IDFA and NMPF Petition to Amend the Milk and Milk Product Standards of Identity to Permit Non-Nutritive Sweeteners
March 2009

**Issue:** The present federal standard of identity for milk (21 CFR §131.110) includes a list of permitted ingredients, such as "Characterizing flavoring ingredients (with or without coloring, nutritive sweeteners, emulsifiers and stabilizers." However, the milk standard does not allow for non-nutritive sweeteners (low or no calorie sweeteners) to be included in a product labeled as "Milk," "Chocolate Milk" or "Strawberry Milk." Non-nutritive sweeteners such as Aspartame (NutraSweet™), Sucralose (Splenda™), Acesulfame-K (Ace-K) , and rebaudioside A (rebiana) have been found safe by FDA and are permitted for use in other foods and beverages, including many competitive products such as juice beverages and diet soda.

**Background:** Non-nutritive sweeteners may be used in milk products, but only under certain circumstances. Products that don't meet the milk standard can use these low calorie sweeteners if labeled as "milk drink' or "milk beverages." In addition, non-nutritive sweeteners are permitted in flavored milk when the product is formulated to meet an FDA-approved nutrient content claim, such as "Reduced-Sugar Chocolate Milk" or "Reduced-Calorie Chocolate Milk." But the ingredients must be flagged with an asterisk and include the statement "*Ingredients not in regular milk." The current standard also limits the ability for milk to qualify for an FDA nutrient content claim because the level of sugar reduction or calorie reduction must be greater than 25 percent.

IDFA was successful in 1998 in amending the standards of identity for ice cream and frozen desserts to allow for the use of alternative non-nutritive sweeteners, such as aspartame and acesulfame potassium in the manufacture of products labeled ice cream. IDFA believes that a petition to amend the standard for milk to permit any type of safe and suitable non-nutritive sweetener would be important to allow for a level playing field for flavored milks and other sweetened milk products. This initiative is well timed as policy makers, school nutritionists, health professionals and parents are demanding lower calorie foods and beverages to help stem the obesity crisis. Dairy products like milk should not be stigmatized with outdated regulations that prohibit the use of these novel low calorie sweeteners.

**Actions:** IDFA and National Milk Producers Federation have jointly filed a citizen's petition with FDA to request an amendment to the federal standard of identity for milk and milk products to include any safe and suitable sweetener as a permitted ingredient. This change will allow for both nutritive sweeteners and non-nutritive sweeteners in any milk or milk products such as flavored milk, eggnog, yogurt, and sweetened creams. It is not known how quickly FDA will act on this request, but typically changes to the standards of identity take at least three years due to the need for formal rulemaking.

For more information, contact Cary Frye, IDFA vice president of regulatory affairs, at cfrey@idfa.org or (202) 220-3543.
March 10, 2009

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Food and Drug Administration
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CITIZEN PETITION

The undersigned, International Dairy Foods Association (“IDFA”) and National Milk Producers Federation (“NMPF”) submit this petition under sections 401 and 701(e) of the Federal Food, Drug, and Cosmetic Act (“FD&C Act”), 21 U.S.C. §§ 341 and 371(e), to request the Food and Drug Administration (“FDA” or the “agency”) to amend the standard of identity for milk, 21 C.F.R. § 131.110, to include optional characterizing flavoring ingredients with any safe and suitable sweetener. In the interest of administrative efficiency, IDFA also requests that the agency amend the standards of identity for seventeen additional dairy products to provide for the use of any safe and suitable sweetener in these products as well.

IDFA represents the nation's dairy manufacturing and marketing industries and their suppliers, with a membership of 570 companies representing a $90 billion a year industry. IDFA's members manufacture more than 85 percent of milk produced and marketed in the United States.

The National Milk Producers Federation, based in Arlington, VA, develops and carries out policies that advance the well being of dairy producers and the cooperatives they own. The members of NMPF’s 31 cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of more than 40,000 dairy producers on Capitol Hill and with government agencies.

A. Action Requested

IDFA and NMPF request the agency to amend the standard of identity for milk, 21 C.F.R. § 131.110, as follows:
§ 131.110 Milk

... (c) *Optional ingredients.* The following safe and suitable ingredients may be used.

