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Re: FDA-2009-P-0147 (Flavored Milk; Petition to Amend the Standard of Identity for Milk and 17 Additional Dairy Products)

Dear Ms. Kux:

The Academy of Nutrition and Dietetics (the “Academy”), formerly the American Dietetic Association, is pleased to comment on the proposed rule “*Flavored Milk; Petition to Amend the Standard of Identity for Milk and 17 Additional Dairy Products*” (FDA-2009-P-0147) published February 20, 2013. The Academy is the world’s largest organization of food and nutrition professionals, with more than 75,000 members comprised of registered dietitian-nutritionists (RDNs), registered dietitians (RDs), dietetic technicians, registered, and advanced-degree nutritionists. Every day we work with Americans in all walks of life—from prenatal care through old age—providing nutrition care and conducting nutrition research. We are committed to improving the nation’s health through food and nutrition and providing evidence-based nutrition counseling services that meet the health needs of all citizens.

Academy Recommends FDA Deny the Petition

The Academy has reviewed the Citizen Petition (the “petition”) submitted by the International Dairy Foods Association (IDFA) and the National Milk Producers Federation (NMPF) (collectively, “petitioners”) and available literature and respectfully requests that FDA deny the petition in its entirety or alternatively, but less desirably, consider a revision solely to the standard of identity for milk only so that consumers of flavored milk can easily read the front of the package (*i.e.*, the principal display panel) to determine whether the flavored milk includes any non-nutritive sweeteners.

Milk Is Nutritious, Beneficial, and Under-Consumed

Milk provides nine essential nutrients that all Americans need, including three of the four nutrients of concern identified by the 2010 Dietary Guidelines for Americans (DGA or “the Guidelines”): calcium, potassium and vitamin D. Milk is an excellent source of calcium that helps build strong and healthy bones. The DGA recognizes “that intake of milk and milk

products is linked to improved bone health, especially in children and adolescents.”¹ The Institute of Medicine (IOM) notes that “[m]ilk and milk products provide more than 70 percent of the calcium consumed by Americans.”²

The Guidelines recommend “3 cups per day of fat-free or low-fat milk and milk products for adults and children and adolescents ages 9 to 18 years, 2 1/2 cups per day for children ages 4 to 8 years, and 2 cups for children ages 2 to 3 years.”³ Unfortunately, “[i]ntake of milk and milk products, including fortified soy beverages, is less than recommended amounts for most adults, children and adolescents ages 4 to 18 years, and many children ages 2 to 3 years.”⁴

As part of the Academy’s commitment to meeting nutrition needs through the lifecycle, we are supportive of efforts to improve calcium intake and bone health by increasing milk consumption as recommended in the Guidelines, in particular consumption by school-aged children. Flavored milk has been shown to be an effective tool in encouraging milk consumption by school-aged children; studies have demonstrated that school-aged children who drink flavored milk meet more of their nutrient needs, do not consume more added sugar, fat or calories, and are similar in weight to non-milk drinkers.⁵ Flavored milk is not a major source of added sugars for children (major sources include soda, fruit drinks, grain desserts, candy, dairy desserts, and cold cereals).⁶ As a result of the transformative Healthy, Hunger-Free Kids Act of 2010, new regulations governing competitive foods sold in schools will soon be finalized by the United States Department of Agriculture Food and Nutrition Service and should positively impact milk consumption and students’ healthy food choices.⁷

¹ Dietary Guidelines for Americans 2010 (“DGA 2010”), United States Departments of Agriculture and Health and Human Services, available at <http://www.cnpp.usda.gov/Publications/DietaryGuidelines/2010/PolicyDoc/PolicyDoc.pdf>, page 38, accessed 14 May 2013.

² Dietary Guidelines for Americans 2005 (“DGA 2005”), United States Departments of Agriculture and Health and Human Services, available at <http://www.health.gov/dietaryguidelines/dga2005/document/html/chapter2.htm>, page 56, accessed 14 May 2013.

³ DGA 2010 at 38.

⁴ *Id.*

⁵ Nutrition Standards for Foods in Schools: Leading the Way Toward Healthier Youth (“IOM Report”), Institute of Medicine, available at <http://www.iom.edu/Reports/2007/Nutrition-Standards-for-Foods-in-Schools-Leading-the-Way-toward-Healthier-Youth.aspx>, page 58, accessed 14 May 2013. *See also*, 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, 631 (2008).

