



1023 6 MAY 11 10:33

May 10, 2006

BY FIRST CLASS MAIL

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

Re: The Sugar Association Citizen Petition Regarding Nutrition
Labeling for Sugar and Other Sweeteners
[Docket No. 2005P-0325/CP 1]

Dear Sir or Madam:

The Corn Refiners Association (CRA) submits these comments in response to the Sugar Association's citizen petition regarding nutrition labeling for sugars and other sweeteners (the Petition) submitted on August 15, 2005. CRA is the national trade association representing the corn refining (wet milling) industry of the United States. CRA and its predecessors have served this important segment of American agribusiness since 1913. Corn refiners manufacture sweeteners, ethanol, starch, bioproducts, corn oil, and feed products from corn components such as starch, oil, protein, and fiber.

Corn sweeteners are the most important category of refined corn products. These include corn syrups, dextrose, high fructose corn syrup (HFCS), and crystalline fructose. In 2004, corn sweeteners supplied nearly 56 percent of the U.S. nutritive sweetener market.¹ CRA objects to requests in the Petition to limit use of the term "sugar" to refer only to sucrose and to rename the

¹ See Econ. Research Serv., U.S. Dept. of Ag., Sugar and Sweeteners: Data Tables, Table 49, available at <http://www.ers.usda.gov/Briefing/Sugar/Data.htm>.

2005P-0325

C2

DC: 2040134-1

May 10, 2006

BY FIRST CLASS MAIL

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

Re: The Sugar Association Citizen Petition Regarding Nutrition
Labeling for Sugar and Other Sweeteners
[Docket No. 2005P-0325/CP 1]

Dear Sir or Madam:

The Corn Refiners Association (CRA) submits these comments in response to the Sugar Association's citizen petition regarding nutrition labeling for sugars and other sweeteners (the Petition) submitted on August 15, 2005. CRA is the national trade association representing the corn refining (wet milling) industry of the United States. CRA and its predecessors have served this important segment of American agribusiness since 1913. Corn refiners manufacture sweeteners, ethanol, starch, bioproducts, corn oil, and feed products from corn components such as starch, oil, protein, and fiber.

Corn sweeteners are the most important category of refined corn products. These include corn syrups, dextrose, high fructose corn syrup (HFCS), and crystalline fructose. In 2004, corn sweeteners supplied nearly 56 percent of the U.S. nutritive sweetener market.¹ CRA objects to requests in the Petition to limit use of the term "sugar" to refer only to sucrose and to rename the

¹ See Econ. Research Serv., U.S. Dept. of Ag., Sugar and Sweeteners: Data Tables, Table 49, available at <http://www.ers.usda.gov/Briefing/Sugar/Data.htm>.

May 10, 2006

“sugars” category in the Nutrition Facts Panel (NFP) as “sugars/syrups.” These requests are inappropriate and unnecessary. The use of the terms “sugar” and “sugars” to refer to all nutritive sweeteners is a well-accepted practice that is consistent with the purposes of nutrition labeling. Current ingredient labeling requirements fully inform consumers about the identity of specific sweeteners in foods. Contrary to implications and unsupported assertions in the Petition, there is no difference in health impacts or outcomes from consumption of sucrose as compared to HFCS. The saccharide composition (glucose to fructose ratio) of HFCS is essentially the same as sucrose. At bottom, the Petition raises competitive concerns that are best resolved in the marketplace and not through regulation.

I. Introduction

A. Summary of the Petition

The Petition includes the following requests:²

- Limit use of the term “sugar” in nutrition labeling to refer only to sucrose from sugar cane or sugar beets.
- Eliminate “sugars” as a mandatory category in the NFP.
- If “sugars” is not eliminated as a category in the NFP, rename the category “sugars” as “sugars/syrups.”

The Petition asserts that the requested changes are necessary to alleviate “consumer confusion about the identities of sweeteners in their foods and beverages and the calories contributed by these ingredients.”³ The Petition contends that consumers are misled about the identity of specific sweeteners in food because (1) nutrient content claims permit use of the term “sugar” to encompass the entire category of sugars, thereby leading consumers to believe that foods labeled as having “less sugar” contain sucrose; and (2) information about alternative sweeteners that are commonly substituted for sugars is not required in nutrition labeling, which

² See Petition at 1-2.

³ *Id.* at 2.

May 10, 2006

“suggests that none of today’s alternative formulated sweeteners are present” in the food.⁴ According to the Petition, the absence of such information in nutrition labeling “leaves consumers misinformed about important modifications to the food they consume where syrups, polyol sweeteners and artificial sweeteners are being substituted for sugar.”⁵

As explained below, the Petition misconstrues the purposes of FDA’s nutrition and ingredient labeling regulations, and fails to advance any compelling reason for altering FDA’s longstanding and well-accepted sweetener labeling requirements.

B. The Petition Implicates Competitive Concerns That Are Best Resolved In The Marketplace And Not Through Regulation

Current nutrition and ingredient labeling requirements truthfully inform consumers about the identity and caloric content of sweeteners in foods. The Petition is a poorly disguised attempt to redirect food manufacturers and consumers towards the sugar industry, which has lost significant market share in recent decades to other nutritive and nonnutritive sweeteners. FDA should not revise its regulations, or expend its limited resources, in response to this type of competitive concern.

As the Petition acknowledges,⁶ since the 1960s, there has been a dramatic shift from the use of sucrose to sweeteners manufactured through starch hydrolysis, including corn sweeteners, in many food products.⁷ Since the mid-1950s, new technology used to purify and crystallize dextrose allowed corn-based sweeteners, for the first time, to compete in some markets that had been the sole domain of the sugar industry. Subsequent developments involving enzyme

⁴ *See id.* at 2-3.

⁵ *See id.* at 3.

⁶ *See id.* at 14-15.

⁷ *See, e.g.,* CRA, The History of Corn Refining, A Brief History of the Corn Refining Industry, available at <http://www.corn.org/historycornrefining.htm>.

May 10, 2006

catalyzed isomerization of dextrose to fructose led to HFCS.⁸ The substitution of sweeteners such as HFCS for sucrose in recent decades is not, as implied by the Petition,⁹ due to any flaw or bias in current food labeling requirements or attributable to any desire by food producers to hide the presence of HFCS. Rather, the increased use of HFCS and other corn sweeteners in lieu of sucrose is attributable to the favorable properties of corn sweetener ingredients.

Corn sweeteners such as HFCS provide food manufacturers and consumers cost, functionality, and taste advantages as compared to sucrose.¹⁰ Corn syrups are valuable sweeteners not only because of the sweetness and energy they provide, but also because of their higher viscosity, ability to provide suspension for other ingredients in food, and ability to improve textures and enhance colors without masking natural flavors. HFCS and crystalline fructose, both syrups, share the advantages of stability and high osmotic pressure, or crystallization control. Different versions of HFCS are used for different purposes. 42-HFCS is popular in canned fruits, condiments, and other processed foods which need mild sweetness that won't mask natural flavors. 55-HFCS commands a major role as a sweetener in ice cream and frozen desserts, and the beverage industry, which "demands over 90 percent of total domestic deliveries."¹¹ 90-HFCS, the sweetest of the HFCS products, is useful in natural and "light" foods "where very little is needed to provide sweetness."¹²

⁸ For more information about market trends for sucrose and corn sweeteners, *see* Econ. Research Serv., U.S. Dept. of Ag., Briefing Room: Sugar and Sweeteners, *available at* <http://www.ers.usda.gov/Briefing/Sugar/>.

⁹ *See, e.g.*, Petition at 14 ("It is important to note that 'less sugar' claims are commonly used by 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.").