(1) Carriers for vitamins A and D.

(2) Characterizing flavoring ingredients (with or without coloring, *any safe and suitable* sweetener, emulsifiers, and stabilizers) as follows:

(i) Fruit and fruit juice (including concentrated fruit and fruit juice).

(ii) Natural and artificial food flavorings.


B. *Statement of Grounds*

Promoting more healthful eating practices and decreasing childhood obesity is one of the most pressing problems facing our country today. One small but valuable step towards achieving that goal would be to update the FDA’s standard of identity for “milk” to include flavored milk (e.g., chocolate milk) that is sweetened with any “safe and suitable” sweetener, not just with sugar or other nutritive sweetener. Milk is a nutritious beverage and the leading source of calcium. The Dietary Guidelines have recommended increased milk consumption by children and teenagers.

Yet, consumption of milk in schools is declining. Studies have shown that school-age children are more likely to consume flavored milk over regular milk, so if the downward trend in milk consumption in schools is to be reversed, there need to be better options available for lower calorie flavored milk. This can be readily achieved by providing milk producers the option of using any “safe and suitable” sweetener in flavored milk—and still call the product “milk.”

The FDA has already updated the ice cream standard for just this very purpose. Doing the same for milk would: (a) incorporate into the standard the ability to use several new sweeteners that have been approved by the FDA since the milk standard of identity was promulgated; (b) promote the public health by providing for a lower calorie, nutritious food consumed largely by children; (c) and meet the laudatory goals of several new legislative initiatives aimed at improving the nutrition and health profile of food served in our nation’s schools.
Finally, updating the food standard of identify for “milk” in this way would promote honesty and fair dealing in the interest of milk consumers by facilitating the sale of flavored milk containing less sugar and fewer calories from sweeteners than the flavored products currently labeled as “milk.”

Additional information in support of this Petition is provided below.

1. The Petition Would Permit the Use in Flavored “Milk” of New Sweeteners Approved by FDA and Widely Used in the Food and Beverage Industries.

   Although the food and beverage industry has developed a number of FDA-approved non-nutritive sweeteners (low or no calorie sweeteners used as sugar substitutes), the standard of identity for milk has not been modified to reflect these developments. In the 1950s, FDA issued standards of identity for milk products including cream, evaporated milk, concentrated milk, sweetened condensed milk, and dried skim milk. 21 C.F.R. § 131.18 (1956). In the 1970s, a standard of identity was added for flavored and unflavored milk, which permitted processors to use nutritive sweeteners to flavor products labeled as “milk.” At the time, saccharin was the only non-nutritive sweetener available in the United States, and its continued use was uncertain. Kathleen Meister, Sugar Substitutes and Your Health 10 (American Council for Science and Health, Inc. 2006), available at http://www.acsh.org/docLib/20060417_sugar_web.pdf. As a result, the milk standard was drafted to include “characterizing flavoring ingredients (with or without coloring, nutritive sweetener, emulsifiers, and stabilizers)” as optional ingredients in milk. 21 C.F.R. § 131.18.2 (1974) (emphasis added). Processors could use nutritive sweeteners, i.e. sucrose, to flavor milk. They could not, however, use non-nutritive sweeteners in products labeled “milk.”

   Since the 1970s, at least five non-nutritive sweeteners have been found safe by FDA and are permitted for use in foods and beverages, including juice beverages and diet soda. The sweeteners include: aspartame (“NutraSweet™”), sucralose (“Splenda™”), acesulfame-K (“Ace-K”), neotame, and saccharin. Aspartame is approved as a food additive for use as a sweetening agent and flavor enhancer in foods. 21 C.F.R. § 172.804. FDA only restricts the amount of aspartame that can be used in baked goods, baking mixes, or as a sugar substitute tablet. Id. Sucralose, acesulfame-K, and neotame are approved food additives for use in food generally, in accordance with current good manufacturing practice and in amounts not to exceed that reasonably required to accomplish the intended technical effect. Id. §§ 172.800, 172.829, 172.831. Saccharin may be added to beverages to achieve a valid dietary purpose in amounts not to exceed 12 milligrams per ounce or for an authorized technological purpose other than calorie reduction. Id. § 180.37.