⁶ Fitch, C., & Keim, K. S. (2012). Position of the Academy of Nutrition and Dietetics: use of nutritive and nonnutritive sweeteners. *Journal of the Academy of Nutrition and Dietetics*, 112(5), 739–758; 744.

⁷ *See*, IOM Report at 86 (“Cullen and Zakeri (2004) found that when children transitioned into middle schools with additional competitive food and beverage options, consumption of fruits, milk, and non-starchy vegetables tended to be lower. Consumption of high-fat vegetables went up.”)

Safety of Non-Nutritive Sweeteners

The Academy is committed to assuring that all Americans have access to a healthy, safe food supply. It is the position of the Academy of Nutrition and Dietetics that consumers can safely enjoy a range of nutritive sweeteners and nonnutritive sweeteners (NNS) when consumed within an eating plan that is guided by current federal nutrition recommendations, such as the [DGA] and the Dietary Reference Intakes, as well as individual health goals and personal preference.⁸ “Consumers who want a sweet taste without added energy can choose from seven FDA-approved [non-nutritive sweeteners] based on their personal taste preference and the intended use (*e.g.*, for cooking or for tabletop use). [Non-nutritive sweeteners], when substituted for nutritive sweeteners, may help consumers limit carbohydrate and energy intake as a strategy to manage blood glucose or weight.”⁹

The Academy acknowledges the IOM’s warning of a level of uncertainty regarding non-nutritive sweeteners and children:

The Food and Drug Administration (FDA) sets safety standards for food additives, including nonnutritive sweeteners. Those that are approved for use have been evaluated extensively and have met the standards. Yet there is still uncertainty, particularly about long-term use and about low-level exposure effects on the health and development of children.¹⁰

The Academy’s Evidence Analysis Library notes the limited or lack of data on the specific effects of artificial sweeteners.¹¹ Other researchers note that “[d]espite their widespread and increasing use, the effects of artificial sweeteners in children have not been well studied.”¹² Given the innate preference of infants and toddlers for sweetened foods, it is likely that, although the desired target for artificially sweetened flavored milk would be school-aged children, there would undoubtedly be consumption by infants and toddlers in daycare and home settings who are susceptible to risk because of rapid brain development and growth. Significant research and reviews thereof are ongoing. Thus, prior to finalizing its dispensation of this petition, the Academy urges FDA to consider any findings and expressions of uncertainty included in the European Food Safety Authority’s Scientific Panel on Food Additives and Nutrient Sources Added to Food’s full reevaluation of aspartame expected November 2013, particularly as it relates to the aspartame use by children.¹³

⁸ Fitch and Keim at 739.

⁹ Fitch and Keim at 754.

¹⁰ IOM Report at 8.

¹¹ Fitch and Keim at 749-752.

¹² Allison Sylvetsky, *Pediatr Clin North Am.* 2011 December; 58(6): 1467–1480, 1468.

¹³ See, European Food Safety Authority, “Aspartame opinion rescheduled until November 2013,” available at <http://www.efsa.europa.eu/en/press/news/130508a.htm>, accessed 14 May 2013.

The Dietary Guidelines do not currently contain recommendations for infants or children under the age of two. In the absence of guidelines specific to this age group, the Academy asks the FDA to use caution when making decisions that may have unintended consequences for this particularly vulnerable age group.

Current Standard of Identity and Requirements for Revision

FDA advises that “[f]ood standards . . . provide a system by which consumer interests are protected and consumer expectations of a food are met. Historically, food standards have been beneficial because they provide assurance to consumers of product uniformity with respect to certain significant characteristics of standardized foods.”¹⁴ The current standard of identity for milk provides consumers with clear front-of-package information about nutrient content claims (*e.g.*, “reduced calorie”), flavorings added (*e.g.*, “chocolate milk” or strawberry milk”), or other material adulterations that ensure consumers are aware of any variation from milk’s basic, pure and wholesome standard of identity detailed in Section 131.110.

