



NEW YORK
CITY BAR

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Division of Dockets Management
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Department of Health and Human Services
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Re: Docket # FDA-2017-P-1298

To Whom It May Concern:

The Animal Law Committee of the New York City Bar Association (“NYCBA Animal Law Committee”) respectfully submits this letter in support of the Citizen Petition to Recognize the Use of Established Common and Usual Compound Nomenclatures for Food filed by the Good Food Institute on March 2, 2017 (the “Petition”).¹

The New York City Bar Association is an independent non-governmental organization of more than 24,000 lawyers, law professors, and government officials, principally from New York City but also from throughout the United States and 50 other countries. The NYCBA Animal Law Committee is the first committee of its kind in the United States and has a history of commenting on bills, proposed rules, and policies concerning animal products.²

A. The Petition

The Petition requests that the FDA promulgate regulations amending 21 C.F.R. § 102.5, General Principles, to clarify that names of new food products may generally reference familiar ones—for instance, that “almond milk” (a comparatively new product) can include the term

¹ The Petition is online at <https://www.regulations.gov/contentStreamer?documentId=FDA-2017-P-1298-0001&attachmentNumber=1&contentType=pdf>. All websites referenced in this letter were last visited August 6, 2017.

² *E.g.*, Letter to the FTC commenting on proposed amendments to regulations under the Fur Products Labeling Act (Nov. 1, 2012), <http://www2.nycbar.org/pdf/report/uploads/20072356-FurRulesReview.pdf>.

“milk” (a familiar product).³ In particular, the Petition would add the following provision to the Part titled “Common or Usual Name for NonStandardized Foods”:

(e) The common or usual name of a food may be —

(1) the common or usual name of another food preceded by a qualifying word or phrase that identifies (i) an alternative plant or animal source that replaces the main characterizing ingredient(s) or component(s) of such other food, or (ii) the absence of a primary characterizing plant or animal source, or of a nutrient, allergen, or other well-known characterizing substance, that is ordinarily present in such other food; or

(2) any other word or phrase comprised of two or more terms, which may be separated by hyphens or spaces; but if such name includes the common or usual name of any other food, it must effectively notify consumers that the product is distinct from such other food.

The use of such a name does not violate section 403 of the act or regulations of this chapter solely because it includes the common or usual name of another food (including a food for which a standard of identity is established) if the entire name serves to notify a reasonable consumer that the product differs from such other food.⁴

Notably, the proposed regulation is not limited to expressly allowing names of plant-based products such as soymilk and almond milk. It would expressly allow product names such as rice noodles, cornbread, and goat milk, among other products.

The Petition also requests that the FDA issue guidance clarifying that such product names may be used, consistent with the proposed regulation.⁵ The Petition correctly argues that courts have held that the names of plant-based milks are not deceptive and that prohibiting the use of the word milk in many plant-based products would be a violation of the First Amendment.

B. Reason for Support

As the Petition states, this proposed regulation would essentially codify existing law and practice, providing clarification to industry and the public that new food products—like “soy milk”—may rightfully reference familiar products—like “milk”—in their names.⁶

This clarification would be particularly helpful given recent actions of elected officials acting in favor of the dairy industry which have received widespread media coverage. For instance, in December 2016, 32 members of Congress wrote to the FDA requesting that the FDA

³ Petition at 1-2.

⁴ Petition at 2.

⁵ Petition at 2.

⁶ See Petition at 13.

investigate and take action against manufacturers of plant-based products labeled “milk.” Representative Welch issued a press release that claimed that plant-based food manufacturers were breaking the law, entitled “Welch Leads Bipartisan Effort to Stop the Illegal Branding of ‘Fake Milk’ as Real Milk.”⁷ Numerous news outlets reported on the efforts of these congressmen in articles that potentially contributed to public confusion with titles such as, “You can’t milk a soybean! Vermont congressman calls on FDA to take action against misleading ‘fake milk,’”⁸ “There’s No Such Thing As Soy Milk,”⁹ and “Soy, Almond, Coconut: If It’s Not From A Cow, Can You Legally Call It Milk?”¹⁰

One month after the members of Congress sent this letter to the FDA, in January 2017, Senator Tammy Baldwin introduced the DAIRY PRIDE Act. The Act sought to prohibit the use of words such as “milk,” “ice cream,” and “cheese” in non-dairy products such as soymilk and almond milk.

The NYC Bar Association Animal Law and Consumer Affairs Committees issued a report opposing the DAIRY PRIDE Act,¹¹ and the Animal Law Committee also sent a letter refuting many of the claims in the letter from the members of Congress.¹² As explained in the Animal Law and Consumer Affairs Committees’ report, the DAIRY PRIDE Act’s legislative finding that consumers were deceived into believing that soymilk and similar products came from cows were unsupported and the legislative findings about nutrition were inaccurate.¹³ Further, because of the legal uncertainty created by such officials’ statements, businesses choosing names for new products may feel unnecessarily limited in their choices.¹⁴ Even if the

⁷ Press Release, Welch Leads Bipartisan Effort to Stop the Illegal Branding of “Fake Milk” as Real Milk (Dec. 16, 2016), <https://welch.house.gov/media-center/press-releases/welch-leads-bipartisan-effort-stop-illegal-branding-fake-milk-real-milk>.

⁸ AP and Snejana Farberov, *You Can’t Milk a Soybean! Vermont Congressman Calls on FDA to Take Action Against Misleading ‘Fake Milk’*, DAILY MAIL (Dec. 23, 2016), <http://www.dailymail.co.uk/news/article-4062694/Congressman-wants-FDA-action-against-fake-milk.html>.

⁹ David Ryan Polgar, *There’s No Such Thing as Soy Milk*, BIG THINK (Dec. 30, 2016), <http://bigthink.com/david-ryan-polgar/there-is-no-such-thing-as-soy-milk>.

¹⁰ Dan Charles, *Soy, Almond, Coconut: If It’s Not From A Cow, Can You Legally Call It Milk?*, MORNING EDITION, NPR (Dec. 21, 2016), <http://www.npr.org/sections/thesalt/2016/12/21/506319408/soy-almond-coconut-if-its-not-from-a-cow-can-you-legally-call-it-milk>.