   The standard of identity for milk should be amended to account for the development of these safe, non-nutritive sweeteners that can serve as a sugar substitute in flavored milk. There is ample precedent among dairy products for FDA to take this action. In 1995, FDA similarly amended the standard for ice cream to allow for “any safe and suitable sweetener” to be used in ice cream rather than only “nutritive carbohydrate sweeteners.” 59 Fed. Reg. 47,072 (Sept. 14, 1994). As a result, non-nutritive sweeteners, such as aspartame and acesulfame-K, may be used in the manufacture of products labeled as “ice cream.” Likewise, permitting milk manufacturers to use non-nutritive sweeteners in products labeled as “milk” would increase the availability of...
nutritious, flavored milks with lower calories than current flavored milks. This petition is consistent with FDA’s modification of the ice cream standard and its efforts to revise outdated regulatory restrictions that discourage the marketing of new food products with lower calorie content.

2. The Petition Would Promote Public Health by Providing Consumers with Lower Calorie Versions of Flavored “Milk.”

Milk provides children with a wide variety of vitamins and minerals and is recommended as part of their daily diet. Furthermore, children are more inclined to drink flavored milk than unflavored milk at school. Milk flavored with non-nutritive sweetener has a lower calorie content than milk flavored with nutritive sweetener. Therefore, this petition serves FDA’s policy objective of promoting healthy lifestyles by encouraging the marketing of lower calorie, nutritious, flavored milks to school-aged children.

Milk is a key source of macronutrients, magnesium, phosphorus, vitamin D, vitamin A, riboflavin, vitamin B₁₂, zinc, and potassium for children and teenagers. Mary M. Murphy, et al., Drinking Flavored or Plain Milk is Positively Associated with Nutrient Intake and Is Not Associated with Adverse Effects on Weight Status in U.S. Children and Adolescents, 108 J. Am. Diet. Assoc. 631, at 631. Milk also provides the most important source of calcium in children’s diets and accounts for 75 percent of the calcium available in the U.S. food supply. Rachel K. Johnson, The Nutritional Consequences of Flavored-Milk Consumption by School-Aged Children and Adolescents in the United States, 102 J. Am. Diet. Assoc. 853, at 853. Although the Dietary Guidelines for Americans recommend children of ages two to nine consume two cups of fat-free or low-fat milk per day, only about one third to one half of American children meet that recommendation. Id. The Dietary Guidelines also recommend people ages nine and older consume three servings of dairy per day, but only one third of adolescent boys and fewer than one in five girls consume this recommended amount. Id.

Flavored milk served in schools is particularly valuable in child and adolescent nutrition efforts. Servings of unflavored and flavored milk provide essentially identical amounts of protein, calcium, phosphorus, magnesium, vitamin A, riboflavin, and potassium. Murphy, supra, at 631-32. Furthermore, children greatly prefer flavored milk over unflavored milk. About 70 percent of all milk consumed in schools is flavored. When the New York City health department recently limited flavored milk sales in a group of test schools, overall milk consumption in the schools declined by ten to fifteen percent. Id. According to the American Dietetic Association, compared to their peers, children who drink flavored milk drink more milk overall and are more likely to meet their calcium needs without consuming more total fat and calories. Johnson, supra, at 853-56. As a result, these children get more of the nutrients they need for healthy growth and development.

In spite of its nutritional benefits, milk flavored with nutritive sweeteners has a higher calorie content from sugar than plain milk. A serving of low-fat plain milk provides approximately 100 calories whereas a serving of low-fat flavored milk made with nutritive sweeteners contains approximately 160 calories. Murphy, supra, at 632.
Milk flavored with non-nutritive sweetener promotes public health by offering children and adolescents a beverage they are more likely to consume than plain milk and that has all of the nutritional benefits of milk and less sugar than milk flavored with nutritive sweetener. Whether milk is flavored with a non-nutritive sweetener, such as aspartame, or a nutritive sweetener, such as sucrose, there is no difference in the amount of flavored milk that children consume. J.F. Wilson, Lunch Eating Behavior of Preschool Children, 70 Physiol. Behav. 27-33 (2000). Overall, however, more calories are consumed by children who drink sucrose-sweetened milk instead of aspartame-sweetened milk. Id. Because milk flavored with non-nutritive sweetener has fewer calories and as much nutritional value as other products labeled “milk,” this petition is consistent with FDA’s objective to help children and youth develop healthy eating habits that will last a lifetime.

