

EXHIBIT 34



Food and Drug Administration
College Park, MD 20740

MAY 30 2012

Ms. Audrae Erickson
President
Corn Refiners Association
1701 Pennsylvania Avenue, N.W.
Suite 950
Washington, DC 20006-5805

Re: Docket No. FDA-2010-P-0491

Dear Ms. Erickson:

This letter responds to your citizen petition filed on September 14, 2010, as supplemented on July 29, 2011. After careful review of your citizen petition and for the reasons described below, the Food and Drug Administration (FDA) is denying your petition in accordance with 21 CFR 10.30(e)(3).

In your petition, you asked us to authorize "corn sugar" as an alternate common or usual name for high fructose corn syrup (HFCS). Specifically, you requested that we amend (1) the generally recognized as safe (GRAS) affirmation regulation for HFCS (21 CFR 184.1866) to designate "corn sugar" as an optional name for HFCS; (2) the standard of identity for dextrose monohydrate (21 CFR 168.111) to eliminate "corn sugar" as an alternate name for dextrose; and (3) the GRAS affirmation regulation for corn sugar (21 CFR 184.1857) to replace all references to "corn sugar" with "dextrose."

As explained below, your petition does not provide sufficient grounds for the agency to authorize "corn sugar" as an alternate common or usual name for HFCS.

First, you contend consumers are confused by the name "high fructose corn syrup" and that the proposed alternate name "corn sugar" more closely reflects consumer expectations and more accurately describes the basic nature of HFCS and its characterizing properties. You base this on the following: You state that HFCS and sugar are equivalent by every parameter of relevance to consumers, for example, that they have equivalent ratios of fructose and glucose and both are metabolized similarly in the body. Based on a consumer research study, you state that many consumers are confused by the name "high fructose corn syrup," that consumers incorrectly believe that HFCS is significantly higher in calories, fructose, and sweetness than sugar, and that the term "corn sugar" more accurately reflects the properties of HFCS based on consumer ratings of this alternative name on these attributes compared to sugar. You cite other evidence of consumer confusion regarding the characteristics of HFCS. You also state that the name "corn sugar" as an alternate common or usual name for HFCS fully

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satisfies the criteria for common or usual names under 21 CFR 102.5(a) because “corn sugar” accurately reflects the source of the food (corn), identifies the basic nature of the food (a sugar), and discloses the food’s function (a sweetener).

However, FDA’s regulatory approach for the nomenclature of sugar and syrups is that sugar is a solid, dried, and crystallized food; whereas syrup is an aqueous solution or liquid food. FDA’s regulations permit the term “sugar” as part of the name for food that is solid, dried, and crystallized, specifically the standards of identity for dextrose monohydrate (21 CFR 168.111) and lactose (21 CFR 168.122), and the GRAS regulation for sucrose (21 CFR 184.1854).¹ FDA’s regulations provide for the terms “syrup” or “sirup” for food that is liquid or is an aqueous solution, specifically the standards of identity for glucose sirup (21 CFR 168.120), cane sirup (21 CFR 168.130), maple sirup (21 CFR 168.140), sorghum sirup, (21 CFR 168.160), and table sirup (21 CFR 168.180). FDA’s approach is consistent with the common understanding of sugar and syrup as referenced in a dictionary.²

Consequently, the use of the term “corn sugar” for HFCS would suggest that HFCS is a solid, dried, and crystallized sweetener obtained from corn. Instead, HFCS is an aqueous solution sweetener derived from corn after enzymatic hydrolysis of cornstarch, followed by enzymatic conversion of glucose (dextrose) to fructose. Thus, the use of the term “sugar” to describe HFCS, a product that is a syrup, would not accurately identify or describe the basic nature of the food or its characterizing properties. As such, using the term “sugar” would not be consistent with the general principles governing common or usual names under 21 CFR 102.5.

Second, with regard to your request to amend both the standard of identity for dextrose monohydrate (21 CFR 168.111) to eliminate “corn sugar” as an alternative name, and the GRAS affirmation regulation for corn sugar (21 CFR 184.1857) to replace the term “corn sugar” with “dextrose,” your petition states that consumers do not commonly associate the term “corn sugar” with dextrose. You also contend that there is strong evidence³ that the term “dextrose” is widely used on food labels to describe ingredients covered by the

¹ The GRAS affirmation regulation for invert sugar (21 CFR 184.1859), which is an aqueous solution of inverted or partly inverted, refined or partly refined sucrose, is not relevant to FDA’s approach to sugar and syrup nomenclature. The GRAS affirmation regulation describes sucrose (sugar) that is inverted. This is irrelevant to the naming of other food substances as _____ sugar to indicate the carbohydrate with its source (e.g., “milk sugar” for lactose (21 CFR 168.122) and “corn sugar” for dextrose derived from corn (21 CFR 168.111)). In the case of invert sugar, the substance originates from sugar (sucrose).

² Sugar is defined as “a sweet, crystalline substance, $C_{12}H_{22}O_{11}$, obtained chiefly from the juice of the sugarcane and the sugar beet, and present in sorghum, maple sap, etc.: used extensively as an ingredient and flavoring of certain foods and as a fermenting agent in the manufacture of certain alcoholic beverages; sucrose.” Syrup, on the other hand, is defined as “any of various thick, sweet liquids prepared for table use from molasses, glucose, etc., water, and often a flavoring agent.” Random House Dictionary, © Random House, Inc. 2012.