¹⁰ *See generally* CRA, Sweeteners; "High Fructose Corn Syrup and Sucrose: Reassuring Similarities and Complementary Differences" in 2004 Corn Annual *available at* <http://www.corn.org>; HFCS Q&A brochure, *available at* <http://www.HFCSFacts.com>.

¹¹ Econ. Research Serv., U.S. Dept. of Ag., Briefing Room: Sugar and Sweeteners, Policy *available at* <http://www.ers.usda.gov/Briefing/Sugar/policy.htm>.

¹² *Id.*

May 10, 2006

In addition to the technical and economic advantages of corn sweetener ingredients, there is no difference in health effects from HFCS or other corn sweeteners as compared to sucrose. (See Part II.E. below.)

Contrary to the Petition's assertions, there is no reasonable basis for distinguishing sucrose from HFCS and other corn sweeteners in nutrition labeling. Current ingredient labeling requirements ensure that consumers are fully informed with respect to the identity and relative proportion of specific sweetener ingredients in food products. At base, the Petition is an attempt to shift the marketplace towards the sugar industry by redesigning nutrition labeling requirements. This is not a reasonable or valid basis to amend the food labeling regulations. Accordingly, the Petition should be denied and sweetener choices left to the marketplace.

In addition, the Petition would require the redesign of nutrition labels and the re-labeling of virtually all packaged food products, imposing a substantial cost burden that would not be justified by any compensating consumer benefit.

II. Use Of The Terms "Sugar" and "Sugars" in Nutrition Labeling To Refer To All Nutritive Sweeteners Is A Longstanding and Well-Accepted Practice, and Consistent With The Purposes Of Nutrition Labeling

Current nutrition labeling regulations utilize the terms "sugar" and "sugars" to refer to all nutritive sweeteners.¹³ The term "sugars" is used in the NFP and the term "sugar" is used in nutrient content claims. Both terms truthfully and appropriately describe a broad category of sugars, which is defined as "the sum of all free monosaccharides and disaccharides (such as glucose, fructose, lactose, and sucrose)."¹⁴ Moreover, the use of these terms satisfies the fundamental purpose of nutrition labeling, which is to communicate to consumers the nutritional value of food. These terms are appropriately used to describe all nutritive sweeteners for nutrition labeling purposes because there is no demonstrated difference in nutritional impact or health outcomes from consumption of sucrose as compared to other sugars such as HFCS.

¹³ See 21 C.F.R. §§ 101.9(c)(6)(ii) and 101.60(c).

¹⁴ 21 C.F.R. § 101.9(c)(6)(ii).

May 10, 2006

A. Use of The Term “Sugars” in the NFP Appropriately Encompasses Nutritive Sweeteners In Addition to Sucrose

FDA regulations require that the NFP contain information about the level of several key nutrients and sub-nutrients, including total calories, total fat, saturated fat, *trans* fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, and vitamins and minerals.¹⁵ Unless a food is exempt or qualifies for an exception, the nutrition information for these nutrients must be presented using the nutrient names specified in the FDA regulation.¹⁶

The FDA regulation provides that:

Sugars shall be defined as the sum of all free mono- and disaccharides (such as glucose, fructose, lactose, and sucrose).¹⁷

FDA thoroughly considered this definition in its nutrition labeling rulemaking in the early 1990s. In the 1990 nutrition labeling proposed rule, FDA defined “sugars” as:

the sum of all free mono- and oligosaccharides (and their derivatives) that contain four or fewer saccharide units.¹⁸

The agency proposed this definition despite its recognition that “the common definition of sugars is usually limited to mono- and disaccharides (i.e., those that contain two or fewer saccharide units).”¹⁹ FDA’s rationale for employing a broader definition of “sugars” was twofold: (1) trisaccharides and tetrasaccharides have “sweetening, metabolic, and nutritional effects similar to the mono- and disaccharides,” and (2) FDA believed the definition was necessary to capture corn syrups, “which are commonly used in many foods [and] contain varying amounts of tri- and

¹⁵ See generally 21 C.F.R. § 101.9(c)(1)-(8).

¹⁶ See 21 C.F.R. § 101.9(c).

¹⁷ 21 C.F.R. § 101.9(c)(6)(ii).

¹⁸ See Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision; Proposed Rule; 55 Fed. Reg. 29487, 29497 (July 19, 1990); see also 55 Fed. Reg. at 29513.

Although the 1990 proposed rule included mandatory nutrition labeling for most nutrients, the agency proposed only voluntary labeling for “sugars.” This was primarily because specific quantitative recommendations for sugars had not been determined.

¹⁹ 55 Fed. Reg. at 29497.

May 10, 2006

tetrasaccharides.”²⁰ FDA expressed concern that the common definition of “sugars” could result in “a substantial under declaration of the sugars content of foods.”²¹

Following publication of the 1990 proposed rule, the Nutrition Labeling and Education Act of 1990²² (the NLEA) was enacted. The NLEA amended the Federal Food, Drug, and Cosmetic Act to require nutrition labeling on foods and to require that certain nutrients, including sugars, be included in nutrition labeling. In response to the NLEA, FDA proposed to revise the 1990 proposed rule by, among other things, adding sugars to the list of required nutrients in nutrition labeling (the 1991 proposed rule).²³ In the 1991 proposed rule, the agency retained the broad definition of “sugars” from the 1990 proposed rule, but requested comments on the definition.²⁴ FDA also acknowledged that the proposed definition differed from “that used by Canada, the Codex Alimentarius Commission, and the European Community, all of which limit the definition of sugars to mono- and disaccharides.”²⁵

In the final rule enacting the NLEA’s nutrition labeling requirements (the 1993 final rule),²⁶ FDA defined “sugars” consistent with the standard, or commonly accepted, definition. That is, FDA determined that the term “sugars” is appropriately and accurately defined to encompass mono- and disaccharides only. The agency explained that the final definition is the

²⁰ *Id.*

²¹ *Id.*

²² Pub. L. 101-535; 104 Stat. 2353 (1990).

²³ Food Labeling: Reference Daily Intakes and Daily Reference Values; Mandatory Status of Nutrition Labeling and Nutrient Content Revision; Proposed Rule; 56 Fed. Reg. 60366 (Nov. 27, 1991).

FDA again recognized that current dietary guidance recommendations had not specified quantitative amounts for sugars, and also explained that comments submitted in response to the 1990 proposed rule split in their support for voluntary versus mandatory nutrition labeling for sugars. *See* 56 Fed. Reg. at 60368.

²⁴ *See* 56 Fed. Reg. at 60369 and 60388.

²⁵ *Id.* at 60369 (internal citations omitted).

²⁶ Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label; Final Rule; 58 Fed. Reg. 2079 (Jan. 6, 1993).

May 10, 2006

“traditional and widely accepted use of the term,” is the definition used by the Institute of Medicine, conforms with international definitions, and there is no compelling health or nutritional reason to include tri- or tetrasaccharides.²⁷ With respect to corn syrups, FDA recognized that “most corn syrup used in sweetening is in the form of [HFCS], which is composed of 95 percent monosaccharides, and that [HFCS] accounts for two thirds of total U.S. corn consumption.”²⁸ FDA was ultimately persuaded that “the usefulness of nutrition labeling will be hindered by adopting a definition [of “sugars”] that is inconsistent with the commonly accepted use, and with the international use of the term.”²⁹ Thus, FDA adopted for nutrition labeling purposes a precise and carefully crafted definition of “sugars” that is explicitly intended to include HFCS.

In the 1993 final rule, FDA recognized that a definition of “sugars” must be based on sound methodology and should be compatible with standardized analytical methods for measuring sugars.³⁰ Indeed, this was one of the reasons that FDA defined “sugars” as it did, because it was “persuaded that compliance with nutrition labeling will be impeded by adopting a definition for sugars that is not supported by validated analytical methods.”³¹ Organic chemistry and food technology define sugars based upon their classification, structure, function, and caloric value. Sucrose, fructose, glucose, and corn sweeteners such as HFCS, clearly meet this definition.

