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*Via regulations.gov*

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Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, Maryland 20852

**Re: Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements; Draft Guidance for Industry; Docket No. FDA-2023-D-0451.**

The Animal Legal Defense Fund (ALDF), on behalf of its members and supporters, respectfully submits these comments in response to the Food and Drug Administration’s (FDA) Draft Guidance for Industry on the Labeling of Plant-Based Milk Alternatives and Voluntary Nutrition Statements.<sup>1</sup> FDA rightfully understands that consumers are not confused by common or usual naming conventions, and the agency correctly upheld the status quo by continuing to allow plant-based milk producers to label and market their products using the widespread and deeply understood naming conventions they have used for decades. However, FDA departs not only from the status quo, but also longstanding labeling law, by recommending that plant-based milk producers make derogatory disclosures and negative comparisons of their products with their direct market competitors. In this respect, FDA’s recommendation treats similar situations differently, discriminates against one sector to favor a competing sector, disregards health science, runs contrary to consumer studies, and contradicts decades of FDA policy on nutrition labeling. As such, FDA should abandon its recommended Voluntary Nutrient Statement when it issues a final Guidance for Industry on the labeling of plant-based milk.

**Statement of Interest**

ALDF is a national non-profit organization founded in 1979 to protect the lives and advance the interests of animals through the legal system. ALDF has over 300,000 members and supporters, including thousands of dedicated attorneys, throughout the United States. ALDF works to ensure the fair treatment of plant-based food products in the marketplace; including preventing the spread of misinformation by the animal agriculture industry that may cause consumer confusion. ALDF is deeply invested in the responsible marketing and labeling of plant-based products. It is in the interest of ALDF as well as plant-based food companies to guarantee honest and accurate labels and labeling standards for plant-based foods.

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<sup>1</sup> Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements; Draft Guidance for Industry, 88 Fed. Reg. 11449 (Feb. 23, 2023) [hereinafter “FDA Draft Guidance on Plant-Based Milk”].

## Background

In 2021, plant-based milk sales in the United States totaled \$2.6 billion, making up 16% of all milk sales.<sup>2</sup> Consumers cite numerous reasons for switching away from animal-based dairy products, including flavor, health, wellness, sustainability, and animal welfare.<sup>3</sup> Concurrent with the rise of plant-based milk is a decline in the consumption of animal-based milk; American household consumption of fluid animal-based milk fell faster during the 2010's than in each of the previous six decades.<sup>4</sup>

The animal-based dairy industry has responded to this increased market competition by pushing for the enactment of laws to prohibit plant-based milk producers from using the word “milk,” and criticizing the health and environmental benefits of switching to plant-based milk. But there is no evidence that consumers misunderstand the nature of plant-based milk. Moreover, there is broad scientific consensus that plant-based milk is healthier for consumers and the planet. Animal-based dairy like cows’ milk contains high levels of cholesterol (which is wholly absent from plant-based milks) and has been linked to numerous chronic diseases such as cancer and cardiovascular disease, the leading cause of preventable deaths in the United States.<sup>5</sup> Many of the reasons that people historically thought drinking milk was healthy, such as maintaining bone health, have been disproven.<sup>6</sup> Furthermore, tens of millions of Americans are lactose intolerant, with the highest rates of intolerance occurring in communities of color. Many people seek out plant-based milk and other plant-based dairy products precisely to avoid the adverse health consequences of animal-based dairy.

A majority of comments submitted to FDA,<sup>7</sup> including many in response to this draft guidance,<sup>8</sup> support the status quo. In particular, consumers do not want any additional burdens

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<sup>2</sup> Exhibit 1, *U.S. Retail Market Data for the Plant-based Industry*, GOOD FOOD INST., <https://gfi.org/marketresearch/#overview>.

<sup>3</sup> Exhibit 2, COMAX FLAVOR, NOT MILKING IT (2017).

<sup>4</sup> *U.S. per capita fluid cow's milk consumption slid further during the 2010s*, USDA ECON. RSCH. SERV. (Jan. 31, 2022), <https://www.ers.usda.gov/data-products/chart-gallery/gallery/chart-detail/?chartId=103091> [<https://perma.cc/D78K-F9F2>].

<sup>5</sup> See *infra* II.b.