Petitioners have the burden to provide adequate justification for changes to a standard of identity.¹⁵ FDA requires that petitions include “convincing data” and “sound scientific and factual data or information that supports the positions.”¹⁶ Food standards must be “based on documented public health need and substantiated with sound science. . . .”¹⁷ Notably, “petitions that make claims about consumer expectations or beliefs for the purposes of defining the basic nature and essential characteristics of a food should also provide information or data that substantiate those claims. Marketing data, food formulary compilations, studies of restaurant menus, and consumer survey and focus group research data are potentially acceptable data sources to substantiate statements and claims made in the petition.”¹⁸ FDA “will deny a petition to revise an existing standard if the proposed revision is inconsistent with any of the general principles that apply to the proposed revision.”¹⁹

Distinguishing Amendments to Ice Cream’s Standard of Identity

In the proposed rule, FDA asked commenters whether “the considerations underlying FDA amendments to the standard of identity for ice cream [are] applicable to the requested

¹⁴ Food Standards; General Principles and Food Standards Modernization, Proposed Rule, 70 Fed. Reg. 97 (20 May 2005) at 29221.

¹⁵ Milk and Cream Products and Yogurt Products; Proposal to Revoke the Standards for Lowfat Yogurt and Nonfat Yogurt and to Amend the Standard for Yogurt, 74 Fed. Reg. 10 (15 January 2009) at 2448.

¹⁶ *Id.* at 2449; 2452.

¹⁷ Food Standards; General Principles and Food Standards Modernization, Proposed Rule, 70 Fed. Reg. 97 (20 May 2005) at 29222.

¹⁸ *Id.* at 29225

¹⁹ *Id.* at 29221

amendments to the standard of identity for milk or the Additional Dairy Standards.”²⁰ The Academy identified several distinguishing considerations.

Milk Has a Unique Character

Milk’s purity and wholesomeness are two of its most essential characteristics, both enshrined in law²¹ and recognized as such by petitioners.²² Unlike ice cream, which is a combination of multiple products (milk, cream, and sugar),²³ milk is milk. Milk’s singular nature and its essential characteristics of purity and wholesomeness necessitate that consumers are readily made aware of any changes to its identity on the front of the package (such as current labeling of fat adulterations), including whether it is flavored or sweetened with non-nutritive sweeteners. Further, the Academy is concerned that the proposed amendments to milk’s standard of identity will be confusing and lead consumers to begin questioning whether “milk” is still the pure, wholesome, and nutritious staple we have come to expect.

Three-Year Window of Disclosure in FDA’s Ice Cream Amendments

In its amendments to ice cream’s standard of identity, FDA indicated it “believe[d] that 3 years [was] an adequate amount of time for people to become aware that ‘ice cream’ may be made with either nutritive carbohydrate sweeteners or alternative sweeteners, and thus that it [becomes] necessary [for the consumer] to check the ingredient list.” Thus, FDA required—for a three year period—“that alternative sweeteners be declared by their common or usual name on the principal display panel of the label as part of the statement of identity . . . to ensure that ice cream sweetened with alternative sweeteners is clearly distinguishable from the traditional food, and so that consumers who want to avoid ice cream that contains alternative sweeteners will be able to do so.”²⁴ Labeling on the principal display panel ensures critical consumers’ (and parents’) awareness of added substances far more effectively than listing them in small typeface on the back panel ingredient list.

The Academy notes that FDA’s determination that the three-year window would be sufficient for consumers to become ostensibly aware that ice cream contains non-nutritive sweeteners (by declaring their presence on the principal display panel) was derived from a similar window for the change in canola oil’s standard of identity. The Academy questions whether the comparison of canola oil to milk label changes is sufficiently appropriate, given

²⁰ Flavored Milk; Petition to Amend the Standard of Identity for Milk and 17 Additional Dairy Products, 78 Fed. Reg 34 (20 February 2013) at 11792.

²¹ 7 U.S.C. § 608c(18) (related to Secretary of Agriculture’s authority with regard to milk prices).

²² Information About the Dairy Industry, NMPF website, available at <http://www.nmpf.org/about-nmpf/information-about-the-dairy-industry>, accessed 12 May 2013 (NMPF “helps to improve the economic well being of dairy farmers and assure the nation’s consumers an adequate supply of pure, wholesome milk and dairy products.”).

