there was no explanation of why the agency would disregard the comments of the American Diabetes Association and the American Dietetic Association, two organizations with special expertise on the information needs of consumers and patients with health concerns related to diet (not to mention General Mills and The Sugar Association), based on a general and unsupported supposition on the part of GMA. The agency’s reasoning is both unexplained and inexplicable, and thus inadequate for judicial review.

**4. The Category for “Sugars” Should Be Eliminated from the Nutrition Facts Panel.**

As discussed above, there is no overarching negative health significance to the class of ingredients denominated “sugars.” Singling out this subset of carbohydrates in the nutrition facts panel is misleading to consumers because it suggests that there is some health-related significance to the class.<sup>92</sup> The category of “sugars” should thus be eliminated from the NFP.

Although this labeling category was created by statute, the statute provides FDA with the authority to eliminate the information from the NFP (or make the information nonmandatory) if the information “is not necessary to assist consumers in maintaining healthy dietary practices.”<sup>93</sup> Because there is no information to be gleaned from information on the content of sweeteners falling into the category of “sugars,” as distinguished from carbohydrates generally, the category should be eliminated.<sup>94</sup>

**5. If the “Sugars” Category Is Not Eliminated, the NFP Should Provide Nonmisleading Information on All Sweeteners.**

If FDA is unprepared to eliminate the category of “sugars” from the NFP, the agency should, at a minimum, provide consumers with appropriate and nonmisleading information on all sweeteners. Seeing a reference to the content of “sugars,” without

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<sup>92</sup> This situation is distinguishable from the labeling fatty acid categories as subsets of the fats. Saturated fats, for example, have known links to heart disease while specific unsaturated fats provide health benefits.

<sup>93</sup> FDCA § 403(q)(2)(B). Indeed, the statute requires a category for complex carbohydrates as well as for sugars, *id.* § 403(q)(1)(D), but the agency found the category for complex carbohydrates to have no established basis and eliminated it as a mandatory category for the nutrition facts panel. *See* Food Labeling; Mandatory Status of Nutrition Labeling and Nutrient Content Revision, 55 Fed. Reg. 29,487, 29,497 (July 19, 1990) (proposed rule).

<sup>94</sup> Should the agency deem it important to include information related to total content of caloric sweeteners, the agency should create a new category for “caloric sweeteners,” which would include polyol sweeteners. As FDA noted in its rulemaking, it would not be appropriate to include polyol sweeteners in a class of ingredients denominated as “sugars.” Food Labeling; Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label, 58 Fed. Reg. 2,079, 2,099 (Jan. 6, 1993).

knowledge of the facts that the category includes syrups such as those derived from cornstarch and that the product may contain alternative polyol and/or artificial sweeteners that may present health concerns, is inappropriate and misleading to consumers. The agency should thus revise the NFP in the following manner:

1. Rename the “sugars” category “sugars/syrups.”
2. Require the mandatory labeling of polyol sweeteners as a category in the NFP as well as the mandatory labeling of each specific polyol ingredient and its corresponding amount. Require also the mandatory identification of each polyol ingredient on the PDP.
3. Require the mandatory labeling of artificial sweeteners as a category in the NFP as well as the mandatory labeling of each specific artificial sweetener ingredient and its corresponding amount. Require also the mandatory identification of each artificial sweetener ingredient on the PDP.

**(a) Sugars/Syrups**

FDA should rename the “sugars” category to prevent consumers from being misled with regard to the ingredients that are now permitted to be considered sugars (monosaccharides plus disaccharides). As discussed above, HFCS and other corn sweeteners are replacing sugar as the dominant and often exclusive sweetener in many products. In the 2004 Gallup poll, when asked, “Can you name some of the ingredients that can be added to foods and beverages to make them sweet?,” less than 8% of the respondents named HFCS.<sup>95</sup> Many consumers are unaware that FDA considers HFCS to be a “sugar.” In the same 2004 Gallup poll, forty-one percent of the respondents disagreed with the designation of HFCS as a “sugar.”<sup>96</sup>

Recent government publications have implicitly acknowledged the potential of this terminology to confuse consumers. The 2005 Dietary Guidelines consumer brochure, *Finding Your Way to a Healthier You: Based on the Dietary Guidelines for Americans*<sup>97</sup> explains that the term “added sugars” refers to “caloric sweeteners.” USDA’s recently released *My Pyramid* amplifies that “[a]dded sugars are sugars and syrups that are added to foods or beverages during processing or preparation.”<sup>98</sup> Again, the term sugars is deemed by USDA to be insufficient to accurately communicate to

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<sup>95</sup> The Gallup Org., *supra* note 53, at 11.

<sup>96</sup> *Id.* at 34.