¹¹ NYC Bar Ass’n Animal Law and Consumer Affairs Committees, Report in opposition to the DAIRY PRIDE Act (Mar. 2017), http://s3.amazonaws.com/documents.nycbar.org/files/201782-DairyPrideAct_FINAL_3.1.17.pdf.

¹² NYC Bar Ass’n Animal Law and Consumer Affairs Committees, Letter to the Food and Drug Administration regarding the Labeling of Plant-Based Milks (Feb. 24, 2017), http://s3.amazonaws.com/documents.nycbar.org/files/20073225-PlantBasedMilksLabeling_FINAL_2.23.17.pdf.

¹³ See, e.g., Report in opposition to the DAIRY PRIDE Act, at 5-6 (Mar. 2017), *supra* note 7 (noting that the legislative findings in the DAIRY PRIDE Act mispresent certain regulations published by the U.S. Department of Health and Human Services and the U.S. Department of Agriculture).

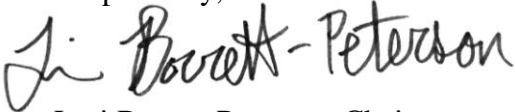
¹⁴ For example, Kite Hill named its non-dairy cheese an “almond milk product” in order to avoid legal risk. Beth Kowitt, *What’s Big Dairy’s Beef With Plant-Based Milk?*, FORTUNE (Feb. 16, 2017), <http://fortune.com/2017/02/16/plant-based-milk-dairy-pride-act>.

FDA remains silent and the proposed regulation is not issued, some damage has already been done.

While the Petition's proposed regulation is not limited in scope to the names of plant-based products, given the recent efforts of politicians to limit the product names of plant-based products, we expect this proposed regulation and the guidance requested in the Petition would limit the effect of such anti-competitive efforts. For further reasons to support the proposed regulation, we refer the FDA to the Committee's earlier report and letter, both of which are attached.

Thank you for your consideration.

Respectfully,

A handwritten signature in black ink that reads "Lori Barrett-Peterson". The signature is written in a cursive, flowing style.

Lori Barrett-Peterson, Chair
Animal Law Committee

Attachments



**NEW YORK
CITY BAR**

**REPORT ON LEGISLATION
BY THE ANIMAL LAW COMMITTEE AND
THE CONSUMER AFFAIRS COMMITTEE**

**S. 130
H.R. 778**

**Sen. Baldwin
Rep. Welch**

AN ACT to require enforcement against misbranded milk alternatives.

DAIRY PRIDE Act

THIS LEGISLATION IS OPPOSED

A. INTRODUCTION

The Defending Against Imitations and Replacements of Yogurt, Milk, and Cheese to Promote Regular Intake of Dairy Everyday Act (DAIRY PRIDE Act), S.130 and H.R. 778, would have the effect of prohibiting the use of the word “milk” in names of products such as “soymilk,” “almond milk,” “coconut milk,” “rice-milk,” and similar plant-based beverages as well as words like “ice cream,” “yogurt,” and “cheese” for plant-based foods. Neither the facts nor the law warrant prohibiting the use of the terms “milk,” “ice cream,” “yogurt,” and “cheese” in plant-based product names because:

- Labeling a plant-based beverage “milk” does not mislead consumers, because no reasonable consumer would believe that such milk comes from a cow;
- The qualified use of the word “milk” in the names of plant-based products is not “a violation of milk’s standard of identity”;
- The names of popular non-dairy ice creams, yogurts, and cheeses already clearly state that they are plant-based, and thus they are not misleading;
- The health claims in the legislative findings misrepresent statements in the Dietary Guidelines published by the U.S. Department of Health and Human Services (HHS) and the U.S. Department of Agriculture (USDA);
- There is no evidence that consumers are misled about the nutritional content of plant-based milks;
- The restriction on the use of the word “ice cream” undercuts the ostensible purpose of the bill to protect the public health; and
- Plant-based milks are a reasonable alternative to consumers who choose not to consume dairy products due to health needs, religious beliefs, and/or concerns about animals and the environment.

B. SUMMARY OF PROPOSED LEGISLATION

The bill would amend section 403 of the federal Food, Drug and Cosmetic Act (21 U.S.C. § 343) to provide that a food using “a market name for a dairy product” may not be introduced or delivered for introduction into interstate commerce unless such food “is, contains as a primary ingredient, or is derived from the lacteal secretion, particularly free from colostrum,¹ obtained by the complete milking of one or more hooved animals.” The bill defines “a market name for a dairy product” as the dairy products defined in Parts 131 and 133 and Sections 135.110, 135.115, and 135.140 of title 21, Code of Federal Regulations and successor regulations, and “any other term for which the Secretary has promulgated a standard of identity² with respect to a food that is formulated with a dairy product (as described in subparagraph (2)) as the primary ingredient.” Part 131 provides descriptions for milk,³ heavy cream,⁴ sour cream,⁵ and yogurt,⁶ among other items.⁷ Part 133 also defines milk (with a different definition than the definition in Part 131).⁸ Part 133 also describes specific types of cheeses made from cow’s, sheep’s, or goat’s milk such as mozzarella cheese,⁹ cheddar cheese,¹⁰ and cream cheese¹¹ though it does not include a description or definition of the generic term “cheese.” Section 135.110 describes cow’s milk ice cream. Section 135.115 describes goat’s milk ice cream. And Section 135.140 describes cow’s milk sherbet.

C. ARGUMENT

1. Labeling a plant-based beverage “milk” does not mislead consumers, because no reasonable consumer would believe that such milk comes from a cow.

The bill’s legislative findings suggest that the purpose of the bill is to protect consumers who are being misled into believing that certain plant-based foods and beverages

¹ Merriam-Webster defines “colostrum” as “milk secreted for a few days after childbirth and characterized by high protein and antibody content.” MERRIAM-WEBSTER DICTIONARY, <https://www.merriam-webster.com/dictionary/colostrum>.

² A standard of identity may be established if “such action will promote honesty and fair dealing in the interest of consumers” in accordance with 9 USC § 341.

³ 21 CFR § 131.110(a) describes milk as “the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows.”

⁴ 21 CFR § 131.150.

⁵ 21 CFR § 131.160.

⁶ 21 CFR § 131.200.

⁷ 21 CFR § 131.206.