²⁷ 58 Fed. Reg. at 2097.

²⁸ *Id.*

²⁹ *Id.* In the 1993 final rule, FDA also considered whether to employ alternative terminology for “sugars.” Some comments suggested terms such as “sweeteners” or “simple carbohydrates”; however, FDA concluded that such terminology would be inappropriate because it does not accurately encompass sugars (e.g., “sweeteners” would also include noncarbohydrate intense sweeteners, which would not be appropriately declared as part of carbohydrate content, which includes sugars; “simple carbohydrates” is too broad to encompass only the traditional sugars (i.e., mono- and disaccharides)). *See* 58 Fed. Reg. at 2098.

³⁰ *See id.*

³¹ *Id.* at 2097.

May 10, 2006

1. Sugars Classification

Carbohydrates are organic molecules that share common chemical characteristics. They are classified into four groups: monosaccharides, derived monosaccharides, oligosaccharides and polysaccharides.³² Carbohydrates are composed principally of the elements carbon, hydrogen and oxygen, and feature a carbonyl group consisting of either an aldehyde or ketone. Most carbon atoms in the carbohydrate molecule additionally bond to a hydroxyl group and are thus classified as aldehyde or ketone derivatives of polyhydroxy alcohols. Sugars is the name commonly given to all low molecular weight carbohydrates by practitioners in the field, and has historically included sucrose and fructose, as well as glucose and low molecular weight polymers of glucose.³³ The fructose and glucose comprising HFCS are called monosaccharides; sucrose is called a di- or oligosaccharide, since it consists of fructose and glucose bonded together. Thus, HFCS and sucrose are properly classified in the same category of organic molecules called carbohydrates.

2. Sugars Structure

Few sugars exist in nature as monosaccharides. Rather, most are found linked to one or more of the same or different sugars in polymers, generally called polysaccharides. Such polysaccharides can be relatively small in the case of the disaccharide sucrose, which is composed of one fructose (chemically termed β -D-fructofuranose) and one glucose (α -D-glucopyranose) joined together by an α,β -glycosidic bond,³⁴ or quite large in the case of

³² Smith EL, et al. *Principles of Biochemistry, General Aspects*, 7th Edition. McGraw-Hill Book Company. New York, 1983. Chapter 6. The Carbohydrates. p.84.

³³ Bemiller JN. Carbohydrates. In J Kroschwitz, ed., *Kirk-Othmer Concise Encyclopedia of Chemical Technology*, 4th Edition. John Wiley & Sons, Inc. New York, 1999. p.316-319.

³⁴ Colonna WJ, U Samaraweera. Sugar. In J Kroschwitz, ed., *Kirk-Othmer Concise Encyclopedia of Chemical Technology*, 4th Edition. John Wiley & Sons, Inc. New York, 1999. p.1913-1914.

May 10, 2006

polysaccharide starch, which is composed of many hundreds of glucose (α -D-glucopyranose) units joined together by α -1 \rightarrow 4 and α -1 \rightarrow 6 glycosidic bonds.³⁵

The α,β -glycosidic bond in sucrose is well known in the food industry to be unstable in acidic systems such as jam, fruit purée and many soft drinks.³⁶ Under such conditions, the bond is hydrolyzed (inverted) at a rate accelerated by increasing acidity and increasing storage temperature, releasing monosaccharide fructose and glucose. The monosaccharide fructose and glucose released from sucrose is identical to that in HFCS. Monosaccharides from sucrose and HFCS share the basic carbohydrate molecular formula, $C_x(H_2O)_y$.³⁷ Thus, monosaccharides fructose and glucose from sucrose and HFCS react identically to specific chemical tests characteristic of carbohydrates such as ring formation, reduction and oxidation, derivatization, etherification and acetalation;³³ and to specific physical tests such as polarimetry, refractive index, density, reducing sugars, high performance liquid chromatography (hplc), gas liquid chromatography (glc) and near-infrared spectroscopy.³⁸

3. Sugars Function

Though sugars are commonly thought to provide only sweetness to foods and beverages, they possess several functional properties that increase their value. In addition to sweetness, sugars contribute to viscosity and texture, accentuate or hide flavors, improve product stability and prolong shelf-life, control freezing point and protect canned and frozen fruit, promote surface browning, reduce calories and serve as a source of fermentable sugars in yeast raised and

³⁵ Whistler RL, JR Daniel. Starch. In J Kroschwitz, ed., *Kirk-Othmer Concise Encyclopedia of Chemical Technology*, 4th Edition. John Wiley & Sons, Inc. New York, 1999. p.1882-1884.

³⁶ Sweetener Glossary. *Inversion*. Dansukker. Accessed March 30, 2006. Found at <http://www.dansukker.com/omsocket/sotningslexikon/skrivut.asp?id=155>.

³⁷ Hendrickson JB, et al. *Organic Chemistry*, Third Edition. McGraw-Hill Book Company. New York, 1970. Chapter 27, The Chemistry of Natural Products. p.1081.

³⁸ Godshall MA. Sugar Analysis. In J Kroschwitz, ed., *Kirk-Othmer Concise Encyclopedia of Chemical Technology*, 4th Edition. John Wiley & Sons, Inc. New York, 1999. p.1914-1915.

May 10, 2006

bacteria cultured products.^{39,40} Sugars also serve as feedstocks for chemical synthesis and fermentation processes, and are important components of pharmaceutical products.³⁴

4. Sugars Caloric Value

Besides being a source of sweetness and functionality in foods, sugars are a source of energy. That energy is derived through the oxidation of foods by metabolic processes in the human body. The energy in foods and food ingredients can be measured in the laboratory by a chemical method called bomb calorimetry. The overall energy released by a food or ingredient is the same whether it occurs in a human being or a bomb calorimeter.⁴¹ It is commonly accepted by nutritionists that fats release 9 kilocalories of energy, while all carbohydrates and proteins generally release 4 kilocalories of energy.⁴² Thus, the sugars in sucrose and HFCS contribute identical energy to foods and beverages — 4 kilocalories.

Accordingly, there is no scientifically valid reason to regulate corn sweeteners differently from sucrose or to require different nomenclature for corn sweeteners.

In sum, use of the term “sugars” in nutrition labeling to include all mono- and disaccharides is scientifically appropriate, and consistent with the commonly accepted and international definitions of “sugars.”⁴³ For nutrition labeling purposes, there is no reason to limit the term “sugar” to sucrose or to distinguish sucrose from other mono- and disaccharides.

³⁹ White JS. Fructose syrup: production, properties and applications. In FW Schenck and RE Hebeda, eds., *Starch Hydrolysis Products*. VCH Publishers, Inc. New York, 1992. p.177-199.

⁴⁰ Hanover LM. Crystalline fructose: production, properties and applications. In FW Schenck and RE Hebeda, eds., *Starch Hydrolysis Products*. VCH Publishers, Inc. New York, 1992. p.201-231.

⁴¹ See ref 32, Chapter 12. Introduction to Metabolism: Principles of Bioenergetics. p.256.

⁴² Saltman P, et al. The California Nutrition Book. Little, Brown and Company. Boston, 1987. p.30.

⁴³ See, e.g., Food and Drug Regulations § B.01.001 (Can.) (“‘sugars’ means all monosaccharides and disaccharides”); Codex Standard for Sugars, Codex Stan. 212-1999 (Amd. 1-2001); Council Directive 90/496/EC, Article 1 § (4)(e) (“‘sugars’ means all monosaccharides and disaccharides present in food, but excludes polyols”).