3. The Petition Responds to Recent Legislative Developments Aimed to Improve the Nutritional Profile of Foods Served in Our Nation’s School.

Since FDA adopted a standard of identity for milk, concern for the growing childhood obesity epidemic has created heightened scrutiny of the foods and beverages marketed and sold to children in schools. States are reviewing and adopting guidelines limiting the amount of sugar and/or calories beverages, including flavored milk, may contain. For instance, according to the Maryland State Department of Education, flavored milk sold during the school day must contain no more than 30 grams of sugar per eight ounce serving. Memorandum from Robin Ziegler, School and Community Nutrition Program Chief, to All School Food Authorities 3 (Mar. 2005) (on file with author), available at http://www.marylandpublicschools.org/NR/rdonlyres/C1ED4EE4-0BE6-4230-82A5-66D4E1C5FE3/11687/MOM0120305.pdf. The Pennsylvania Department of Education has a similar policy for competitive foods that schools must meet in order to receive reimbursements in the School Lunch Program. Nutrition Standards for Competitive Foods in Pennsylvania Schools 4, 7 (2008), available at http://www.pde.state.pa.us/food_nutrition/lib/food_nutrition/nutrition_guidelines_r_3_-final.pdf.


Granting this petition would promote honesty and fair dealing by creating consistency in the names of flavored milk products. The limitation on the use of sweeteners contained in the standard of identity for milk creates the potential for consumer confusion. The current milk standard permits nutritive sweeteners to be used as an optional ingredient for flavoring milk. The standard, however, prevents food processors from marketing as flavored milk without further qualification (e.g., “reduced calorie chocolate milk”) for milk made with non-nutritive sweeteners. However, use of the phrase “reduced calorie” is not attractive to children and contributed to the overall decline in milk consumption.

Unlike ice cream, consumers do not recognize milk as a product that necessarily contains sugar. When FDA amended the ice cream standard to include any “safe and suitable sweetener” in products labeled as “ice cream,” the agency also required that non-nutritive sweeteners used in the products be declared as part of the name of the ice cream (i.e., “reduced fat ice cream sweetened with aspartame”) for a period of three years until consumers became aware of the fact that some ice cream products are made with non-nutritive sweeteners. 59 Fed. Reg. 47,072 (Sept. 14, 1994). FDA reasoned that ice cream is a product that traditionally includes ice, milk, and sugar, and consumers have an expectation that the ice cream they purchase also includes those ingredients.

In contrast, consumers do not recognize milk or even flavored milk as a beverage that contains substantial amounts of sugar. Rather, milk is viewed as a healthy drink, particularly for school-aged children. Children and adolescents are the largest consumer of flavored milk, but as consumers, they are not inclined to recognize that the milk they drink contains added sugar. Milk flavored with non-nutritive sweetener, which has less sugar than other flavored milk, provides the same nutritional benefits as other flavored labeled “milk” but with fewer calories. Thus, milk flavored with non-nutritive sweeteners should be labeled as “milk” without further qualification so that consumers can more easily identify its overall nutritional value.

5. Conforming Amendments and Administrative Efficiency

The additional standards listed in the attached appendix should also be changed as conforming amendments. For purposes of administrative efficiency, as long as the agency is using the time and resources to amend the standard of identity for milk to provide for safe and suitable sweeteners and having already amended the standard of identity for ice cream, it is sensible to amend the standards of identity for the additional dairy products at the same time. Furthermore, because the standards for the additional dairy products present the same issues as the milk standard with respect to safe and suitable sweeteners, it is most efficient to consider them all together.

C. Environmental Impact

Preparation of an environmental assessment is not required for a petition to establish or amend a food standard. 21 C.F.R. § 25.32(a).
D. Certification

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

Pursuant to 21 C.F.R. § 130.5(c) (2008), petitioner commits to substantiate the information in the petition by evidence in a public hearing, if such a hearing becomes necessary.