⁸ 21 CFR § 133.3 defines milk as “the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows, which may be clarified and may be adjusted by separating part of the fat therefrom; concentrated milk, reconstituted milk, and dry whole milk. Water, in a sufficient quantity to reconstitute concentrated and dry forms, may be added.”

⁹ 21 CFR § 133.155.

¹⁰ 21 CFR § 133.133.113.

¹¹ 21 CFR § 133.133.

come from cows or other hooved animals. The findings state, “Plant-based products labeled as milk are misleading to consumers.” Yet the legislative findings offer no specific evidence to support these claims. And in fact, courts in recent cases have concluded just the opposite: that the plant-based beverages labeled “milk” are not misleading to consumers, for the simple reason that no reasonable consumer would believe that “soy milk,” for instance, is the same as the “milk” that comes from a cow.

In particular, two federal courts have recently found it implausible that a reasonable consumer¹² could confuse soymilk or similar products with milk from a cow. In *Ang v. Whitewave Foods Co.*, Case No. 13-cv-1953, 2013 U.S. Dist. Lexis 173185 (N.D. Cal., Dec. 10, 2013), the U.S. District Court for the Northern District of California rejected the very statement in the legislative findings. There, plaintiffs claimed that the defendants had misbranded plant-based products by using names like “soymilk,” “almond milk,” and “coconut milk.” They noted that 21 C.F.R. § 131.110 describes “milk” as a secretion from cows, and they argued that reasonable consumers were likely to believe that “soymilk,” “almond milk,” and “coconut milk” likewise came from a cow. The Court disagreed and dismissed the claims, finding that it was “simply implausible” that a consumer would mistake such plant-based products with dairy milk¹³ and that it was “highly improbable” that a reasonable consumer would simply disregard the words preceding the word “milk” in products like “soymilk” and “almond milk” and assume that the beverages came from cows.

Similarly, in *Gitson v. Trader Joe’s Co.*, Case No. 3:13-cv-01333, 2015 U.S. Dis. Lexis 170401 (N.D. Cal., Oct. 4, 2013), the U.S. District Court for the Northern District of California held that the use of the word “soymilk” in Trader Joe’s products could not conceivably violate the federal Food, Drug and Cosmetic Act. The Court found that a reasonable consumer—and even “the least sophisticated consumer”—would not think that soymilk comes from a cow.

We note that the use of the word “milk” for plant-based beverages is centuries old. Notably, the Oxford English Dictionary documents a reference to almond milk—or “mylke of almaundes”—dating from the early-fifteenth century.¹⁴ The term “rice milk” has been used since at least 1914.¹⁵ And the word “soymilk” has been used since at least 1936.¹⁶

¹² The FDA uses the “reasonable consumer” standard in evaluating labeling for dietary supplements and conventional foods. FDA, GUIDANCE: QUALIFIED HEALTH CLAIMS IN THE LABELING OF CONVENTIONAL FOODS AND DIETARY SUPPLEMENT (Dec. 2002), <http://www.fda.gov/ohrms/dockets/98fr/02d-0515-gdl0001.pdf>.

¹³ *Ang*, at *12-13.

¹⁴ See OXFORD ENGLISH DICTIONARY, <http://oed.com> (enter “milk”; then click “Go”) (citing CURYE ON INGLYSCH at 114 (eds. Constance B. Heatt and Sharon Butler) (1985)). The dictionary notes several other similar historical references, as well as more recent ones.

¹⁵ WILLIAM SHURTLEFF & AKIKO AOYAGI, HISTORY OF SOYMILK AND OTHER NON-DAIRY MILKS (1226 TO 2013) 6 (2013), <http://www.soyinfocenter.com/pdf/166/Milk.pdf>.

¹⁶ *Id.* at 7.

2. The qualified use of the word “milk” in the names of plant-based products is not “a violation of milk’s standard of identity.”

The legislative findings suggest that plant-based products violate milk’s standard of identity. They say that there is a “proliferation of plant-based products in the marketplace that are mislabeled as milk despite the standard of identity defined for this substance” and call on the Food and Drug Administration (FDA) to improve enforcement against these mislabeling practices “to avoid misleading consumers.”

The proposed legislation fails to acknowledge the fact that the plant-based beverages at issue are not labeled just “milk”; rather, they simply include the word “milk” in their name. And in fact, in *Gitson* (see Section C.1 above), the U.S. District Court for the Northern District of California drew on just this distinction in holding that a manufacturer’s use of the word “soymilk” did not violate milk’s “standard of identity.”¹⁷ The Court reasoned that the fact that milk has a standard of identity “does not categorically preclude a company from giving any food product a name that includes the word ‘milk.’”¹⁸ Rather, the “standardization of milk simply means that a company cannot *pass off* a product as “milk” if it does not meet the regulatory definition of milk.”¹⁹ The Court found that the manufacturer in that case did not purport to pass off its product as cow’s milk because the product clearly identified itself as derived from soy—“soymilk.”²⁰

3. The names of popular non-dairy ice creams, yogurts, and cheeses state their plant-based sources clearly, and thus they would not be misleading to a reasonable consumer.

The legislation would not allow non-dairy ice creams to use the word “ice cream” in their product names. Yet current product names for popular non-dairy ice creams would not mislead a reasonable consumer to believe that they come from cow’s or goat’s milk. The brands So Delicious and Ben & Jerry calls their products “non-dairy frozen desserts.” The brand Tofutti calls its soy-based products “frozen dessert.” And Luna & Larry’s brand calls its dessert “Coconut Bliss.”

Likewise popular non-dairy yogurts clearly state that they are plant-based. For example, “cultured coconut” (So Delicious brand), “dairy-free yogurt alternative” (Silk brand), “cultured soy” (Nancy’s brand), “cultured almondmilk” (Amande), “soy yogurt” (Stonyfield brand), and “soyogurt” (Wildwood brand).

And popular cheese alternatives clearly state that they are dairy free. For example, “cream cheese alternative” (Go Veggie and Teese brands), “Dairy Free Mozzarella” (Tofutti brand), “vegan gourmet shreds” (Follow Your Heart brand), “tree nut cheese” (Dr. Cow brand), “cheddar style shreds” (Daiya brand, package says in large letters “deliciously dairy free”).

¹⁷ *Gitson*, at *5-6.

