



NEW YORK  
CITY BAR

**COMMITTEE ON ANIMAL LAW**

LORI A. BARRETT  
**CHAIR**  
PHONE: (347) 388-8478  
animallawcommittee@hotmail.com

CHRISTOPHER WLACH  
**SECRETARY**  
PHONE: (917) 747-7297  
cwlach@gmail.com

**CONSUMER AFFAIRS COMMITTEE**

CARLA A. LATTY  
**CHAIR**  
PHONE: (212) 815-1885  
clatty@dc37.net

ELLIOT DOLBY-SHIELDS  
**SECRETARY**  
PHONE: (212) 425-1020  
edshieldslaw@gmail.com

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.<sup>1</sup> 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-old<sup>2</sup> use of the term “milk” for plant-based beverages—like the “soy milk” and “almond milk”

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

<sup>2</sup> 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 The dictionary notes several other similar historical references, as well as more recent ones.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 consumer<sup>3</sup> 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 milk<sup>4</sup> 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.

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<sup>3</sup> 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>.

<sup>4</sup> *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.”<sup>5</sup> 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.<sup>6</sup>

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.”<sup>7</sup> 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.’”<sup>8</sup> 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.”<sup>9</sup> 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.”<sup>10</sup>

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,”

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<sup>5</sup> 21 U.S.C. § 341.

<sup>6</sup> 21 CFR § 131.110(a).

<sup>7</sup> *Gitson*, at \*5-6.

<sup>8</sup> *Gitson*, at \*6.

<sup>9</sup> *Id.*

<sup>10</sup> *Id.* at \*6-7.

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

**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 label<sup>12</sup> 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,<sup>13</sup> pointing to the fact that a reasonable consumer could simply consult the Nutrition Facts label for information about nutrient content.<sup>14</sup>

**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”<sup>15</sup>—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

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<sup>11</sup> 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.

<sup>12</sup> 9 CFR Part 317.

<sup>13</sup> *Gitson* at \*4.

<sup>14</sup> *Id.*

<sup>15</sup> 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.<sup>16</sup>

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,<sup>17</sup> (ii) are lactose intolerant,<sup>18</sup> (iii) have a moral conviction that it is unjust for humans to exploit non-human animals,<sup>19</sup> (iv) have animal welfare concerns relating the treatment of dairy cows,<sup>20</sup> (v) have adopted plant-based diets on the recommendation of their doctors and nutritionists,<sup>21</sup> (vi) have concerns about the environment,<sup>22</sup> (vii) possess certain religious beliefs,<sup>23</sup> or (viii) prefer the taste of plant-based milks.

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

<sup>17</sup> 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](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.))

<sup>18</sup> 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>.)

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

<sup>20</sup> 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>.

<sup>21</sup> 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

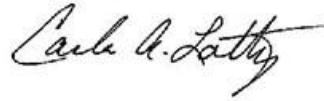
## C. SUMMARY

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

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

<sup>22</sup> 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>.

<sup>23</sup> 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](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>.