<sup>6</sup> See Exhibit 3, R. G. Cumming & R. J. Klineberg, *Case-Control Study of Risk Factors for Hip Fractures in the Elderly*, 139(5) *Am. J. Epidemiology* 493 (1994) (finding that “[c]onsumption of dairy products . . . was associated with an increased risk of hip fracture”); Exhibit 4, Diane Feskanich et al., *Milk Consumption During Teenage Years and Risk of Hip Fractures in Older Adults*, 168(1) 54 *JAMA PEDIATRICS* (2014) (finding that higher rates of teenage milk consumption was correlated with higher rates of bone fractures as adults).

<sup>7</sup> See Exhibit 5, *More Than 75% of Commenters Tell FDA: Allow Plant-Based Alternatives to Use Dairy Terms*, PLANT BASED FOOD ASS'N (Apr. 22, 2019), <https://www.plantbasedfoods.org/commenters-tell-fda-allow-plant-based-alternatives-to-use-dairy-terms/>.

<sup>8</sup> *E.g.*, Comment from Tru Joi Curtis (Apr. 5, 2023) (“In my opinion, plant-based milk being labeled as milk does not cause consumer confusion. Ever since I started seeing plant-based milk (soy milk, almond milk, etc.) on the shelves I knew that it was not ‘real’ milk.”); Comment from Katie Winkelman (Mar. 16, 2023) (“In short, no[]body is confused.”); Comment from Holly Smith (Mar. 2, 2023) (“Literally no one is confused that a nut milk is the same as dairy milk . . . Many, many people purchase plant based milks out of necessity for health (family member with an anaphylactic allergy to cow's milk) or because cow's milk makes them sick or stuffed up . . . This is much ado about nothing.”); Comment from Pamela Koslyn (Mar. 2, 2023) (“Of course consumers know plant “milk” isn't from cows. That's why we buy it. Plant-Based Milk Alternatives products aren't hiding anything; these manufacturers go out their way to name their products using the plant name, and often have images of nuts on their packaging.”); Comment from Tom Wolf (Feb. 26,

placed on plant-based milks. To facilitate FDA’s goal of “improv[ing] dietary patterns in the United States to help reduce the burden of nutrition-related chronic diseases and advance health equity,”<sup>9</sup> the agency should not discriminate against plant-based dairy producers by recommending they voluntarily compare their products unfavorably with marketplace competitors—an anticompetitive first in the history of the agency.

## Argument

### I. FDA rightfully concluded that consumers understand plant-based dairy product labels.

In the Draft Guidance, FDA concluded that the word “milk” is “strongly rooted in consumers’ vocabulary when describing and talking about plant-based milk alternatives” and that names like “almond milk” or “soy milk” are those products common or usual names.<sup>10</sup> ALDF commends FDA on this decision as it reflects historical uses and consumer understanding of these terms. Plant-based foods do not seek to be, and in practice are not, confused for animal-based products. Quite the opposite is true: Plant-based products rely on their ability to differentiate themselves from animal-based products to justify their prices and to market to consumers who value animal-free products for health, allergy, religious, environmental, or ethical reasons. Current and historic statements of identity for plant-based products, such as “soymilk,” “oat milk,” and “almond milk” conform with FDA’s requirements and ensure that consumers understand the nutritional information, use, and defining ingredients of the products they purchase. As such, FDA is right to confirm that these statements of identity are the common and usual names for plant-based milk.

#### a. Evidence of consumer understanding overwhelmingly demonstrates that consumers are not confused by the use of “milk” on plant-based products.

FDA rightfully acknowledged that plant-based milk qualifying terms such as “almond milk,” “soymilk,” or “coconut milk” are not confusing to consumers and are these products’ common and usual names.<sup>11</sup> In all the time that plant-based milk has been on the market, there has not been any reliable evidence demonstrating consumer confusion. Instead, there is considerable empirical research showing that consumers are well aware of both the differences between the identity of plant-based and animal-based milks as well as the nutritional content of plant-based milk products compared to animal-based milks.

Researchers at the University of Oklahoma found no confusion between animal-based and plant-based milk products both labeled with the term “milk.”<sup>12</sup> Participants in the study accurately

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2023) (“[T]hanks for ignoring the absurd arguments from the dairy industry that try to paint us consumers as idiots who can't figure out that soy milk isn't cow's milk to try to protect their industry . . . Plant milks have been around forever.”); Comment from Robert Foley (Feb. 26, 2023) (“[T]here is no confusion in the retail marketplace between plant-based milks and cow milk.”); Comment from Sharon Behl (Feb. 23, 2023) (“I agree that soy milk and other plant based milk should continue to be called milk as that is an commonly understood and accepted term.”); Comment from Christy Dennison (Feb. 22, 2023) (“This is a much needed step in the right direction. No one has ever been fooled by non-dairy milks and I feel so proud that you all are trying to fix this ridiculous problem.”).