¹⁸ *Gitson*, at *6.

¹⁹ *Id.*

²⁰ *Id.* at *6-7.

For the reasons explained in the cases cited in sections C.1 and C.2 above, like plant-based milks, these plant-based foods would not mislead a reasonable consumer into believing they were made with cow's milk. And given that the products already clearly identify themselves as being plant-based and/or dairy free, it's not clear what consumer-protection problem this legislation is trying to remedy.

4. The health claims in the legislative findings misrepresent recommendations in the 2015-2020 Dietary Guidelines published by the U.S. Department of Health and Human Services and the U.S. Department of Agriculture (“Dietary Guidelines”).²¹

The legislative findings say that the Dietary Guidelines state, “Dairy products are an important part of a healthy diet for both children and adults,” “most Americans are not meeting recommended intake for the dairy food group,” and “dairy foods are excellent sources of critical nutrients for human health, including vitamin D, calcium, and potassium, all of which are under consumed by people of the United States.”

Astonishingly, the legislative findings fail to disclose a crucial fact: The Dietary Guidelines include fortified soymilk in the dairy group.²² So all of the legislative findings quoted above apply to at least one plant-based milk. The Dietary Guidelines recommend that Americans increase consumption of certain foods in the dairy group, including fortified soymilk, as follows: “Most individuals in the United States would benefit by increasing dairy intake in fat-free or low-fat forms, whether from milk (including lactose-free milk), yogurt, and cheese or from *fortified soy beverages (soymilk)*.”²³

The legislative findings also state, “The amount of calcium per calorie is lower for most plant-based alternative milk products. To obtain the amount of calcium contained in one cup of non-fat fluid milk from a plant-based milk alternative, the portion size and calorie intake must be greater.” But the differences are negligible, and do not hold true for low-fat and reduced fat milks.²⁴

The Dietary Guidelines rank 36 food sources by amounts of calcium and energy per standard food portions and per 100 grams of foods.²⁵ Both almond milk and soymilk have more calcium per 100 grams than skim milk, and rice drink is not far behind. This is how one

²¹ The Dietary Guidelines are available on HHS's website at https://health.gov/dietaryguidelines/2015/resources/2015-2020_Dietary_Guidelines.pdf.

²² HHS & USDA, 2015–2020 DIETARY GUIDELINES FOR AMERICANS 8TH EDITION 23 (Dec. 2015) (“Soy beverages fortified with calcium, vitamin A, and vitamin D, are included as part of the dairy group because they are similar to milk based on nutrient composition and in their use in meals. Other products sold as “milks” but made from plants (e.g., almond, rice, coconut, and hemp “milks”) may contain calcium and be consumed as a source of calcium, but they are not included as part of the dairy group because their overall nutritional content is not similar to dairy milk and fortified soy beverages (soymilk).”).

²³ *Id.* at 49.

²⁴ See DIETARY GUIDELINES, *supra* note 18, FOOD SOURCES OF CALCIUM, APPENDIX 11 at 108-111.

²⁵ *Id.*

cup each of almond milk, soymilk, and rice drink compare with one cup of cow’s milk in the Dietary Guidelines’ ranking:

| Rank | Food | Calories in Standard Portion | Calcium in Standard Portion (mg) | Calories per 100 grams | Calcium per 100 grams (mg) |
|-----------|---------------------------|------------------------------|----------------------------------|------------------------|----------------------------|
| 6 | Almond milk | 91-120 | 451 | 38-50 | 188 |
| 15 | Soymilk | 109 | 340 | 45 | 140 |
| 24 | Low-fat milk (1%) | 102 | 305 | 42 | 125 |
| 26 | Skim milk (nonfat) | 83 | 299 | 34 | 122 |
| 27 | Reduced fat milk (2%) | 122 | 293 | 50 | 120 |
| 31 | Rice drink | 113 | 283 | 47 | 118 |
| 34 | Whole milk | 149 | 276 | 61 | 113 |

In fact, both tofu and spinach both rank higher in calcium than cow’s milk.²⁶

5. There is no evidence that consumers are misled about the nutritional content of plant-based milks.

The legislative findings state that “dairy foods are excellent sources of critical nutrients for human health, including vitamin D, calcium, and potassium, all of which are under consumed by people of the United States” and “Imitation dairy products, such as plant-based products . . . often do not provide the same nutrition content as real milk, cheese, and yogurt derived from dairy cows,” implying that plant-based milks are inferior. The next finding says that plant-based products are misleading to consumers, suggesting that consumers do not understand that plant-based products have a different nutritional content than milk.

The USDA-mandated Nutrition Facts label²⁷ ensures that consumers are not misled about plant-based beverages’ nutritional content. Thus, there is no likelihood that a reasonable consumer would be misled into believing a plant-based beverage has the same nutritional content as cow’s milk. Indeed, in *Gitson v. Trader Joe’s Co.* (discussed in Section C.1 above), the Court found that a reasonable consumer would not assume that soymilk and cow’s milk have the same nutritional content,²⁸ pointing to the fact that a reasonable consumer could simply consult the Nutrition Facts label for information about nutrient content.²⁹

6. The restriction on the use of the word “ice cream” undercuts the ostensible purpose of the bill to protect the public health.

The legislative findings imply that the purpose of the bill is to protect the public health; indeed, five of the eight legislative findings concern nutrition and two state that plant-

²⁶ *Id.*

²⁷ 9 CFR Part 317.

²⁸ *Gitson* at *4.

²⁹ *Id.*

based milk product names are misleading. But if the purpose of the proposed legislation is to protect the public health, why then does the legislation bar plant-based desserts from calling themselves “ice cream”? The Dietary Guidelines urge individuals to “limit calories from added sugars and saturated fats . . .”³⁰ and The USDA recommends that individuals “cut back on foods containing saturated fat including . . . ice cream and other dairy desserts.”³¹ The Dietary Guidelines also say, “[I]ndividuals should eat as little dietary cholesterol as possible while consuming a healthy eating pattern.”³² Individuals who wish to minimize their intake of cholesterol, and thus reduce their risk of cardiovascular disease,³³ can do so by avoiding animal products.