May 10, 2006

B. Use of The Term “Sugar” In Nutrient Content Claims Appropriately Encompasses Nutritive Sweeteners In Addition to Sucrose

Nutrient content claims are claims which expressly or impliedly characterize the level of any nutrient in food labeling.⁴⁴ Such claims must use terms defined by FDA.⁴⁵ Foods may bear a claim about sugar content where the claim uses terms defined by FDA and is made in accordance with FDA’s general principles for nutrient content claims.⁴⁶ FDA regulations authorize the use of nutrient content claims such as “sugar free,” “no added sugar,” and “reduced sugar” or “less sugar.”⁴⁷ The agency has clearly articulated that nutrient content claims for sugars are not limited to sucrose, but “include a class of sweeteners of which sucrose is just one.”⁴⁸ FDA has explained that it is important for nutrient content claims to be consistent with the NFP, “which serves as a source of specific information for consumers concerning the nutritional value of food.”⁴⁹

FDA’s initial rulemaking for nutrient content claims for sugars proposed that the term “sugars,” as opposed to “sugar,” be used in such claims. This distinction was based upon the agency’s concern that “there would be potential for confusion if the nutrient content claim were to use the term ‘sugar,’ and the [NFP] were to specify information using the term ‘sugars.’”⁵⁰

⁴⁴ See 21 U.S.C. § 343(r)(1)(A).

⁴⁵ See 21 U.S.C. § 343(r)(2)(A)(i).

⁴⁶ FDA has promulgated general and specific regulations regarding the use of nutrient content claims in food labeling in 21 C.F.R. § 101.13 and 21 C.F.R. Part 101, Subpart D.

⁴⁷ 21 C.F.R. § 101.60(c).

⁴⁸ Food Labeling: Declaration of Ingredients; Final Rule; 58 Fed. Reg. 2850, 2857-58 (Jan. 6, 1993) (“[W]hen sweeteners other than sucrose are used in a food ... claims such as ‘no sugar added’ may reasonably be expected to convey to consumers that the food contains no added nutritive sweeteners, such as [HFCS], malt syrup, or honey. Claims such as ‘no sugar added’ refer not only to sucrose but to a class of sweeteners of which sucrose is just one.”).

⁴⁹ Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definitions of Terms; Proposed Rule; 56 Fed. Reg. 60421, 60436 (Nov. 27, 1991).

⁵⁰ *Id.*

May 10, 2006

However, FDA acknowledged that “it has been a common practice to use the term ‘sugar free’ rather than ‘sugars free.’”⁵¹ FDA was ultimately persuaded that “sugar” instead of “sugars” should be used in nutrient content claims (i.e., “sugar free” instead of “sugars free”) because this approach would be consistent with requirements in Canada and other countries, and the term “sugars free” is unfamiliar to consumers and will confuse many of them.⁵²

The Petition cites consumer research to support the assertion that use of the term “sugar” in nutrient content claims to refer to nutritive sweeteners in addition to sucrose is misleading. However, these studies are inherently flawed and provide little support for the Petition. The National Quorum Survey cited in the Petition asked respondents whether a product’s labeling is misleading if it bears a “50% less sugar” claim “when it contains no sugar but is actually sweetened with [HFCS].”⁵³ Without the benefit of a complete food label (i.e., full nutrition and ingredient labeling), a consumer cannot fairly respond to this question. The question itself creates confusion by using the term “sugar” to refer to both a class of nutritive sweeteners and a single nutritive sweetener, sucrose. A copy of a NFP, were one provided, would have clarified the total amount of sugars in the food, and an ingredient list would have identified HFCS as an added ingredient. This information was absent from the survey question and not available to consumers to inform their responses. The National Quorum Survey also failed to provide additional information about the identity of, and quantitative comparison to, an appropriate reference food that is required to accompany a nutrient content claim. FDA requires this information to assure a product’s labeling is truthful and not misleading.⁵⁴ Without the benefit of

⁵¹ *Id.*

⁵² *See* 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; Final Rule; 58 Fed. Reg. 2302, 2325 (Jan. 6, 1993).

⁵³ *See* Petition at 13 (citing Wirthlin Worldwide, Quorum 2004, at 2 (Apr. 2-5, 2004) (The question appeared as follows in this study: “Recently, there has been considerable attention focused on the amount of carbohydrates in foods. Do you feel that a product that promotes on its package that it contains ‘50% less sugar’ when it contains no sugar but is actually sweetened with high fructose corn syrup is misleading?”)).

⁵⁴ 21 C.F.R. § 101.13(j)(2). *See also, e.g.*, 56 Fed. Reg. at 60445.

May 10, 2006

the NFP, ingredient list, and accompanying reference food information, the consumers surveyed did not have a fair basis to evaluate the claim. The same criticisms apply to the survey question in the 2004 telephone poll conducted by the Gallup Organization and cited in the Petition, which asked respondents whether it mattered whether a soft drink sweetened with HFCS and an artificial sweetener was labeled with a “50% less sugar” claim.⁵⁵

The Petition also states that “less sugar” claims are often used in labeling for soft drinks sweetened with HFCS, and argues that consumers are “ignorant of the fact that they are consuming HFCS, not sucrose.”⁵⁶ This conclusion is belied by current FDA regulations, which require soft drink labeling to disclose each specific sweetener ingredient used in the beverage. Accordingly, there is no basis to conclude that consumers are misled by nutrient content claims using the term “sugar” to refer to nutritive sweeteners in addition to sucrose.

C. FDA Did Not Violate The Administrative Procedure Act When It Promulgated Nutrition Labeling Regulations For Sugars

The Petition argues that FDA’s nutrient content labeling requirements for sugars are unlawful because “they were not promulgated in accordance with the notice and comment requirements of the Administrative Procedure Act (APA).”⁵⁷ As noted, FDA initially proposed that nutrient content claims use the term “sugars,” but changed the term to “sugar” in the final rule. The Petition asserts that the agency did not provide adequate notice and opportunity for comment to support this revision and did not adequately address comments in the final rule. Contrary to the Petition’s arguments, FDA engaged in valid rulemaking and did not violate the APA.

⁵⁵ See Petition at 14 (citing The Gallup Org., Sugar Assoc. Poll 35 (Aug. 2004) (The polling question asked the following: “If a soft drink is sweetened using HIGH FRUCTOSE CORN SYRUP and an artificial sweetener but says on the front of the can 50 per cent [sic] LESS SUGAR, do you feel it is okay or not, or doesn’t it matter?”)).

⁵⁶ See Petition at 14.

⁵⁷ Petition at 17. See generally Petition at 17-22.

May 10, 2006

In the final rule defining nutrient content claims for sugars, as fully explained in Part II.B. above, FDA reconsidered the use of the term “sugars” and decided that the term “sugar” in nutrient content claims was appropriate.⁵⁸ The agency explained that it was persuaded by arguments in comments that “sugar” instead of “sugars” should be used in nutrient content claims (i.e., “sugar free” instead of “sugars free”) because this approach would be consistent with Canada’s and other countries’ food labeling requirements. Furthermore, FDA concluded that comments demonstrated that the term “sugars free” is unfamiliar to consumers and will create confusion.⁵⁹ FDA used the same reasoning to change “less sugars” to “less sugar,” explaining that use of the term “sugars” could be confusing and that “sugar” is more appropriate for consistency.⁶⁰

The Petition claims that FDA violated the APA by adopting a position in the final rule that was “radically different from the position originally proposed for comment in the absence of notice that the agency is considering both positions.”⁶¹ The Petition asserts that “the term ‘less sugar’ had never been proposed for comment in any manner,” and there was no opportunity to comment on the proposition that the term “less sugar” should be required “for consistency.”⁶²

Under the APA, an agency’s obligation to provide notice and an opportunity for comment⁶³ is fulfilled when the agency “provides sufficient factual detail and rationale for the rule to permit interested parties to comment meaningfully.”⁶⁴ The test for determining whether this requirement has been satisfied is whether the final rule promulgated by the agency is a

⁵⁸ See 58 Fed. Reg. at 2325.