<sup>9</sup> FDA Draft Guidance on Plant-Based Milk, at 3.

<sup>10</sup> *Id.* at 5, 8.

<sup>11</sup> *See id.* at 8.

<sup>12</sup> Exhibit 6, Silke Feltz & Adam Feltz, *Consumer Accuracy at Identifying Plant-based and Animal-based Milk Items*, 4(1) FOOD ETHICS 19 (2019).

identified the source of animal-based milk products 84% of the time, plant-based milk products 88% of the time, animal-based cheese products 81% of the time, and plant-based cheese products 74% of the time.<sup>13</sup> In fact, participants consistently performed better when measuring differences between plant and animal-based milk products than when measuring the differences among animal-based milk products.<sup>14</sup> These findings were confirmed by a second study in which 87% of participants correctly identified that products labeled with statements such as “revolutionizing dairy with plants,” “made from plants,” “lactose free,” and “cruelty free” did not contain animal products.<sup>15</sup> A similarly high percentage of participants understood that the product was made only with plants, did not use any animals, and was not made with cows’ milk.<sup>16</sup>

Relatedly, research from the Plant Based Foods Association found that 78% of cows’ milk drinkers agree that “milk” is the most appropriate term for products like soy milk or almond milk.<sup>17</sup> A 2018 study by the Good Food Institute also revealed that consumers are more than capable of determining the differences between cows’ milk and plant-based milk:

- 96% of consumers correctly selected soybeans as the primary ingredient used to make soy milk;
- 94% correctly selected cows’ milk as the primary ingredient used to make 2% milk;
- 94% correctly selected cows’ milk as the primary ingredient used to make whole milk;
- 93% correctly selected almonds as the primary ingredient used to make almond milk; and
- 89% correctly selected cows’ milk as the primary ingredient used to make skim milk.<sup>18</sup>

Based on empirical evidence like this, federal courts have widely agreed that the term “milk” on plant-based product labels is not confusing for consumers. The District Court for the Northern District of California has held that plant-based product’s use of the words “butter”<sup>19</sup> or “milk”<sup>20</sup> is not misleading to consumers.<sup>21</sup> This conclusion has been echoed in at least two other cases in the Northern District of California.<sup>22</sup> In *Ang v. Whitenave Foods Co.*, the court reasoned that it was “simply implausible that a reasonable consumer would mistake a product like soymilk or almond milk with dairy milk from a cow.”<sup>23</sup> Similarly, in *Gitson v. Trader Joe’s Co.*, the court explained that “[t]he reasonable consumer (indeed, even the least sophisticated consumer) does not think soymilk

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<sup>13</sup> *Id.*

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

<sup>15</sup> Exhibit 7, Expert Declaration on Miyoko’s Labeling Conventions, Dr. Adam Feltz, Dr. Silke Feltz, *Miyoko’s Kitchen v. Ross*, No. 20-CV-00893-RS, 2021 WL 4497867 (2021).

<sup>16</sup> *Id.*

<sup>17</sup> Exhibit 8, Shannon Campagna, PBFA Oral Remarks at FDA Hearing July 26, 2018. Similar results have been found with other plant-based dairy products, such as plant-based butters. A 2020 study by Jareb Gleckel of Cornell University compared responses to the phrases “cultured vegan butter” versus “cultured vegan spread.” Exhibit 9, Jared Gleckel, *Are Consumers Really Confused by Plant-Based Food Labels? An Empirical Study*, U. LOUISVILLE J. ANIMAL & ENVTL. L. (forthcoming). Gleckel found that more participants (92% compared to 71%) were able to correctly identify “cultured vegan butter” as not containing dairy from cows. *Id.* Furthermore, a higher share of participants understood how to use “cultured vegan butter,” for example, that it may be used on pasta. *Id.*

<sup>18</sup> Exhibit 10, KERI SZEJDA, GOOD FOOD INST., CONSUMER PERCEPTIONS OF INGREDIENT SOURCES (2018).

<sup>19</sup> *Miyoko’s Kitchen v. Ross*, No. 20-cv-00893-RS, 2020 WL 8361994, at \*5 (N.D. Cal. Aug. 21, 2020).