Ice cream made from dairy milk tends to contain significantly more saturated fat than plant-based ice creams, with the exception of plant-based ice creams made from coconut milk, and no plant-based ice creams contain cholesterol. Here’s how the sugar, total fat, saturated fat, and cholesterol, in ½ cup of six popular brands of vanilla compare:

| Brand | Total fat | Saturated fat | Sugar | Cholesterol |
|---------------------------------------------------------------------------------|------------------|----------------------|--------------|--------------------|
| Haagen Dazs Vanilla Dairy Ice Cream ³⁴ | 17g | 10g | 20g | 90mg |
| Ben & Jerry’s Vanilla Dairy Ice Cream ³⁵ | 16g | 10g | 20g | 90mg |
| Breyer’s Vanilla Natural Dairy Ice Cream ³⁶ | 7g | 4g | 14g | 20mg |
| Luna & Larry’s Organic Coconut Bliss Vanilla (Coconut milk based) ³⁷ | 16g | 14g | 13g | 0mg |
| Almond Dream Vanilla Dairy-Free (Almond milk based) ³⁸ | 7g | 1g | 12g | 0mg |
| So Delicious Vanilla Dairy-Free (Soy milk based) ³⁹ | 3g | 0g | 14g | 0mg |

³⁰ DIETARY GUIDELINES, *supra* note 18, at xii.

³¹ USDA, Choose Foods and Beverages with Less Saturated Fat, Sodium, and Added Sugars, Choose My Plate, <https://www.choosemyplate.gov/saturated-unsaturated-and-trans-fats>.

³² DIETARY GUIDELINES, *supra* note 18, at 32.

³³ *Id.* (“Strong evidence from mostly prospective cohort studies but also randomized controlled trials has shown that eating patterns that include lower intake of dietary cholesterol are associated with reduced risk of CVD [cardiovascular disease], and moderate evidence indicates that these eating patterns are associated with reduced risk of obesity.”)

³⁴ Haagen-Dazs, Vanilla, <https://www.haagendazs.us/products/2473/ice-cream/vanilla>.

³⁵ Ben & Jerry’s, Vanilla, <http://www.benjerry.com/flavors/vanilla-ice-cream>.

³⁶ Smartlabel, Breyers, Ice Cream, Natural Vanilla, <http://smartlabel.breyers.com/product/2749366/nutrition?locale=en-US>.

³⁷ Luna & Larry’s Coconut Bliss, Vanilla Island, <http://coconutbliss.com/bliss/vanilla-island>.

³⁸ Almond Dream, Vanilla, <http://www.dreamplantbased.com/product/almond-dream-vanilla>.

³⁹ So Delicious Dairy Free, Creamy Vanilla, <http://sodeliciousdairyfree.com/products/soy-milk-frozen-desserts/creamy-vanilla>.

7. Plant-based milks are a reasonable alternative to consumers who choose not to consume dairy products due to health needs, religious beliefs, and/or concerns about animals and the environment.

There is no evidence that prohibiting the use of words such as “milk,” “ice cream,” “cheese,” and “yogurt” in plant-based products would cause consumers to buy more animal-based dairy products instead of plant-based products. The simple fact is that the growing consumer interest in plant-based milks, ice cream, yogurt, and cheese is due *not* to any confusion about what these milks contain; rather, it is in large part due to consumers’ deliberate choice to consume non-dairy alternatives. Some consumers do not drink or limit their intake of cow’s milk because they (i) are allergic to it,⁴⁰ (ii) are lactose intolerant,⁴¹ (iii) have a moral conviction that it is unjust for humans to exploit non-human animals,⁴² (iv) have animal welfare concerns relating the treatment of dairy cows,⁴³ (v) have adopted plant-based diets on the recommendation of their doctors and nutritionists,⁴⁴ (vi) have concerns

⁴⁰ Cow’s milk is a “major food allergen” (21 USC § 321(qq)(1)) for which there is no suitable therapy available except avoidance. Approximately 0.6–2.5% of preschoolers, 0.3% of older children and teens, and less than 0.5% of adults are allergic to cow’s milk. (Heidrun Hochwallner *et al.*, *Cow’s Milk Allergy: From Allergens to New Forms of Diagnosis, Therapy and Prevention*, 66 METHODS 22 (March 2014), available at http://ac.els-cdn.com/S1046202313003034/1-s2.0-S1046202313003034-main.pdf?_tid=9fc54a30-dbf-11e6-afd8-0000aacb361&acdnat=1484579054_d1c2edf9a82bc48c4f06be67e7de2524.) The current treatment for a cow’s milk allergy is the elimination of cow’s milk from the diet. (*Id.* at 28.) For people who are allergic to cow’s milk, plant-based milks are often a reasonable alternative. Plant-based milks that are made from tree nuts and soy also contain allergens (21 USC § 321(qq)), but not all people who are allergic to cow’s milk are allergic to plant-based milks. (*See, e.g., id.* (Soy milk induces allergic reactions in up to 15% of infants who are allergic to cow’s milk.)).

⁴¹ People who are lactose intolerant, for instance, are unable to fully digest the lactose (a sugar) in milk. (Mayo Clinic, Lactose Intolerance, Definition (Sept. 2, 2016), available at <http://www.mayoclinic.org/diseases-conditions/lactose-intolerance/basics/definition/con-20027906>.) As a result, they have uncomfortable symptoms such as diarrhea, gas, and bloating after consuming dairy products. (*Id.*) Unlike people who are allergic to dairy milk, lactose intolerant individuals may consume dairy products, but limiting intake of dairy products is one way to reduce symptoms. (Mayo Clinic, Lactose Intolerance, Lifestyle and Home Remedies (Sept. 2, 2016), available at <http://www.mayoclinic.org/diseases-conditions/lactose-intolerance/basics/lifestyle-home-remedies/con-20027906>.)

⁴² *See generally* the website of the American Vegan Society at www.americanvegan.org; the website of the Peace Advocacy Network at <http://www.peaceadvocacynetwork.org>.