⁵⁹ *Id.*

⁶⁰ *Id.* at 2350.

⁶¹ Petition at 20.

⁶² *Id.* (quoting 58 Fed. Reg. at 2350).

⁶³ 5 U.S.C. § 553(b) and (c).

⁶⁴ See, e.g., *American Water Works Ass’n v. EPA*, 40 F.3d 1266, 1274 (D.C. Cir. 1994) (quoting *Florida Power & Light Co. v. United States*, 846 F.2d 765, 771 (D.C. Cir. 1988)).

May 10, 2006

“logical outgrowth” of the proposed rule.⁶⁵ In determining whether a final rule is the “logical outgrowth” of a proposed rule, courts inquire “whether a new round of comments would provide the first opportunity for interested parties to offer comments that could persuade the agency to modify its rule,”⁶⁶ whether the regulated party “should have anticipated that such a requirement might be imposed,”⁶⁷ and whether notice was “sufficient to advise interested parties that comments directed to the controverted aspect of the final rule should have been made.”⁶⁸

Based on these principles, it is clear that FDA complied with the APA’s notice and comment requirements in its rulemaking defining nutrient content claims for sugars. FDA’s shift from the term “sugars” to “sugar” was not a “radically different” position. FDA provided ample notice and opportunity to comment on this aspect of the rule. A new proposal would not have provided the Sugar Association the first opportunity to comment on this issue. The Sugar Association could have reasonably anticipated that this change might be made in the final rule. First, the agency’s discussion of “sugar free” claims in the proposed rule clearly indicated that FDA considered this term to encompass more than sucrose.⁶⁹ Second, FDA acknowledged that “it has been a common practice to use the term ‘sugar free’ rather than ‘sugars free.’”⁷⁰ Finally, FDA also clearly articulated its goal of maintaining consistency in nutrition labeling, which necessarily includes consistency among nutrient content claims themselves.⁷¹

⁶⁵ See *id.* (citations omitted). See also, e.g., *United Steelworkers v. Marshall*, 647 F.2d 1189, 1221 (D.C. Cir. 1980) (“Where the change between the proposed rule and final rule is important, the question for the court is whether the final rule is a ‘logical outgrowth’ of the rulemaking proceeding.”); *Nat’l Mining Ass’n v. Mine Safety and Health Admin.*, 116 F.3d 520, 531 (D.C. Cir. 1997).

⁶⁶ *American Water Works Ass’n*, 40 F.3d at 1274.

⁶⁷ *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 549 (D.C. Cir. 1983).

⁶⁸ *First Am. Discount Corp. v. CFTC*, 222 F.3d 1008, 1015 (D.C. Cir. 2000).

⁶⁹ 56 Fed. Reg. at 60436 (“In considering the appropriateness for defining the term ‘sugar free,’ the agency took into account ... the potential for the term to be misleading.”).

⁷⁰ *Id.*

⁷¹ The Petition also asserts that there were no comments on why the term “less sugar” should not be considered because “the term did not appear in the proposed regulation” (*see* Petition at 19); however, the term “less sugars” did appear in the proposed rule (*see* 56 Fed. Reg. at 60452-53), (continued...)

May 10, 2006

The Petition also challenges the nutrient content claim regulation for sugars based upon FDA's alleged failure to consider and address comments in the final rule. An agency is "required to give reasoned responses to all significant comments in a rulemaking proceeding."⁷² An agency must respond to "specific challenges that are sufficiently central to its decision."⁷³ There is no requirement that FDA address and respond to every comment. Rather, FDA's responsibility is to "respond in a reasoned manner to those comments that raise significant problems."⁷⁴ There were no comments on the proposed rule that raised significant concerns about the use of the term "less sugar." Moreover, in both the proposed and final rules, FDA discussed its concerns about whether and how "sugar free" and "sugars free" claims might mislead consumers,⁷⁵ and discussed comments suggesting the use of other terms such as "sucrose free" and "no refined sugar."⁷⁶

D. Use Of The Term "Sugars/Syrups" Would Be Misleading and Contrary to the Purposes of Nutrition Labeling

As noted, use of the terms "sugar" and "sugars" in nutrient content claims and the NFP to describe monosaccharides and disaccharides is fully consistent with the purposes of nutrition labeling. Consistency in nutrition labeling is important because it "serves as a source of specific information for consumers concerning the nutritional value of food."⁷⁷

and even that term and its definition received very few comments. *See* 58 Fed. Reg. at 2350 ("Only a few comments addressed the term."). A lack of comments on a specific issue should not be viewed as failure to provide adequate notice and opportunity to comment. Clearly, the "less sugars" claim was raised in the proposed rule, yet no comments provided any arguments about why the claim should be used or eliminated. *See id.*

⁷² *Int'l Fabricare Inst. v. EPA*, 972 F.2d 384, 389 (D.C. Cir. 1992).

⁷³ *Id.*

⁷⁴ *Dr. Zinovy v. Reyblatt*, 105 F.3d 715, 722 (D.C. Cir. 1997).

⁷⁵ *See* 56 Fed. Reg. at 60435-36; 58 Fed. Reg. at 2325.

⁷⁶ 58 Fed. Reg. at 2325.

⁷⁷ 56 Fed. Reg. at 60436.

May 10, 2006

The Petition's request to replace the mandatory category of "sugars" in the NFP with "sugars/syrups" is unnecessary and would be misleading to consumers. The NFP is designed to disclose basic categories of nutrients.⁷⁸ The NFP lists nutrients with important subtypes, for example: total fat with saturated fat and *trans* fat; total carbohydrate with dietary fiber and sugars. There is no requirement to identify the *source* of each nutrient or subtype in the NFP. Such identification is unnecessary in light of the fact that a food label is required to declare nutrient sources in the ingredient list.⁷⁹ Because specific source information about nutrients is already declared in the ingredient list, it would be redundant to require that such information be repeated in the NFP.

"Sugars," which fall under the umbrella of carbohydrates, are clearly a specific type of nutrient. The NFP reflects this fact by requiring that sugars be indented and declared under the heading of "total carbohydrate."⁸⁰ There are multiple nutritive sweeteners that the term "sugars" accurately encompasses, including, "table sugar (sucrose), brown sugar, raw sugars, glucose (dextrose), fructose, maltose, lactose, honey, syrup, corn sweeteners, [HFCS], molasses, and fruit juice concentrate."⁸¹ "Syrup" is only one form of nutritive sweetener. "Syrup" does not constitute a category of nutrients that is appropriate to include in the NFP. A listing of "sugars/syrups" would be misleading because not all nutritive sweeteners are syrups, and whether a sweetener is in syrup form has no bearing on its nutritional properties. "Syrup" is merely a description of the physical form of an ingredient and has no bearing on the nutritional profile or ultimate properties of the finished food.

The Petition asserts that consumers are misled about the presence of HFCS in foods and beverages because few consumers are able to name HFCS as a sweetener, and many consumers

⁷⁸ See generally 21 C.F.R. § 101.9(c).

⁷⁹ See 21 C.F.R. § 101.4.

⁸⁰ See 21 C.F.R. § 101.9(c)(6)(ii). See generally 58 Fed. Reg. at 2095-2101.

⁸¹ 56 Fed. Reg. at 60436. See also, e.g., 58 Fed. Reg. at 2857 (identifying sucrose, HFCS, malt syrup, or honey).