Respectfully Submitted,

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APPENDIX

§ 131.111 Acidified milk.

(e) Other optional ingredients.

... (2) Nutritive carbohydrate sweeteners. Sugar (sucrose), beet or cane; invert sugar (in paste or sirup form); brown sugar; refiner's sirup; molasses (other than blackstrap); high fructose corn sirup; fructose; fructose sirup; maltose; maltose sirup, dried maltose sirup; malt extract, dried malt extract; malt sirup, dried malt sirup; honey; maple sugar; or any of the sweeteners listed in part 168 of this chapter, except table sirup.

(3) Any additional safe and suitable sweetener.

§ 131.112 Cultured milk.

(d) Other optional ingredients.

... (2) Nutritive carbohydrate sweeteners. Sugar (sucrose), beet or cane; invert sugar (in paste or sirup form); brown sugar; refiner's sirup; molasses (other than blackstrap); high fructose corn sirup; fructose; fructose sirup; maltose; maltose sirup, dried maltose sirup; malt extract, dried malt extract; malt sirup, dried malt sirup; honey; maple sugar; or any of the sweeteners listed in part 168 of this chapter, except table sirup.

(3) Any additional safe and suitable sweetener.

§ 131.120 Sweetened condensed milk.

(b) Optional ingredients. The following safe and suitable characterizing flavoring ingredients, with or without coloring and any safe and suitable sweeteners, may be used:

(1) Fruit and fruit juice, including concentrated fruit and fruit juice.

(2) Natural and artificial food flavoring.

§ 131.125 Nonfat dry milk.

(b) Optional ingredients. Safe and suitable characterizing flavoring ingredients (with or without coloring and any safe and suitable
sweetener) as follows:

(1) Fruit and fruit juice, including concentrated fruit and fruit juice.

(2) Natural and artificial food flavorings.

§ 131.127 Nonfat dry milk fortified with vitamins A and D.

(c) Optional ingredients. The following safe and suitable optional ingredients may be used:

(1) Carriers for vitamins A and D.

(2) Characterizing flavoring ingredients, with or without coloring and any safe and suitable sweetener, as follows:

(i) Fruit and fruit juice, including concentrated fruit and fruit juice.

(ii) Natural and artificial food flavorings.

§ 131.130 Evaporated milk.

(c) Optional ingredients. The following safe and suitable ingredients may be used:

(1) Carriers for vitamins A and D.

(2) Emulsifiers.

(3) Stabilizers, with or without dioctyl sodium sulfosuccinate (when permitted by and complying with the provisions of Sec. 172.810 of this chapter) as a solubilizing agent.

(4) Characterizing flavoring ingredients, with or without coloring and any safe and suitable sweeteners, as follows:

(i) Fruit and fruit juice, including concentrated fruit and fruit juice.

(ii) Natural and artificial food flavoring.

§ 131.149 Dry cream.

(b) Optional ingredients. The following safe and suitable optional
ingredients may be used:

(1) Emulsifiers.

(2) Stabilizers.

(3) Anticaking agents.

(4) Antioxidants.

(5) Any safe and suitable sweeteners.

(6) Characterizing flavoring ingredients, with or without coloring, as follows:

(i) Fruit and fruit juice, including concentrated fruit and fruit juice.

(ii) Natural and artificial food flavoring.

§ 131.150 Heavy cream.

(b) Optional ingredients. The following safe and suitable optional ingredients may be used:

(1) Emulsifiers.

(2) Stabilizers.

(3) Any safe and suitable sweeteners.

(4) Characterizing flavoring ingredients (with or without coloring) as follows:

(i) Fruit and fruit juice (including concentrated fruit and fruit juice).

(ii) Natural and artificial food flavoring.

§ 131.155 Light cream.

(b) Optional ingredients. The following safe and suitable ingredients may be used:

(1) Stabilizers.
(2) Emulsifiers.

(3) **Any safe and suitable** sweeteners.

(4) Characterizing flavoring ingredients (with or without coloring) as follows:

   (i) Fruit and fruit juice (including concentrated fruit and fruit juice).

   (ii) Natural and artificial food flavoring.

§ 131.157 **Light whipping cream.**

(b) *Optional ingredients.* The following safe and suitable optional ingredients may be used:

   (1) Stabilizers.