⁴³ Woodstock Farm Sanctuary, *Cows for Dairy*, available at <http://woodstocksanctuary.org/learn/animals-used-for-food/cows-for-dairy>. For example, some consumers find the common industry practice of taking one- and two-day-old calves away from mother cows unconscionable; or they find reports about violations of animal cruelty laws by employees of dairy producers disconcerting. For example, Wisconsin’s Wiese Brothers Farms workers, Abelardo Jaimes and Lucia Martinez, were convicted of multiple counts of animal cruelty relating to treatment of dairy cows in April 2014. Katie DeLong, *Animal cruelty: Two more convictions tied to Wiese Bros. Farm*, Fox6, (May 6, 2014), available at <http://fox6now.com/2014/05/06/two-more-connected-to-wiese-brothers-farm-convicted-of-animal-cruelty>.

⁴⁴ *See, e.g.*, Thomas Campbell, MD, T. Colin Campbell Center for Nutrition Studies, *How to Get Calcium Without Dairy* (Dec. 12, 2014) (suggesting that plant-based sources of calcium are strongly preferable to cow’s milk, for which health problems may be attributable), available at <http://nutritionstudies.org/how-to-get-calcium-without-dairy>.

about the environment,⁴⁵ (vii) possess certain religious beliefs,⁴⁶ or (viii) prefer the taste of plant-based milks.

D. SUMMARY

For the reasons explained above, the Animal Law Committee and Consumer Affairs Committee oppose the Dairy Pride Act.

Lori A. Barrett
Chair, Animal Law Committee

Carla A. Latty
Chair, Consumer Affairs Committee

March 2017

⁴⁵ See, e.g., FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, ANIMAL PRODUCTION AND HEALTH DIVISION, GREENHOUSE GAS EMISSIONS FROM THE DAIRY SECTOR (2010) (“The global dairy sector contributes 4.0 percent to the total global anthropogenic GHG [greenhouse gas] emissions”), available at <http://www.fao.org/docrep/012/k7930e/k7930e00.pdf>; Beth Gardiner, *How Growth in Dairy Is Affecting the Environment*, NY TIMES (May 1, 2015), available at <https://www.nytimes.com/2015/05/04/business/energy-environment/how-growth-in-dairy-is-affecting-the-environment.html>.

⁴⁶ E.g., Charles Camosy, *Why all Christians Should go Vegan*, WASHINGTON POST (Jan. 5, 2017) (“The Bible is clear, and early Christians understood it: Animals are meant to be our companions, not our food.”), available at https://www.washingtonpost.com/posteverything/wp/2017/01/05/why-all-christians-should-go-vegan/?postshare=9371483625693074&tid=ss_fb-bottom&utm_term=.bced95051698; The Jewish Vegetarian Society, *What’s Jewish About Being Veg?*, (“There is no disputing that, according to the Torah, God asked human beings to be vegans in his very first conversation with Adam and Eve.”), available at <https://www.jewishveg.org/whats-jewish-about-being-veg>.



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February 24, 2017

Dr. Stephen Ostroff, M.D.
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Labeling of Plant-Based Milks

Dear Commissioner Ostroff:

The Animal Law Committee of the New York City Bar Association writes in response to a December 16, 2016 letter from 32 members of Congress to Robert M. Califf, Commissioner of the Food & Drug Administration.¹ In their letter, the Members request that the FDA investigate and take action against manufacturers of plant-based products labeled “milk.”

The New York City Bar Association is a private, non-profit organization of more than 24,000 attorneys, judges and law professors and is one of the oldest bar associations in the United States. The Animal Law Committee regularly addresses legal issues involving non-human animals on local, state, national, and international levels.

A. INTRODUCTION

In their letter, the 32 members of Congress (“Members”) object to the centuries-old² use of the term “milk” for plant-based beverages—like the “soy milk” and “almond milk”

¹ The letter is available online at <http://www.nmpf.org/files/Welch-Simpson%20Letter.pdf>. (All websites last visited February 23, 2017.)

² Notably, the Oxford English Dictionary documents a reference to almond milk - or “mylke of almaundes” - dating from the early-fifteenth century. *See* OXFORD ENGLISH DICTIONARY, at <http://oed.com> (enter “milk”; then click “Go”) (citing CURYE ON INGLYSCH at 114 (eds. Constance B. Hieatt and Sharon Butler) (1985)). The dictionary notes several other similar historical references, as well as more recent ones.

found in nearly every grocery store. Specifically, the Members claim that using this term (1) misleads consumers, (2) is a “violation of milk’s standard of identity,” and (3) harms the dairy industry. The Members further allege that, by labeling such plant-based beverages “milk,” manufacturers of these beverages are engaging in illegal activity. The Members accordingly urge the FDA to investigate and take action against such manufacturers.

We respectfully submit that the FDA should not do so. As explained below, neither the facts nor the law warrant prohibiting the use of the term “milk” in plant-based products because: (1) labeling a plant-based beverage “milk” does not mislead consumers, because no reasonable consumer would believe that such milk comes from a cow; (2) the qualified use of the word “milk” in the names of plant-based products is not “a violation of milk’s standard of identity”; (3) the Members’ concern that consumers are confused about the nutritional content of plant-based milk is unsupported by facts; and (4) the FDA should not make public safety decisions based on the financial state of the dairy industry.

B. ARGUMENT

1. Labeling a plant-based beverage “milk” does not mislead consumers, because no reasonable consumer would believe that such milk comes from a cow.

The Members assert, “[T]he use of the term ‘milk’ by manufacturers of plant-based products is misleading to consumers.” Yet they offer no evidence in support of this claim. And in fact, courts in recent cases have concluded just the opposite: that the plant-based beverages labeled “milk” are not misleading to consumers, for the simple reason that no reasonable consumer would believe that “soy milk,” for instance, is the same as the “milk” that comes from a cow.

In particular, two federal courts have recently found it implausible that a reasonable consumer³ could confuse soymilk or similar products with milk from a cow. In *Ang v. Whitewave Foods Co.*, Case No. 13-cv-1953, 2013 U.S. Dist. Lexis 173185 (N.D. Cal., Dec. 10, 2013), for instance, the U.S. District Court for the Northern District of California rejected the very argument that the Members make here. There, plaintiffs claimed that the defendants had misbranded plant-based products by using names like “soymilk,” “almond milk,” and “coconut milk.” They noted that 21 C.F.R. § 131.110 describes “milk” as a secretion from cows, and they argued that reasonable consumers were likely to believe that “soymilk,” “almond milk,” and “coconut milk” likewise came from a cow. The Court disagreed and dismissed the claims, finding that it was “simply implausible” that a consumer would mistake such plant-based products with dairy milk⁴ and that it was “highly improbable” that a reasonable consumer would simply disregard the words preceding the word “milk” in products like “soymilk” and “almond milk” and assume that the beverages came from cows.