³ Based on your discussion of Mintel’s data on ingredients that are used in new food products launched in the U.S. between January 1, 2004 and June 16, 2010.

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dextrose standard of identity, and that the terms “corn sugar” and “corn sugar monohydrate” are seldom used on food labels.

However, the petition does not support amending FDA’s longstanding regulations, which describe and define corn sugar as “dextrose,” to instead identify corn sugar as an alternative name for a sweetener that is different from dextrose. We are not persuaded by the arguments in the petition that consumers do not associate “corn sugar” with dextrose. The term “corn sugar” has been used to describe dextrose for over 30 years. The Select Committee on GRAS Substances used the term “corn sugar” to describe dextrose as early as 1976⁴. FDA proposed in 1982 and finalized in 1988 its GRAS affirmation regulation for corn sugar (21 CFR 184.1857)⁵. FDA amended in 1993 the standard of identity for dextrose monohydrate (21 CFR 168.111) to allow “corn sugar” as a permissible name.⁶

In addition, a search of the scientific literature⁷ and various public websites demonstrates that “corn sugar” is often the term that is used to describe dextrose. Examples of definitions and the use of the term “corn sugar” to refer to dextrose in online dictionaries⁸ and other websites include corn sugar sold as food,⁹ description as a food ingredient,¹⁰ and use in beer brewing.¹¹

⁴ Select Committee on GRAS Substances Opinion: Corn Sugar (Dextrose), ID Code 50-99-7, 1976.

⁵ 47 FR 53917 (Nov. 30, 1982); 53 FR 44876 (Nov. 7, 1988)

⁶ One public comment in the rulemaking process stated that identifying corn as a food source is of concern to Jews observing dietary laws during Passover (58 FR 2850 at 2865, January 6, 1993).

⁷ William H. Peck and Stephanie C. Tubman, “Changing Carbon Isotope Ratio of Atmospheric Carbon Dioxide: Implications for Food Authentication,” Journal of Agricultural and Food Chemistry, Feb 24, 2010, 58 (4): 2364-7.

Martin P Day, Patricia Correia, and David A. Hammond, “C-IRIS: An Improved Method to Detect the Addition of Low Levels of C₄-Derived Sugars to Juices,” Journal of AOAC International, May-Jun 2001, 84(3): 957-63.

J.M. Dunn and V.C. Speer, “Nitrogen Requirement of Pregnant Gilts,” Journal of Animal Science, May 1991, 69(5): 2020-5.

“Glucose (“Corn Sugar,” So-Called) in Foods Undeclared on Labels,” American Journal of Public Health, Oct 1930, 20(10): 1121-2.

⁸ The American Heritage Dictionary:

<http://www.thefreedictionary.com/corn+sugar>

Merriam-Webster Dictionary:

<http://www.merriam-webster.com/dictionary/corn+sugar?show=0&t=1305828930>. It notes that the word “corn sugar” was first used in 1850.

⁹ http://goodbrewerstore.com/index.php?main_page=index&cPath=2_11, <http://www.brewps.com/corn-sugar-34-cup-to-prime-5g-bps-mxd00sugar.html>, and <http://www.annapolishomebrew.com/shopEXTos.asp>

¹⁰ http://recipes.wikia.com/wiki/Corn_sugar

¹¹ <http://www.beertools.com/html/tutorial/phase03/step02.php>

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Moreover, “corn sugar” has been known to be an allowed ingredient for individuals with hereditary fructose intolerance or fructose malabsorption,¹² who have been advised to avoid ingredients that contain fructose.¹³ ¹⁴ Because such individuals have associated “corn sugar” to be an acceptable ingredient to their health when “high fructose corn syrup” is not, changing the name for HFCS to “corn sugar” could put these individuals at risk and pose a public health concern.

For the reasons discussed above, we conclude that your petition does not provide sufficient grounds for the agency to authorize “corn sugar” as an alternate common or usual name for HFCS. Therefore, FDA is denying your petition in accordance with 21 CFR 10.30(e)(3).

Sincerely yours,



Michael M. Landa
Director
Center for Food Safety
and Applied Nutrition

¹² <http://www.diet.com/g/fructose-intolerance>

¹³ Hereditary fructose intolerance is a condition that affects a person's ability to digest the sugar fructose. The incidence of hereditary fructose intolerance is estimated to be 1 in 20,000 to 30,000 individuals each year worldwide. In people with fructose malabsorption, the cells of the intestine cannot absorb fructose normally, leading to bloating, diarrhea or constipation, flatulence, and stomach pain. Fructose malabsorption is thought to affect approximately 40 percent of individuals in the Western hemisphere; its cause is unknown. <http://ghr.nlm.nih.gov/condition/hereditary-fructose-intolerance>

¹⁴ <http://www.gastro.org/patient-center/diet-medications/food-allergies-fructose-intolerance-and-lactose-intolerance#Fructose%20Intolerance> and <http://www.bu.edu/aldolase/HFI/hfiinfo/detail.html>