<sup>97</sup> HHS, *Finding Your Way to a Healthier You: Based on the Dietary Guidelines for Americans* (2005), at <http://www.healthierus.gov/dietaryguidelines> (Tab 27).

<sup>98</sup> USDA, *MyPyramid.gov*, *Inside the Pyramid, Discretionary Calories: What are “Added Sugars”?*, at [http://www.mypyramid.gov/pyramid/discretionary\\_calories\\_sugars.html](http://www.mypyramid.gov/pyramid/discretionary_calories_sugars.html) (last visited June 19, 2005) (Tab 28).

consumers the ingredients used as sweeteners in today's food supply. Even experts find the terminology difficult.<sup>99</sup>

To properly inform consumers that this category includes a variety of products, the majority of which are syrups, the category should be renamed "sugars/syrups."

**(b) Polyol Sweeteners**

Polyol sweeteners (currently referred to in FDA regulations as "sugar alcohols") do not fall within the category presently denominated as "sugars" and are not required to be included in the NFP unless the product is labeled with a health claim.<sup>100</sup> In years past, polyol sweeteners were used primarily in "no sugar added" foods marketed to diabetics. In more recent years, however, polyol sweeteners have been used increasingly in foods marketed as "low-carb" to the general public. Whether or not FDA retains a category in the NFP for "sugars," the agency should amend its regulations to ensure that diabetics and other consumers are also informed about polyol sweeteners in their food products.<sup>101</sup>

Failure to include polyol sweeteners along with the category denominated as "sugars" in the NFP contributes to the notion that polyol sweeteners do not contribute to caloric content. The Joslin Diabetes Center warns that diabetics mistakenly think that foods containing polyol sweeteners will have no effect on their blood sugars and "since, many people typically *overeat* 'sugar free' or 'no sugar added' foods, their blood sugar may be significantly elevated."<sup>102</sup> The experts at Joslin warn that "[f]oods containing these sugar alcohols need to have their calories and carbohydrate content accounted for in [a diabetic's] overall meal plan . . . ."<sup>103</sup> Nondiabetics are subjected to the same confusion due in part to the widespread and increasing use of the term "net carbs" by some food manufacturers. Consumers are consequently misled to believe that polyol sweeteners are "free" carbohydrates, which are promoted as carbohydrates that do not contribute to weight gain because they do not elicit a glycemic response.

Because people have different tolerance levels for the various types of polyol sweeteners, they may experience laxative effects without knowing the exact cause. The

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<sup>99</sup> Madeleine Sigman-Grant & Jaime Morita, *Defining and Interpreting Intakes of Sugars*, 78 Am J. Clinical Nutrition, 815S (Supp. 78 2003) (Tab 29).

<sup>100</sup> 21 C.F.R. § 101.9(c)(6)(iii).

<sup>101</sup> This category of ingredients should be referred to in the NFP as "polyol sweeteners" rather than as "sugar alcohols." As expressed in the petition filed by the Calorie Control Council (the Council) in 1995, this modification will reduce consumer confusion. In support of its petition, the Council submitted a survey in which 78% of those surveyed thought that the term "sugar alcohol" indicates that a product contains some sugar even when the product is labeled "sugar free." Calorie Control Council Citizen Petition, FDA Docket No. 95P-0099 Supp. 1 (June 13, 2005). The survey also found that, 69% of the survey participants believed that the product also contains some alcohol. *See id.*

<sup>102</sup> Joslin Diabetes Ctr., *What are Sugar Alcohols?* (2005), at [http://www.joslin.org/education/library/sugar\\_alcohols.shtml](http://www.joslin.org/education/library/sugar_alcohols.shtml) (Tab 30).

<sup>103</sup> *Id.*

disclosure in the NFP of the amount of each polyol sweetener contained in a food will help consumers to evaluate their particular sensitivity to particular polyols and to the levels of polyol content that produce their gastrointestinal problems. Currently, consumers receive information on potentially problematic polyol content only through warning statements that are triggered by certain polyol thresholds that are established for individual polyols based on data related to the general population.<sup>104</sup> Individual tolerances may vary among individuals and the warnings do not assist consumers in identifying specific problem polyols with regard to foods that contain multiple polyol sweeteners. Furthermore, since a potential negative health impact is not the message a manufacturer wishes to emphasize, these warning labels are often obscure and difficult for the consumer to find.