   (2) Emulsifiers.

   (3) **Any safe and suitable** sweeteners.

   (4) Characterizing flavoring ingredients (with or without coloring) as follows:

      (i) Fruit and fruit juice (including concentrated fruit and fruit juice).

      (ii) Natural and artificial food flavoring.

§ 131.160 **Sour cream.**

(b) *Optional ingredients.* (1) Safe and suitable ingredients that improve texture, prevent syneresis, or extend the shelf life of the product.

   (2) Sodium citrate in an amount not more than 0.1 percent may be added prior to culturing as a flavor precursor.

   (3) Rennet.

   (4) **Any safe and suitable** sweeteners.

   (5) Salt.
(6) Flavored ingredients, with or without safe and suitable coloring, as follows:

   (i) Fruit and fruit juice (including concentrated fruit and fruit juice).
   (ii) Safe and suitable natural and artificial food flavoring.

§ 131.162 Acidified sour cream.

(b) Optional ingredients. (1) Safe and suitable ingredients that improve texture, prevent syneresis, or extend the shelf life of the product.

   (2) Rennet.

   (3) Any safe and suitable sweeteners.

   (4) Salt.

(5) Flavored ingredients, with or without safe and suitable coloring, as follows:

   (i) Fruit and fruit juice, including concentrated fruit and fruit juice.
   (ii) Safe and suitable natural and artificial food flavoring.

§ 131.170 Eggnog.

(2) Nutritive carbohydrate sweeteners. Sugar (sucrose), beet or cane; invert sugar (in paste or sirup form); brown sugar; refiner's sirup; molasses (other than blackstrap); high fructose corn sirup; fructose; fructose sirup; maltose; maltose sirup, dried maltose sirup; malt extract, dried malt extract; malt sirup, dried malt sirup; honey; maple sugar; or any of the sweeteners listed in part 168 of this chapter, except table sirup.

(3) Any additional safe and suitable sweetener.

§ 131.180 Half-and-half.

(b) Optional ingredients. The following safe and suitable optional ingredients may be used:

   (1) Emulsifiers.

   (2) Stabilizers.
(3) **Any safe and suitable** sweeteners.

(4) Characterizing flavoring ingredients (with or without coloring) as follows:

(i) Fruit and fruit juice (including concentrated fruit and fruit juice).
(ii) Natural and artificial food flavoring.

§ 131.200 Yogurt.

(d) Other optional ingredients.

…

(2) Nutritive carbohydrate sweeteners. Sugar (sucrose), beet or cane; invert sugar (in paste or sirup form); brown sugar; refiner's sirup; molasses (other than blackstrap); high fructose corn sirup; fructose; fructose sirup; maltose; maltose sirup, dried maltose sirup; malt extract, dried malt extract; malt sirup, dried malt sirup; honey; maple sugar; or any of the sweeteners listed in part 168 of this chapter, except table sirup.

(3) **Any additional safe and suitable sweetener.**

§ 131.203 Lowfat yogurt.

(d) Other optional ingredients.

…

(2) Nutritive carbohydrate sweeteners. Sugar (sucrose), beet or cane; invert sugar (in paste or sirup form); brown sugar; refiner's sirup; molasses (other than blackstrap); high fructose corn sirup; fructose; fructose sirup; maltose; maltose sirup, dried maltose sirup; malt extract, dried malt extract; malt sirup, dried malt sirup; honey; maple sugar; or any of the sweeteners listed in part 168 of this chapter, except table sirup.

(3) **Any additional safe and suitable sweetener.**

§ 131.206 Nonfat yogurt.

(d) Other optional ingredients.

…

(2) Nutritive carbohydrate sweeteners. Sugar (sucrose), beet or cane; invert sugar (in paste or sirup form); brown sugar; refiner's sirup; molasses (other than blackstrap); high fructose corn sirup; fructose; fructose sirup; maltose; maltose sirup, dried maltose sirup; malt extract, dried malt extract; malt sirup,
dried malt sirup; honey; maple sugar; or any of the sweeteners listed in part 168 of this chapter, except table sirup.

(3) Any additional safe and suitable sweetener.