

March 7, 2019

Mr. Frank Yiannas Deputy Commissioner for Food Policy and Response U.S. Food & Drug Administration (FDA) 10903 New Hampshire Ave. Silver Spring, MD 20993

Re: FDA Enforcement of the Standard of Identity for Milk

Dear Deputy Commissioner Yiannas:

I am writing on behalf of the Vermont House Committee on Agriculture and Forestry regarding FDA's enforcement of standards of identity for milk and cream. Plant-based beverages are being sold across the nation as "milk" or "dairy products" in clear violation of FDA standards of identity and labeling rules. To avoid consumer confusion, ensure equity across industries, and avoid misappropriation of consumer trust in the nutritional benefits of milk, FDA should enforce its standards of identity and require manufacturers of plant-based beverages to remove the words "milk" or "dairy" from the labeling and advertising of their misbranded products.

A. Plant-Based Beverages Sold As Milk Are Misbranded Because These Products Do Not Comply with FDA's Standard of Identity for Milk

FDA's standards of identity clearly define "milk" as "the lacteal secretion . . . obtained by the complete milking of one or more healthy cows." All other FDA standards of identity for milk or cream rely on the standard of identity for milk. Whether the product is cream, yogurt, eggnog, or half and half, the product is derived in whole or in part from the lacteal secretions of a cow.²

Plant-based beverages, as intuited from their name and as clearly noted on an ingredients label of any of these products, are not derived from lacteal secretions of a cow.3 FDA acknowledged this fact when it stated in July of 2018 that:

"...[W]e've seen a proliferation of products made from soy, almond or rice calling themselves milk. However, these alternative products are not the food that has been standardized under the name "milk" and which has been known to the

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¹ See 21 C.F.R. § 131.110.

² See 21 C.F.R. part 131.

³ See, e.g. Ingredients of Blue Diamond, Unsweetened Original Almond Milk: (filtered water, almonds), calcium carbonate, sea salt, potassium citrate, sunflower lecithin, gellan gum, natural flavors, vitamin A palmitate, vitamin D2, D-Alpha-Tocopherol (natural vitamin E), available at https://www.bluediamond.com/brand/almond-breeze/almondmilk/unsweetened-original.

American public as "milk" long before the 1938 Federal Food, Drug, and Cosmetic Act (FD&C Act) was established."⁴

Moreover, FDA Commissioner Scott Gottlieb plainly stated that plant-based beverages do not meet the standards of identity for milk, cream, and other dairy products, because "an almond doesn't lactate."⁵

Under the FD&C Act, a product is misbranded if it <u>purports to be</u> or is <u>represented as a food</u> for which FDA has issued a standard identity but the product does not conform to the standard.⁶ Plant-based beverages clearly violate this test and likely never will meet the standard of identity for milk or dairy products. Thus, FDA should utilize one of its various enforcement tools⁷ to prohibit plant-based beverages from being sold, labeled, or advertised as milk.

B. Labeling Plant-Based Beverages As "Milk" Is Misleading and Can Have Significant Negative Health Effects for Misled Consumers

A primary purpose of the FD&C Act is to prevent misleading labeling of foods.⁸ Allowing a plant-based product to be labeled as a "milk" when it clearly conflicts with an FDA standard of labeling is on its face misleading. Moreover, labeling plant-based beverages as milk can create consumer confusion not only with regard to ingredients but also with regard to the nutritional benefit of the product.

Milk and dairy products provide nutrients that are vital for health, including calcium, potassium, vitamin D, and protein. Intake of dairy products is linked to improved bone health, may reduce the risk of osteoporosis, and may reduce the risk of developing cardiovascular disease, type 2 diabetes, and hypertension. Moreover, dairy products are especially important to bone health during childhood and adolescence, when bone mass is being built. 11

In contrast, plant-based beverages can vary widely in nutritional content, and FDA has noted that these products are not nutritionally equivalent to milk or dairy products. This can have significant health consequences when consumers believe that a plant-based beverage is the same nutritionally as a dairy product. In fact, FDA has noted that such consumer confusion can lead to underconsumption of key nutrients, the risk of which is heightened in children when parents substitute plant-based beverages for milk. To avoid misleading consumers into the belief that plant-based beverages have the same nutritional benefit as milk, FDA should prohibit plant-based beverages from being sold, labeled, or advertised as milk.

⁴ See Statement from FDA Commissioner Scott Gottlieb, M.D., on the Process FDA is Undertaking for Reviewing and Modernizing the Agency's Standards of Identity for Dairy Products (July 26, 2018), available at https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm614851.htm.

⁵ See Gottlieb: FDA to crack down on labeling nondairy products as 'milk', available at https://www.politico.com/story/2018/07/17/almond-lactate-nondairy-milk-scott-gottlieb-725974.

^{6 21} U.S.C. § 343(g).

⁷ See Types of FDA Enforcement Actions, available at https://www.fda.gov/AnimalVeterinary/ResourcesforYou/ucm268127.htm.

⁸ See 21 U.S.C. § 343.

⁹ U.S.D.A. Choose My Plate; Dairy Nutrients and Health Benefits, available at https://www.choosemyplate.gov/dairy-nutrients-health. ¹⁰ Id.

¹¹ Id

¹² See, Statement from FDA Commissioner Scott Gottlieb, M.D., on modernizing standards of identity and the use of dairy names for plant-based substitutes (Sept. 27, 2018), available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm621824.htm.
¹³ Id.

C. Prohibiting the Sale, Labeling, or Advertising of Plant-Based Beverages As Milk Will Provide Regulatory Equity for Dairy Producers

Vermont produces the majority of the milk in New England. The dairy industry generates over \$2.2 billion annually for the State's economy and employ more than 6,000 persons in Vermont. However, the dairy industry is struggling as market constraints and market volatility keep prices artificially low. During these struggles, farmers should not need to fear market loss from misbranded products falsely claiming to be milk.

Plant-based beverages mislabeled as "milk" clearly do not meet the standard of identity for milk and dairy products, are patently misbranded as milk, and unfairly mislead consumers. FDA should exercise its enforcement authority to prohibit the sale and advertising of plant-based beverages until they are relabeled to prevent misleading consumers as to the ingredients and nutritional content of the product. We ask that the FDA initiate this enforcement as soon as possible.

We thank you in advance for reviewing this letter and taking the action necessary to prevent the sale and advertising of plant-based beverages as milk. If you need additional information, please contact us by telephone through our staff attorney Michael O'Grady at (802) 828-2282.

Sincerely,

Rep. Carolyn Partridge Chair, House Committee on Agriculture and Forestry