May 10, 2006

are “unaware that FDA considers HFCS to be a ‘sugar.’”⁸² These assertions are unavailing. The presence of HFCS or any other corn sweetener must be specifically declared in the ingredient list. Moreover, the contribution of HFCS to the caloric value of food is included in the declaration for “sugars” in the NFP. Indeed, FDA has made clear that, “from a nutritional standpoint, the amount of added sugars is not significant information when considering overall sugar content. It is the total sugars content that has nutritional importance ... [and] this amount will be determinable through the nutrition label.”⁸³ Thus, consumers are fully informed about the presence of HFCS in their food based upon information contained in the ingredient list, and are fully informed about the amount of total sugars in food based on information contained in the NFP.

The Petition also cites recent government publications and a nutrition study to support the assertion that nutrition labeling about “sugars” confuses consumers. Contrary to the Petition’s contention, the 2005 Dietary Guidelines consumer brochure actually supports the adequacy of current ingredient and nutrition labeling requirements.⁸⁴ The brochure explains that consumers can check the ingredient list to identify added sugars and that “[s]ome names for added sugars (caloric sweeteners) include sucrose, glucose, [HFCS], corn syrup, maple syrup, and fructose.”⁸⁵

The Petition also argues that, because the U.S. Department of Agriculture’s (USDA) *My Pyramid* states that “added sugars are *sugars and syrups* that are added to foods or beverages,” the term “sugars” is considered by USDA to be “insufficient to accurately communicate to consumers the ingredients used as sweeteners” in foods.⁸⁶ The Petition misconstrues USDA’s

⁸² Petition at 23 (citing The Gallup Org., Sugar Ass’n Poll 11 and 34).

⁸³ 58 Fed. Reg. at 2859.

⁸⁴ See Petition at 23 (citing HHS, Finding Your Way to a Healthier You: Based on the Dietary Guidelines for Americans (2005), available at <http://www.healthierus.gov/dietaryguidelines>).

⁸⁵ HHS, Finding Your Way to a Healthier You: Based on the Dietary Guidelines for Americans at 6 (2005), available at <http://www.healthierus.gov/dietaryguidelines>.

⁸⁶ Petition at 23-24 (emphasis added) (citing USDA, MyPyramid.gov, Inside the Pyramid, Discretionary Calories: What Are “Added Sugars”?, available at http://www.mypyramid.gov/pyramid/discretionary_calories_sugars.html).

May 10, 2006

position by emphasizing this single reference to “syrops,” whereas many other USDA publications make no distinction between sugars and syrups in discussions about sweeteners.⁸⁷

Significantly, the Petition fails to mention that the *My Pyramid* article goes on to explain that:

Reading the ingredient label for processed foods can help to identify added sugars. Names for added sugars on food labels include: brown sugar, corn sweetener, corn syrup, dextrose, fructose, fruit juice concentrates, glucose, [HFCS], honey, invert sugar, lactose, maltose, malt syrup, molasses, raw sugar, sucrose, sugar, syrup.⁸⁸

USDA’s list makes clear that “syrops” are only one form and type of sugar. The Petition also cites a 2003 article to support its position that terminology to describe the sugars content of foods is “difficult” to understand.⁸⁹ However, the article supports the nutrition and ingredient labeling definitions of the terms “sugars” and “sugar,” and does not advocate “syrops” as a qualifying term to correct any alleged confusion about “sugars.”⁹⁰

Finally, the denomination of “sugars” instead of “sugars/syrups” in nutrition labeling is consistent with international food labeling laws and guidelines. FDA acknowledged this fact when it defined “sugars” as limited to monosaccharides and disaccharides.⁹¹ Canadian

⁸⁷ See, e.g., Stephen Haley, Jane Reed, Biing-Hwan Lin, & Annetta Cook, Sweetener Consumption in the United States: Distribution by Demographic and Product Characteristics (Econ. Research Serv., USDA Aug. 2005) (categorizing sweeteners as sugar, corn sweeteners (HFCS, glucose, and dextrose), honey, and “other edible syrups” (e.g., sorgo, maple and sugarcane syrup, edible molasses, and edible refiners syrup)).

⁸⁸ USDA, MyPyramid.gov, Inside the Pyramid, Discretionary Calories: What Are “Added Sugars”?, available at http://www.mypyramid.gov/pyramid/discetionary_calories_sugars.html.

⁸⁹ See Petition at 24 (citing Madeleine Sigman-Grant & Jaime Morita, *Defining and Interpreting Intakes of Sugars*, 78 Am. J. Clinical Nutrition, 815S (Supp. 78 2003)).

⁹⁰ See Madeleine Sigman-Grant & Jaime Morita, *Defining and Interpreting Intakes of Sugars*, 78 Am. J. Clinical Nutrition, 817S (Supp. 78 2003) (explaining that workshop attendees agreed that “sugars” refers to monosaccharides and disaccharides and “sugar” refers to sucrose; each definition is consistent with FDA’s labeling requirements for nutrition and ingredient labeling, respectively).

⁹¹ See 58 Fed. Reg. at 2097.

May 10, 2006

regulations specify that the nutrition label state the amount of “sugars,” not “sugars/syrups.”⁹² Similarly, the European Union requires nutrition labeling to specify “sugars,” which encompasses monosaccharides and disaccharides.⁹³ Other international nutrition labeling requirements are also analogous to nutrition labeling requirements in the United States. All of these authorities support the conclusion that use of the term “sugars” instead of “sugars/syrups” in nutrition labeling is accurate, truthful and not misleading.

E. There Is No Difference In Health Effects From Consumption Of Sucrose Versus Corn Sweeteners

Use of the term “sugars” to encompass nutritive sweeteners, including corn sweeteners and sucrose, in nutrition labeling is also supported by the fact that there is no difference in health impacts or outcomes from consumption of sucrose as compared to HFCS.

Corn sweeteners have been affirmed by FDA as generally recognized as safe (GRAS) to be added to foods.⁹⁴ When the agency affirmed the GRAS status of HFCS for direct addition to foods, including beverages, it explained that part of the basis for the GRAS listing was that “the saccharide composition (glucose to fructose ratio) of [HFCS] is approximately the same as that of honey, invert sugar, and the disaccharide sucrose,” which were already affirmed as GRAS.⁹⁵ Moreover the agency explained that because of the similarities between HFCS and sucrose, “any reported adverse health effects of sucrose consumption are likely to occur also from consumption of [HFCS].”⁹⁶ Other than the contribution to dental caries, FDA found no evidence that sucrose,

⁹² See Food and Drug Regulations § B.01.401 (Nutrition Labeling; Core Information) (Can.).

⁹³ Council Directive 90/496/EC, Article 1 § (4)(e).

⁹⁴ See 21 C.F.R. §§ 184.1857 (corn sugar; commonly called D-glucose or dextrose); 184.1865 (corn syrup; commonly called glucose sirup or glucose syrup); 184.1866 (HFCS).

⁹⁵ Proposed Affirmation of GRAS Status of High Fructose Corn Syrup; Proposed Rule; 53 Fed. Reg. 44904 (Nov. 7, 1988); GRAS Status of Corn Sugar, Corn Syrup, Invert Sugar, and Sucrose; Final Rule; 53 Fed. Reg. 44862 (Nov. 7, 1988).

⁹⁶ 53 Fed. Reg. at 44905.

May 10, 2006

corn sugar, or corn syrup are hazards to public health.⁹⁷ Indeed, the Petition itself cites numerous authoritative sources confirming the safety of sugars, including sucrose and corn sweeteners, and demonstrating that there is no direct link between sugars and lifestyle diseases.⁹⁸

An Expert Panel commissioned by the International Life Sciences Institute (ILSI) in 1993 thoroughly reviewed the literature on fructose and purported adverse health effects.⁹⁹ The Panel concluded that “fructose is a valuable, traditional source of food energy, and there is no basis for recommending increases or decreases in its use in the general food supply or in special dietary use products.”