³ The FDA uses the “reasonable consumer” standard in evaluating labeling for dietary supplements and conventional foods. FDA, GUIDANCE: QUALIFIED HEALTH CLAIMS IN THE LABELING OF CONVENTIONAL FOODS AND DIETARY SUPPLEMENT (Dec. 2002), available at <http://www.fda.gov/ohrms/dockets/98fr/02d-0515-gdl0001.pdf>.

⁴ *Ang*, at *12-13.

Similarly, in *Gitson v. Trader Joe's Co.*, Case No. 3:13-cv-01333, 2015 U.S. Dis. Lexis 170401 (N.D. Cal., Oct. 4, 2013), the U.S. District Court for the Northern District of California held that the use of the word “soymilk” in Trader Joe’s products could not conceivably violate the federal Food, Drug and Cosmetic Act. The Court found that a reasonable consumer—and even “the least sophisticated consumer”—would not think that soymilk comes from a cow.

2. The qualified use of the word “milk” in the names of plant-based products is not “a violation of milk’s standard of identity.”

The Members’ second, related claim—that dairy milk’s “standard of identity” is violated by the use of the word “milk” in the names of plant-based products—likewise lacks support. As background, the Food, Drug, and Cosmetics Act authorizes the FDA to prescribe a “standard of identity” if “such action will promote honesty and fair dealing in the interest of consumers.”⁵ In their letter, the Members observe that the description of milk in the FDA’s regulations is “the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows” and that plant-based milk does not meet this standard because it does not come from cows.⁶

Yet the Members fail to address the fact that the plant-based beverages at issue are not labeled just “milk”; rather, they simply *include the word “milk” in their name*. And in fact, in *Gitson* (see Section B.1 above), the U.S. District Court for the Northern District of California drew on just this distinction in holding that a manufacturer’s use of the word “soymilk” did not violate milk’s “standard of identity.”⁷ The Court reasoned that the fact that milk has a standard of identity “does not categorically preclude a company from giving any food product a name that includes the word ‘milk.’”⁸ Rather, the “standardization of milk simply means that a company cannot *pass off* a product as “milk” if it does not meet the regulatory definition of milk.”⁹ The Court found that the manufacturer in that case did not purport to pass off its product as cow’s milk because the product clearly identified itself as derived from soy—“soymilk.”¹⁰

Notably, while the Members claim that a plant-based beverage like soymilk violates milk’s standard of identity because it does not come from cows, they do not claim that goat’s milk and sheep’s milk—which also do not come from cows—violate milk’s standard of identity. Yet they provide no reason for treating plant-based “milks” differently from milks that come from other animals. And indeed, there is none. In the cases of goat’s milk and sheep’s milk, the preceding words “goat” and “sheep” put consumers on notice that the product does not come from a cow. Likewise, the use of words like “soy,” “rice,” “almond,”

⁵ 21 U.S.C. § 341.

⁶ 21 CFR § 131.110(a).

⁷ *Gitson*, at *5-6.

⁸ *Gitson*, at *6.

⁹ *Id.*

¹⁰ *Id.* at *6-7.

“cashew,” “coconut,” “hemp,” etc., put consumers on notice that a particular plant-based milk does not come from a cow.¹¹

3. The Members’ concern that consumers are confused about the nutritional content of plant-based milks is unsupported by facts.

The Members ask the FDA to take action against plant-based milk producers to “provide consumers with the accurate information they expect,” which suggests that consumers are not receiving accurate nutritional information about plant-based milks.

The USDA-mandated Nutrition Facts label¹² ensures that consumers are not misled about plant-based beverages’ nutritional content. Thus, there is no likelihood that a reasonable consumer would be misled into believing a plant-based beverage has the same nutritional content as cow’s milk. Indeed, in *Gitson v. Trader Joe’s Co.* (discussed in Section B.1 above), the Court found that a reasonable consumer would not assume that soymilk and cow’s milk have the same nutritional content,¹³ pointing to the fact that a reasonable consumer could simply consult the Nutrition Facts label for information about nutrient content.¹⁴

4. The FDA should not make public safety decisions based on the financial state of the dairy industry.

The Members also note that dairy farmers are “facing a serious financial crisis” and notes that milk prices have plunged 40 percent since 2014 and sales of dairy milk declined by 7 percent in 2015. The Members also observe that there has been “tremendous growth in the sale of plant-based products” and that, in the past five years, sales of certain plant-based milks grew 250 percent.

The FDA—which is charged with “protect[ing] the public health by ensuring that . . . foods are safe, wholesome, sanitary, and properly labeled”¹⁵—should not make its public safety decisions based on the financial state of the dairy industry. And indeed, the FDA has no legal authority to enforce its regulations with a goal of helping an industry overcome a

¹¹ The National Milk Producers Federation made a claim that soymilk violates milk’s standard of identity in a letter to the FDA dated February 14, 2000. (As of the date of this writing, the link to the letter on the Federation’s website appears to be broken.) The Soyfoods Association of North America responded to that claim by letter to the FDA dated March 9, 2000, *available at* <http://www.fda.gov/ohrms/dockets/dailys/00/apr00/041700/c000012.pdf>. On page 2 of the letter, Soyfoods makes an apt analogy to the labeling of wheat products: although the standard of identity of “bread” requires wheat, there seems to be no objection to product labels for “rye-bread” and “oatmeal bread,” which are not made of wheat.

¹² 9 CFR Part 317.

¹³ *Gitson* at *4.