²³ Frozen Desserts: Removal of Standards of Identity for Ice Milk and Goat’s Milk Ice Milk; Amendment of Standards of Identity for Ice Cream and Frozen Custard and Goat’s Milk Ice Cream, 59 Fed. Reg. 177 (14 September 1994) FR Doc. No. 94-22646.

²⁴ *Id.*

the vastly different consumer expectations for and beliefs about the two products. Given the differences between canola oil and ice cream, simply selecting the same three-year window appears somewhat arbitrary. The Academy is also unaware of any proffered convincing evidence suggesting that consumers have, since the closing of the three-year window, become sufficiently aware that products simply labeled “ice cream” may contain non-nutritive sweeteners. Given FDA’s admonition that “claims about consumer expectations or beliefs for the purposes of defining the basic nature and essential characteristics of a food should also provide information or data that substantiate those claims,”²⁵ it is imperative that such data would be provided to and relied upon FDA before any similar window either opens or closes related to revisions to milk’s standard of identity.

Petitioners Do Not Meet Their Required Burden for the Asserted Claims

The petition largely focuses on the perceived benefits to children of revising milk’s standard of identity, including petitioners’ assertion that the proposed amendments would promote more healthful eating practices and reduce childhood obesity. The Academy concludes the petition fails to cite the requisite convincing, sound scientific or factual data showing that the recommended amendments will promote honesty and fair dealing in the interest of consumers and are therefore inappropriate under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341). The Academy also concludes that petitioners have offered no substantiated data in support of revising the standards of identity for the seventeen other dairy products, necessitating that FDA deny the proposed amendments to their standards of identity. Further, a review of the limited available evidence appears to contradict the petition’s claims of perceived benefits. As such, the Academy respectfully requests that the petition as submitted be denied in its entirety, with petitioners offered the opportunity to petition for a revision only to milk’s standard of identify that ensures consumers are made aware whenever artificial sweeteners are added to flavored milk on the principal display panel.

Claim 1: “Reduced Calorie” Label Is Not Attractive to Children

Petitioners claim that nutrient content claims such as, “use of the phrase ‘reduced calorie’ is not attractive to children” without proffering any evidence in support. The Academy’s review of available evidence suggests the claim may be unfounded. While evidence related specifically to the impact of nutrient content claims on flavored milk purchase habits is lacking, these labeling attributes have been studied recently for other foods with pre-adolescent children, and the result was actually the increased likelihood of selection of foods bearing nutrient content claims.²⁶ In the study by Dixon et al, the impact of nutrient content claims on selection decisions appears to have been mediated by an increase in

²⁵ Food Standards; General Principles and Food Standards Modernization, Proposed Rule, 70 Fed. Reg. 97 (20 May 2005) at 29225.

²⁶ Dixon, H., Scully, M., Niven, P., Kelly, B., Chapman, K., Donovan, R., ... Wakefield, M. (2013). Effects of nutrient content claims, sports celebrity endorsements and premium offers on pre-adolescent children’s food preferences: experimental research. *Pediatric obesity*. doi:10.1111/j.2047-6310.2013.00169.x

perceived nutritional value of the foods, suggesting that the studied eleven year-old children were incorporating relative health value into their decision making process.²⁷

If, however, the “reduced calorie” phrase on the front of the package actually does influence consumer attitudes as petitioners suggest, then the salient nature of the information is relevant to FDA’s question whether “the inclusion of the non-nutritive sweeteners in the ingredient statement provide[s] consumers with sufficient information to ensure that consumers are not misled regarding the characteristics of the milk they are purchasing.”²⁸ Information consumers deem highly relevant should not be removed from its prominent place on the principal display panel (and relegated solely to the ingredient statement) to entice otherwise disinterested consumers. In the absence of additional convincing, sound scientific or factual data to substantiate it, FDA should dispense with Claim 1.