There is also no scientific evidence to show that sucrose and HFCS are metabolized differently. The Petition states that there is concern about “increasing consumption of free (chemically unbonded) fructose from increased intakes of fructose-enriched corn syrups.”¹⁰⁰ Based on two studies, it asserts that “limited” available data “generally supports the view that fructose molecularly bonded in sucrose generates physiologic effects distinct from those established by molecularly free fructose.”¹⁰¹ These studies, however, offer no proof that monosaccharide fructose is metabolically different from disaccharide fructose. Neither study included test variables that would support the Petition’s assertion. Rather, the studies are merely

⁹⁷ See *id.* at 44906. See also Direct Food Substances Affirmed as Generally Recognized as Safe; High Fructose Corn Syrup; Final Rule; 61 Fed. Reg. 43447 (Aug. 23, 1996); Substances Generally Recognized as Safe; High Fructose Corn Syrup and Insoluble Glucose Isomerase Enzyme Preparations; Final Rule; 48 Fed. Reg. 5716, 5718 (Feb. 8, 1983) (stating that HFCS is “as safe as sucrose, corn sugar, corn syrup, and invert sugar”).

⁹⁸ See Petition at 4-5 (citing, for example, reports the FDA Sugar Task Force Report, National Academy of Sciences Report on Diet and Health, and a joint report by the Food and Agricultural Organization of the United Nations and the World Health Organization).

⁹⁹ Forbes AL and BA Bowman, eds. Health Effects of Dietary Fructose. *Am J Clin Nutr.* 1993;58(5S):721S-823S.

¹⁰⁰ *Id.* at 16.

¹⁰¹ *Id.* at 16, n.68 (citing 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 (Supp. 5, 2002); Hella Jurgens et al., *Consuming Fructose-sweetened Beverages Increases Body Adiposity in Mice*, 13 *Obesity Research* 1146, 1156 (2005)).

May 10, 2006

examples of investigations into the effects of nearly pure fructose, which is not the same substance as HFCS. The Anderson, et al. (2002) study¹⁰² involved three different experiments, only one of which tested sucrose against a fructose-glucose mixture, among other substances; however, the fructose-glucose mixture contained 80% fructose and 20% glucose, a ratio that is clearly not intended to simulate HFCS or any other corn syrup.¹⁰³ Similarly, the Jurgens, et al. (2005) study¹⁰⁴ did not make a direct comparison between HFCS and sucrose. Instead, that study tested pure fructose (15% solution in water), a sucrose-sweetened soft drink (10% sucrose in solution), and a noncaloric diet soft drink. Based upon the designs in both the Anderson, et al. (2002) and Jurgens, et al. (2005) studies, these studies do not support the Petition's position that "free" fructose in HFCS or any other fructose-enriched corn syrup would generate a different metabolic response than "bonded" fructose present in sucrose.

There are studies not cited in the Petition that confirm there is little metabolic difference between sucrose and HFCS when the two are compared directly. Akgun and Ertel showed similar metabolic effects on plasma glucose in diabetic subjects with sucrose and HFCS.¹⁰⁵ Melanson et al recently compared the effects of HFCS and sucrose sweetened beverages consumed with isocaloric diets on several metabolic parameters. They reported no differences

¹⁰² 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 (Supp. 5, 2002) (cited in Petition at 16, n.68).

¹⁰³ Indeed, glucose was only added to the fructose-glucose mixture in this study to permit consumption of fructose without poor side effects. *See id.* at 1024. The authors explained that "[a] mixture of fructose and glucose, rather than fructose alone, was given as a treatment in experiment 3 because <50% of the population has a limited absorptive capacity for fructose and presents with symptoms of nausea and diarrhea after consuming as little as 25 g fructose. To increase fructose absorption, 20% glucose was added to the fructose preload in our study." *Id.* at 1029 (citations omitted).

¹⁰⁴ Hella Jurgens et al., *Consuming Fructose-sweetened Beverages Increases Body Adiposity in Mice*, 13 Obesity Research 1146, 1156 (2005) (cited in Petition at 16-17, n.68).

A. ¹⁰⁵ Akgun S and NH Ertel. The effects of sucrose, fructose, and high-fructose corn syrup meals on plasma glucose and insulin in non-insulin-dependent diabetic subjects. *Diabetes Care*. 1985;8(3):279-283.

May 10, 2006

between HFCS and sucrose on glucose, leptin, insulin and ghrelin levels.¹⁰⁶ And Perrigue et al also recently compared the effect of soft drinks sweetened with sucrose versus HFCS on hunger, satiety and energy. They detected no differences in hunger, fullness, thirst, desire to eat or energy intake between sugar-sweetened soft drinks, milk or aspartame-sweetened soft drinks.¹⁰⁷

Finally, in a 2005 review of the scientific literature, Schorin concluded that HFCS is absorbed and metabolized in a manner similar to sucrose.¹⁰⁸

The Petition asserts that “[i]t is important to distinguish different health outcomes associated with different sugars just as we differentiate different health outcomes of individual dietary fatty acids.”¹⁰⁹ Current nutrition labeling distinguishes between different dietary fatty acids by requiring declarations of saturated fat and *trans* fat under the declaration of “total fat.”¹¹⁰ FDA has explained that information about the amount of saturated and *trans* fats in foods is necessary in food labeling because these substances raise total blood and low-density lipoprotein (LDL) cholesterol levels and create a risk of coronary heart disease.¹¹¹ Moreover, the separate listing of saturated fats and *trans* fats is required because it “will help consumers understand that *trans* fat is chemically distinct from saturated fat and will assist them in maintaining healthy dietary practices.”¹¹² Nutrition labeling for “sugars” is not analogous to nutrition labeling for fats because there is no scientific evidence supporting any distinction between sucrose and HFCS or other corn sweeteners. There are no disparate health or safety

¹⁰⁶ Melanson KJ, et al. Similar effects of high fructose corn syrup and sucrose consumption on circulating levels of glucose, leptin, insulin and ghrelin. *Experimental Biology*. Abstract # 391.2, 2006.

¹⁰⁷ Perrigue M. Hunger and satiety profiles and energy intakes following the ingestion of soft drinks sweetened with sucrose or high fructose corn syrup (HFCS). *Experimental Biology*. Abstract # _____, 2006.

¹⁰⁸ Schorin MD. High fructose corn syrups, part 1. *Nutrition Today*. 2005;40(6):248-252.

¹⁰⁹ Petition at 16-17.

¹¹⁰ See 21 C.F.R. § 101.9(c)(2).

¹¹¹ See, e.g., 58 Fed. Reg. at 2088-89; Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims; Final Rule; 68 Fed. Reg. 41434 (July 11, 2003).

¹¹² 68 Fed. Reg. at 41436.

May 10, 2006

concerns that would warrant separate declarations for these substances in the NFP in order to assist consumers in maintaining health dietary practices.

III. Current Ingredient Labeling Requirements Fully Inform Consumers About The Identity Of Specific Sweeteners In Food

Throughout the Petition, the Sugar Association argues that use of the terms “sugars” and “sugar” to refer to nutritive sweeteners other than sucrose is misleading. As discussed above, these terms accurately and appropriately encompass all monosaccharides and disaccharides for purposes of nutrition labeling, including the NFP and nutrient content claims. However, for purposes of *ingredient* labeling, the term “sugar” is limited to sucrose. This satisfies the purposes of ingredient labeling and assures that consumers are informed regarding the source of each sweetener.

A. Nutrition And Ingredient Labeling Have Different Purposes And Goals

As previously stated, the purpose of nutrition labeling is to “serve[] as a source of specific information for consumers concerning the nutritional value of food.”¹¹³ Ingredient labeling has a different purpose: to specifically identify and distinguish among the different ingredients in food. The ingredient list is “intended to assist consumers with purchase decisions by providing them with information on the relative levels of ingredients in the food.”¹¹⁴ FDA has explained that ingredient listing requirements are not intended “to assure that the food label provides consumers with all the information they may need” because there are other labeling regulations, such as those for nutrition labeling, that “provide additional, more specific, consumer assistance.”¹¹⁵ FDA explained the following concerning nutrition versus ingredient labeling:

¹¹³ 56 Fed. Reg. at 60436.