¹⁴ *Id.*

¹⁵ 21 U.S.C. § 393.

financial crisis. That task is left to the U.S. Department of Agriculture, which has statutory authority to provide support to the dairy industry to help it with a financial crisis.¹⁶

Further, even if the FDA *did* have authority to direct some manufacturers to change their products' names to financially benefit manufacturers of competitor products (which it does not), there is no evidence that doing so here would cause consumers to buy more cow's milk instead of plant-based milks. The simple fact is that the growing consumer interest in plant-based milks is due *not* to any confusion about what these milks contain; rather, they are in large part due to consumers' deliberate choice to drink non-dairy alternatives. Some consumers do not drink or limit their intake of cow's milk because they (i) are allergic to it,¹⁷ (ii) are lactose intolerant,¹⁸ (iii) have a moral conviction that it is unjust for humans to exploit non-human animals,¹⁹ (iv) have animal welfare concerns relating the treatment of dairy cows,²⁰ (v) have adopted plant-based diets on the recommendation of their doctors and nutritionists,²¹ (vi) have concerns about the environment,²² (vii) possess certain religious beliefs,²³ or (viii) prefer the taste of plant-based milks.

¹⁶ See e.g., Agricultural Act of 2014, Pub. L. No. 113-79 (Feb. 7, 2014), Title I, Subtitle D.

¹⁷ Cow's milk is a "major food allergen" (21 USC § 321(qq)(1)) for which there is no suitable therapy available except avoidance. Approximately 0.6–2.5% of preschoolers, 0.3% of older children and teens, and less than 0.5% of adults are allergic to cow's milk. (Heidrun Hochwallner *et al.*, *Cow's Milk Allergy: From Allergens to New Forms of Diagnosis, Therapy and Prevention*, 66 *METHODS* 22 (March 2014), available at http://ac.els-cdn.com/S1046202313003034/1-s2.0-S1046202313003034-main.pdf?_tid=9fc54a30-dbf-11e6-afd8-0000aacb361&acdnat=1484579054_d1c2edf9a82bc48c4f06be67e7de2524.) The current treatment for a cow's milk allergy is the elimination of cow's milk from the diet. (*Id.* at 28.) For people who are allergic to cow's milk, plant-based milks are often a reasonable alternative. Plant-based milks that are made from tree nuts and soy also contain allergens (21 USC § 321(qq)), but not all people who are allergic to cow's milk are allergic to plant-based milks. (See, e.g., *id.* (Soy milk induces allergic reactions in up to 15% of infants who are allergic to cow's milk).)

¹⁸ People who are lactose intolerant, for instance, are unable to fully digest the lactose (a sugar) in milk. (Mayo Clinic, Lactose Intolerance, Definition (Sept. 2, 2016), available at <http://www.mayoclinic.org/diseases-conditions/lactose-intolerance/basics/definition/con-20027906>.) As a result, they have uncomfortable symptoms such as diarrhea, gas, and bloating after consuming dairy products. (*Id.*) Unlike people who are allergic to dairy milk, lactose intolerant individuals may consume dairy products, but limiting intake of dairy products is one way to reduce symptoms. (Mayo Clinic, Lactose Intolerance, Lifestyle and Home Remedies (Sept. 2, 2016), available at <http://www.mayoclinic.org/diseases-conditions/lactose-intolerance/basics/lifestyle-home-remedies/con-20027906>.)

¹⁹ See generally the website of the American Vegan Society at www.americanvegan.org; the website of the Peace Advocacy Network at <http://www.peaceadvocacynetwork.org>.

²⁰ Woodstock Farm Sanctuary, *Cows for Dairy*, available at <http://woodstocksanctuary.org/learn/animals-used-for-food/cows-for-dairy>. For example, some consumers find the common industry practice of taking one- and two-day-old calves away from mother cows unconscionable; or they find reports about violations of animal cruelty laws by employees of dairy producers disconcerting. For example, Wisconsin's Wiese Brothers Farms workers, Abelardo Jaimes and Lucia Martinez, were convicted of multiple counts of animal cruelty relating to treatment of dairy cows in April 2014. Katie DeLong, *Animal cruelty: Two more convictions tied to Wiese Bros. Farm*, Fox6, (May 6, 2014), available at <http://fox6now.com/2014/05/06/two-more-connected-to-wiese-brothers-farm-convicted-of-animal-cruelty>.

²¹ See, e.g., Thomas Campbell, MD, T. Colin Campbell Center for Nutrition Studies, *How to Get Calcium Without Dairy* (Dec. 12, 2014) (suggesting that plant-based sources of calcium are strongly preferable to cow's

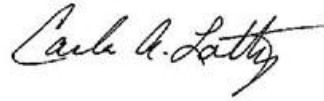
C. SUMMARY

For the reasons above, the FDA should reject the Members' request to investigate and take action against manufacturers of plant-based "milks."

Respectfully submitted,



Lori Barrett
Chair, Committee on Animal Law



Carla A. Latty
Chair, Consumer Affairs Committee

Cc: Hon. Earl Blumenauer
Hon. K. Michael Conaway
Hon. Mike Fitzpatrick
Hon. Kirsten Gillibrand
Hon. Collin Peterson
Hon. Pat Roberts
Hon. Chuck Schumer
Hon. Debbie Stabenow
Signatories to Dec. 16, 2016 letter to Robert M. Califf, Commissioner of the Food & Drug Administration

milk, for which health problems may be attributable), available at <http://nutritionstudies.org/how-to-get-calcium-without-dairy>.

²² See, e.g., FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, ANIMAL PRODUCTION AND HEALTH DIVISION, GREENHOUSE GAS EMISSIONS FROM THE DAIRY SECTOR (2010) ("The global dairy sector contributes 4.0 percent to the total global anthropogenic GHG [greenhouse gas] emissions"), available at <http://www.fao.org/docrep/012/k7930e/k7930e00.pdf>; Beth Gardiner, *How Growth in Dairy Is Affecting the Environment*, NY TIMES (May 1, 2015), available at <https://www.nytimes.com/2015/05/04/business/energy-environment/how-growth-in-dairy-is-affecting-the-environment.html>.

²³ E.g., Charles Camosy, *Why all Christians Should go Vegan*, WASHINGTON POST (Jan. 5, 2017) ("The Bible is clear, and early Christians understood it: Animals are meant to be our companions, not our food."), available at https://www.washingtonpost.com/posteverything/wp/2017/01/05/why-all-christians-should-go-vegan/?postshare=9371483625693074&tid=ss_fb-bottom&utm_term=.bced95051698; The Jewish Vegetarian Society, *What's Jewish About Being Veg?*, ("There is no disputing that, according to the Torah, God asked human beings to be vegans in his very first conversation with Adam and Eve."), available at <https://www.jewishveg.org/whats-jewish-about-being-veg>.