Claim 2: “Reduced Calorie Label” Contributed to Overall Decline in Milk Consumption

Petitioners claim that use of the phrase “reduced calorie” “contributed to the overall decline in milk consumption” and that “[o]nly milk flavored with a non-nutritive sweetener” could meet the nutritional needs of children while complying with current and future restrictions without proffering any evidence in support. The Academy’s review of available evidence suggests the claim may be unfounded. A 2012 study by Bethany Yon and Drs. Johnson and Stickle of the University of Vermont measured the quantities of unconsumed flavored milk at elementary schools (five schools that had recently changed to reformulated products that met the sugar content restrictions cited by the petitioners) and revealed no significant differences in the proportions of children who drank the majority of their milk (greater than seven ounces) among the schools, with or without adjustments for demographic differences.²⁹ In the absence of additional convincing, sound scientific or factual data to substantiate it, FDA should dispense with Claim 2.

Claim 3: Consumers Do Not Recognize Sugar in Flavored Milk

Petitioners assert that “consumers do not recognize milk or even flavored milk as a beverage that contains substantial amounts of sugar” without proffering any evidence in support. In the absence of any substantiating evidence, such as marketing data, consumer survey, or focus group research data, FDA should deny Claim 3.

Claim 4: Revision Would Have Positive Impact on Childhood Obesity

Petitioners assert that “[b]ecause 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” without proffering any evidence to support their claim that flavored milk sweetened with non-nutritive sweeteners is likely to have any positive impact on childhood obesity. The DGA concluded that “replacing added sugars with non-

²⁷ *Id.*

²⁸ Flavored Milk; Petition to Amend the Standard of Identity for Milk and 17 Additional Dairy Products, 78 Fed. Reg 34 (20 February 2013) at 11792.

²⁹ Yon, B. A., Johnson, R. K., & Stickle, T. R. (2012). School children’s consumption of lower-calorie flavored milk: a plate waste study. *Journal of the Academy of Nutrition and Dietetics*, 112(1), 132–136.

caloric sweeteners may reduce calorie intake in the short term, yet questions remain about their effectiveness as a weight management strategy.”^{30 31} Moreover, the limited studies available not only do not support such a claim, they suggest a possible correlation between artificially sweetened products and children’s increased caloric intake at mealtime.^{32 33} Coupled with that literature, the fact that flavored milk sweetened with nutritive sweeteners has *not* been associated with adverse effects on children’s weight status³⁴ may contraindicate petitioners’ request to revise the standards of identity to promote artificially sweetened milk in schools.

The Academy appreciates the opportunity to comment on the petition to amend the standards of identity for milk and seventeen other dairy products, and we recognize the confusion of many commenters surrounding this issue. The Academy respectfully requests that FDA either deny the petition as submitted or less desirably, consider a revision to the standards of identity that ensures consumers of flavored milk can easily look at the principal display panel to determine whether it includes non-nutritive sweeteners. As one of the first professional groups to embrace evidence-based practice, the Academy created the world’s first evidence-analysis nutrition library (EAL) from which these comments are based. We hope you will look towards the Academy and our EAL as you finalize FDA’s response to the petition. Please contact either Jeanne Blankenship at 202-775-8277 ext. 1730 or by email at jblankenship@eatright.org or Pepin Tuma at 202-775-8277 ext. 6001 or by email at ptuma@eatright.org with any questions or requests for additional information.

Sincerely,



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³⁰ DGA 2010 at 19

³¹ *See also*, Rebecca J Brown, *Int J Pediatr Obes.* 2010 August; 5(4): 305–312 abstract (“Data from large, epidemiologic studies support the existence of an association between artificially-sweetened beverage consumption and weight gain in children. Randomized controlled trials in children are very limited, and do not clearly demonstrate either beneficial or adverse metabolic effects of artificial sweeteners.”)

³² *See, Id.* at 6 (“Although not all studies agree, the general trend is that artificial sweeteners may reduce total caloric intake when consumed between meals, but when consumed with meals, children may compensate for low-calorie snacks or drinks by increasing meal-associated calories.”).

³³ *See, Sylvetsky* at 4 (“While it is expected that substituting artificially sweetened beverages in place of sugar-sweetened beverages would lead to weight loss due the lower caloric intake, experimental studies have shown that the assumed calorie deficit is not maintained. One reason for this is that people tend to compensate for the ‘missing calories’ in an artificially sweetened food or drink by subsequently eating more.”).

³⁴ *See, Murphy et al.* at 631.