¹¹⁴ Food Labeling; Declaration of Ingredients; Proposed Rule; 56 Fed. Reg. 28592 (June 21, 1991).

¹¹⁵ *Id.*

May 10, 2006

FDA is requiring the declaration of total sugars in the nutrition label. [FDA] believes that information on the quantity of sugars in a finished food product is more effectively conveyed as part of nutrition labeling, than ingredient labeling. The total amount of sugars, including both added and indigenous sugars, is declared in the nutrition label, whereas the information on sugars content provided through ingredient labeling includes only added sweetening ingredients in order of predominance by weight. The ingredient label does not give information regarding the amounts of those sugars.¹¹⁶

Because nutrition and ingredient labeling serve different purposes, they convey different kinds of information. FDA was fully aware of this difference when it defined the term “sugar” differently for nutrient content claims and ingredient labeling: “[I]n the ingredient label, the term ‘sugar’ is limited to sucrose, and ... the broader term ‘sugars’ [is used] in the nutrition label.”¹¹⁷

B. Ingredient Labeling Clearly Identifies Specific Sweeteners In Food

FDA regulations require each ingredient in a food to be listed on the food label.¹¹⁸ The ingredient declaration must identify each ingredient by its common or usual name in order of predominance by weight. The name of the ingredient must be a “specific name and not a collective (generic) name”;¹¹⁹ however, there are some exceptions, including one for the generic name “sugar.” This exception provides that “[f]or purpose of ingredient labeling, the term *sugar* shall refer to sucrose, which is obtained from sugar cane or sugar beets in accordance with the provisions of § 184.1854.”

Section 184.1854 provides that sucrose is sucrose sugar, cane sugar, or beet sugar.¹²⁰ Because FDA has determined that “sucrose is the only sweetener that has traditionally been referred to as ‘sugar’ by industry and consumers,” it consequently concluded that “use of this

¹¹⁶ 58 Fed. Reg. at 2858.

¹¹⁷ 56 Fed. Reg. at 60436.

¹¹⁸ See 21 C.F.R. § 101.4(a).

¹¹⁹ 21 C.F.R. § 101.4(b).

¹²⁰ 21 C.F.R. § 184.1854(a). See also 53 Fed. Reg. 44870 (Nov. 7, 1988).

May 10, 2006

term in the ingredient list is not misleading.”¹²¹ Accordingly, the agency has “traditionally held that the term ‘sugar’ in an ingredient list means ‘sucrose’ and does not include other sugars.”¹²²

Because an ingredient list denoting “sugar” only conveys that sucrose has been added to the food, the ingredient list must also identify other added sweeteners, if any. During rulemaking for ingredient labeling requirements, FDA considered requiring that all sweeteners be grouped together parenthetically in the ingredient list, instead of requiring that each ingredient be separately declared.¹²³ The agency ultimately chose to forego this option and required the separate identification of each sweetener ingredient instead.¹²⁴

FDA recently reaffirmed the current regulatory requirement for listing individual sweetener ingredients in its consideration of “and/or” labeling of nutritive sweeteners in soft drinks. In the past, some soft drink manufacturers often listed sweeteners in their products with an “and/or” designation, such as “high fructose corn syrup and/or sugar.” Last summer, FDA confirmed that “and/or” labeling may not be used for HFCS and sugar in soft drinks.¹²⁵ The agency reminded the soft drink industry of current labeling requirements and encouraged manufacturers “to review the ingredient statements on their soft drink labels and assure that the

¹²¹ 58 Fed. Reg. at 2857.

¹²² 56 Fed. Reg. at 60435. *See also* 58 Fed. Reg. at 2857.

The Sugar Association provided the impetus for defining “sugar” as sucrose for purposes of ingredient labeling. In a separate petition, the Sugar Association argued the narrower definition of “sugar” was necessary “due to the ever-increasing number of beverages that list sugar as part of their ingredient list when such beverages either fail to contain any sucrose whatsoever or contain a blend of sucrose with other sweeteners.” 56 Fed. Reg. at 28606. According to FDA, that petition included a variety of documents to support the Sugar Association’s petition to establish that “sucrose is the only sweetener that has traditionally been referred to as ‘sugar’ by industry, consumers, and government regulatory agencies.” *Id.*

¹²³ *See* 56 Fed. Reg. 28592; 58 Fed. Reg. at 2857.

¹²⁴ *See* 58 Fed. Reg. at 2858-59.

¹²⁵ *See* CFSAN/Office of Nutritional Products, Labeling, and Dietary Supplements, Letter to Food Manufacturers about “And/Or” Ingredient Labeling of Nutritive Sweeteners in Soft Drink Products, from Barbara O. Schneeman, Director, ONPLDS, CFSAN, FDA (dated July 5, 2005), available at <http://www.cfsan.fda.gov/~dms/fl-ltr5.html>.

May 10, 2006

sweetening ingredients in the product are listed accurately.”¹²⁶ This approach dispels any notion that consumers can be misled about the types of sweeteners added to their foods. Consumers cannot be misled about whether a food contains “sugar” or “HFCS” or another sweetener because the ingredient list is required to separately declare each of them. Indeed, based on its comments to the agency on this issue, the Sugar Association would agree that “and/or” labeling was misleading and the prohibition against this type of labeling remedies any consumer confusion or deception about the sweetener ingredients in foods.¹²⁷

In fact, FDA advises consumers to refer to the ingredient list to identify specific sugars or other ingredients in a food. For example, FDA explains the following to consumers:

If you are concerned about your intake of sugars, make sure that added sugars are not listed as one of the first few ingredients. Other names for added sugars include: corn syrup, high-fructose corn syrup, fruit juice concentrate, maltose, dextrose, sucrose, honey, and maple syrup.¹²⁸

Because the ingredient list clearly identifies specific sweeteners by their common or usual name and in order of predominance, including sucrose and HFCS, one cannot reasonably argue that consumers are misled about the presence of these ingredients in food.

IV. Conclusion

The Petition’s requests to limit use of the term “sugar” to refer only to sucrose and to recast the “sugars” category in the NFP as “sugars/syrups” are unnecessary and inappropriate. Current sweetener labeling requirements reflect longstanding and well-accepted practices, and

¹²⁶ *Id.*

¹²⁷ *See, e.g.*, Letter to David M. Kessler, Comm’r, FDA, from Sarah Barnett, Vice Pres. Public Affairs, The Sugar Ass’n (dated Aug. 15, 1996) (stating that “and/or” labeling permitted “economic fraud and consumer deception to be perpetrated on American consumers” and requesting that the agency enforce its regulations prohibiting this type of labeling).

¹²⁸ *See, e.g.*, FDA/CFSAN, “How to Understand and Use the Nutrition Facts Label,” *available at* <http://www.cfsan.fda.gov/~dms/foodlab.html> (June 2000, Updated July 2003 and Nov. 2004). *See also* USDA, MyPyramid.gov, Inside the Pyramid, Discretionary Calories: What Are “Added Sugars”?, *available at* http://www.mypyramid.gov/pyramid/discetionary_calories_sugars.html.

May 10, 2006

are consistent with the purposes of nutrition labeling. There are no differences in nutritional properties or health effects between HFCS and sucrose that would justify any revision in nutrition labeling requirements. The separate requirements for ingredient labeling accurately inform consumers about the identity and source of each sweetener used in food. Accordingly, FDA should take no action on these aspects of the Petition.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "A. Erickson".

Audrae Erickson
President