Consumers should thus be provided with information in the NFP not only with regard to total content of polyol sweeteners but also with regard to each polyol ingredient expressed in grams per serving to assist individuals in learning to comprehend their varying tolerance of individual polyol sweeteners. The technology is available for unequivocally quantifying these ingredients and there can be no excuse for failing to provide this information.<sup>105</sup>

This category of ingredients should be referred to in the NFP as “polyol sweeteners” rather than as “sugar alcohols.” As expressed in the petition filed by the Calorie Control Council (the Council) in 1995, this modification will reduce consumer confusion. In support of its petition, the Council submitted a survey in which 78% of those surveyed thought that the term “sugar alcohol” indicates that a product contains

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<sup>104</sup> The label and labeling of food whose reasonably foreseeable consumption may result in a daily ingestion of 20 grams of mannitol or 50 grams of sorbitol shall bear the statement “Excess consumption may have a laxative effect.” 21 C.F.R. §§ 180.25(e), 184.1835(e). Moreover, for polydextrose, if a single serving of a food would exceed 15 grams of this additive, the label and labeling must include the following warning: “Sensitive individuals may experience a laxative effect from excessive consumption of this product.” *Id.* § 172.841(e).

<sup>105</sup> This information is currently required in Canada. See Food and Drug Regulation §§ B.01.018, B.01.021 (2004 as amended) (Tab 31) Canadian Food Inspection Agency, Guide to Food Labeling and Advertising § 6.2.4.1, VI-31-VI-32 (1997 as amended) (Tab 31). Health Canada considers it important for consumers to be made aware that polyols and/or polydextrose are added to certain foods, to recognize the names of these compounds, and to be aware that over-consumption of such foods could lead to gastrointestinal discomfort and laxative effects. See SOR/93-276 C. Gaz. Vol. 127(12) 2601, 2606-07 (May 25, 1993) (Tab 31); Health Products and Food Branch, Health Canada, Food Program: Sugar Alcohols (Polyols) & Polydextrose Used as Sweeteners in Foods, available at [http://www.hc-sc.gc.ca/food-aliment/cs-ipc/fr-ra/e\\_polyols\\_polydextrose\\_factsheet.html](http://www.hc-sc.gc.ca/food-aliment/cs-ipc/fr-ra/e_polyols_polydextrose_factsheet.html) (last updated Feb. 16, 2005) (Tab 31). Because of the known gastrointestinal and laxative effects caused by over-consumption of polyols and/or polydextrose and the wide variation of sensitivity between individuals to these effects, Canada adopted regulations requiring disclosure of such compounds in the Nutrition Facts table by their total content expressed in grams per serving. *Id.* Health Canada promulgated these regulations to make consumers aware of these potential adverse effects, not only to prevent “untoward effects . . . , but also to avoid unnecessary and costly medical intervention and possible misdiagnosis of the cause of such effects.” SOR/93-276 C, *supra*. at 2607. Further, in a policy statement on the declaration of polyols and their total content, Health Canada indicated that such information is important to assist individuals in learning to recognize the amount of polyols and/or polydextrose they can tolerate. Health Products and Food Branch, Health Canada, Food Program: Sugar Alcohols (Polyols) & Polydextrose Used as Sweeteners in Foods, *supra*.

some sugar even when the product is labeled “sugar free.”<sup>106</sup> The survey also found that, 69% of the survey participants believed that the product also contains some alcohol.<sup>107</sup>

Polyol ingredients should also be identified on the PDP. This will alert consumers with sensitivities to examine the NFP to determine the amount of the polyol that is in the product.<sup>108</sup>

**(c) Artificial Sweeteners**

Currently, artificial sweeteners such as aspartame, saccharin, and sucralose are not required to be identified in the NFP. The failure to provide information on this class of sweeteners in the NFP deprives consumers of important information on an increasingly significant category of sweeteners.

Food marketers have been required to disclose the presence of other artificial ingredients contained in foods and beverages since the passage of the FDCA in 1938. Congress clearly believed strongly that consumers know whether the foods they consume contain artificial ingredients, and specifically required disclosure of artificial flavoring and artificial coloring.<sup>109</sup> FDA’s regulations promulgated in 1949 made clear that the agency considered disclosure of these artificial ingredients to be particularly important by requiring that a statement of artificial flavoring or artificial coloring be given prominence on the PDP such that it will be “likely to be read by the ordinary individual under customary conditions of purchase and use of such food.”<sup>110</sup>

FDA’s regulations reflect that the agency considers it particularly important for consumers to know when a natural flavoring has been replaced by an artificial flavoring. The same standard should be applied when an artificial sweetener has replaced a natural nutritive sweetener. The agency’s regulations require that, (1) if the label, labeling, or advertising of a food designates the type of flavor in a food considered the characterizing flavor and (2) that food contains any artificial flavor that simulates, resembles or reinforces the characterizing flavor, the name of the food on the PDP or panels of the label must be accompanied by the name of the characterizing flavor and the words “artificial” or “artificially flavored.”<sup>111</sup> The regulations for special dietary foods used to reduce or maintain caloric intake or body weight require that any food formulated with a

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<sup>106</sup> Calorie Control Council Citizen Petition, FDA Docket No. 95P-0099 Supp. 1 (June 13, 2005).

<sup>107</sup> *See id.*

<sup>108</sup> Some products marketed in Canada have provided disclosure of polyol ingredients on the PDP. *See, e.g.*, (Tab 32).

<sup>109</sup> FDCA § 403(k) provides that a food shall be deemed to be misbranded “[i]f it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact.”

<sup>110</sup> 21 C.F.R. § 1.12(c) (1949) (re-codified as amended at 21 C.F.R. § 101.22(c)).

<sup>111</sup> 21 C.F.R. § 101.22(i)(2).

nonnutritive sweetener must declare on its label that it contains a nonnutritive ingredient, e.g., “Sweetened with nonnutritive sweetener(s).”<sup>112</sup>

The important distinction between natural ingredients and substitute artificial ingredients reinforces the need for disclosure of artificial sweeteners along with other sweeteners in the NFP so that consumers can be made aware not only of the substitution but also of the degree of substitution and the overall levels of these ingredients. Disclosure of artificial sweeteners contained in food products will assist consumers in making informed decisions about the consumption of foods containing artificial sweeteners, and at what amounts, as well as more clearly disclose which artificial sweetening agents are being used to replace “sugar” in their food products.<sup>113</sup>

The presence of artificial sweeteners should also be declared on the PDP. Consumers are entitled to disclosure of the presence of artificial sweeteners on the PDP just as they are entitled to disclosure of artificial favoring. Moreover, consumers should be provided on the PDP with the identities of the artificial sweetener ingredients so that they may be alerted to the presence of ingredients of concern such as aspartame and sucralose.<sup>114</sup>

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<sup>112</sup> *Id.* § 105.66(b). In addition to special dietary foods, the labeling for artificially sweetened canned fruits must disclose that the canned fruit is artificially sweetened as part of the statement of identity, e.g., “artificially sweetened apricots.” *See, e.g., id.* § 145.116(b)(1).

<sup>113</sup> Canada’s food labeling regulations require that artificial sweeteners be declared in the Nutrition Information panel in milligrams. Food and Drug Regulation §§ B.01.014-B.01.015 (aspartame), B.01.016-B.01.017 (sucralose), B.01.019-B.01.020 (acesulfame-potassium); Canadian Food Inspection Agency, Guide to Food Labeling and Advertising § 6.2.4.1, VI-31-VI-32 (Tab 31).

<sup>114</sup> Canada requires a statement on the PDP disclosing the presence of aspartame, sucralose, or acesulfame-potassium (e.g., “Contains Aspartame”; “Sweetened with Sucralose”). Food and Drug Regulation §§ B.01.014-B.01.020. (Tab 31).

(d) The Revised NFP

As proposed above, an NFP might be presented as follows:

<b>Nutrition Facts</b>	
Serving Size 1 cup (228g)	
Servings Per Container 2	
<b>Amount Per Serving</b>	
<b>Calories</b> 250	Calories from Fat 110
<b>% Daily Value</b>	
<b>Total Fat</b> 12g	18%
Saturated Fat 3g	15%
<i>Trans</i> Fat 3g	
<b>Cholesterol</b> 30mg	10%
<b>Sodium</b> 470mg	20%
<b>Total Carbohydrate</b> 31g	10%
Dietary Fiber 0g	0%
Sugars/Syrups 5g	
Polyol Sweeteners 5g	
Lactitol 2.5g	
Sorbitol 2.5g	
<b>Artificial Sweeteners</b> 20mg	
Aspartame 10mg	
Sucralose 10mg	
<b>Protein</b> 5g	
Vitamin A	4%
Vitamin C	2%
Calcium	20%
Iron	4%

6. Conclusion

FDA's food labeling regulations have not kept pace with changes in the food industry with regard to sweeteners. Sugar is now being replaced in large measure with an array of starch-hydrolysis formulations, polyols, and artificial sweeteners. Consumers are being misled by labeling that (1) confuses sugar content with caloric content, (2) confuses sugar content with content of starch-hydrolysis sweeteners, and (3) masks the replacement of sugar with polyol sweeteners and artificial sweeteners. FDA must revise its regulations to ensure that consumers will no longer be misled regarding caloric content, sugar content, and replacement sweeteners that may raise health concerns for some consumers. This is necessary to protect the integrity of food labeling regarding sweeteners and to protect the integrity of FDA's fundamental policies on food labeling.

***C. ENVIRONMENTAL IMPACT***

As provided in 21 C.F.R. § 15.30 neither an environmental assessment nor an environmental impact statement is required.

***D. ECONOMIC IMPACT***

As provided in 21 C.F.R. § 10.30(b) economic impact information is to be submitted only when requested by the Commissioner following review of the petition.

***E. CERTIFICATION***

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

Respectfully submitted,



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