<sup>20</sup> *Gitson v. Trader Joe’s Co.*, No. 13-CV-01333-VC, 2015 WL 9121232, at \*2 (N.D. Cal. Dec. 1, 2015); *Ang v. Whitenave Foods Co.*, No. 13-CV-1953, 2013 WL 6492353, at \*4 (N.D. Cal. Dec. 10, 2013).

<sup>21</sup> *Miyoko’s Kitchen*, 2020 WL 8361994, at \*5.

<sup>22</sup> *Gitson*, 2015 WL 9121232, at \*1; *Ang*, 2013 WL 6492353, at \*4.

<sup>23</sup> *Ang*, 2013 WL 6492353, at \*4.

comes from a cow.”<sup>24</sup> In a similar case, the District Court for the Middle District of Louisiana wrote that there was “compelling evidence indicating that consumers are not confused by [the plant-based producer’s] labeling.”<sup>25</sup>

In the context of plant-based meat labeling, federal courts have concluded that consumers are more than capable of reading labels in full.<sup>26</sup> As a court explained in one such case, concluding that the that simple use of a word like “burger” or “butter” is confusing “requires the assumption that a reasonable consumer will disregard all other words found on the label.”<sup>27</sup> By that logic, the court continued, “a reasonable consumer might also believe that veggie bacon contains pork, that flourless chocolate cake contains flour, or that e-books are made out of paper.”<sup>28</sup>

Federal courts that have addressed plant-based products’ naming conventions have similarly noted that “[n]o reasonable consumer could be misled” by “unambiguous labeling or factually accurate nutritional statements” on almond milk containers,<sup>29</sup> and concerns about consumer confusion “stretch[] the bounds of credulity.”<sup>30</sup> These courts have held that “it is implausible that the use of the word ‘soymilk’ misleads any consumer into believing the product comes from a cow.”<sup>31</sup> These courts have also noted that the states defending laws that constrain plant-based products’ naming conventions have failed to show any evidence that consumers are confused by these products.<sup>32</sup>

Thus, ample evidence demonstrates how consumers understand the common or usual names of plant-based dairy products. This is unsurprising, given how long these names have been around and how widespread their use is in today’s world.

**b. Plant-based dairy terms like “almond milk” and “soymilk” are not confusing to consumers because they are well-established, with a long history and wide pervasiveness of use, including by FDA.**

Plant-based milk terms like “soymilk” and “almond milk” are historically well-established and widely used by government and industry alike. Use of the phrase “almond milk” dates at least as far back as the 14th Century.<sup>33</sup> “Almaund mylke” and “amlaunde mylke” both appear repeatedly in

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<sup>24</sup> *Gitson*, 2015 WL 9121232, at \*1.

<sup>25</sup> *Turtle Island Foods SPC v. Strain*, 594 F. Supp. 3d 692, 702 (M.D. La. Mar. 28, 2022).

<sup>26</sup> See, e.g., *Turtle Island Foods SPC v. Soman*, No. 4:19-CV00514-KGB, 2022 WL 4627711, at \*15 (E.D. Ark. Sept. 30, 2022); *Turtle Island Foods SPC v. Soman*, 424 F. Supp. 3d 552, 574 (E.D. Ark. 2019); *Ang*, 2013 WL 6492353, at \*4.

<sup>27</sup> *Turtle Island Foods*, 424 F. Supp. 3d at 574.

<sup>28</sup> *Ang*, 2013 WL 6492353, at \*4.

<sup>29</sup> *Painter v. Blue Diamond Growers*, No. CV 17-02235-SVW-AJW, 2017 WL 4766510, at \*2 (C.D. Cal. May 24, 2017).

<sup>30</sup> *Ang*, 2013 WL 6492353, at \*4.

<sup>31</sup> *Gitson*, 2015 WL 9121232, at \*2.

<sup>32</sup> *Miyoko’s Kitchen*, 2020 WL 8361994, at \*5 (noting that the state had not produced a single academic study supporting their claim of consumer confusion); *Turtle Island Foods v. Soman*, 2022 WL 4627711, at \*15 (“[T]he State has not come forward with evidence of any broad marketplace confusion around plant-based meat alternatives to bolster its claim.”); *Turtle Island Foods v. Strain*, 594 F. Supp. 3d at 702 (finding that the state had failed “to produce evidence indicating that consumers are confused by plaintiff’s labeling.”).

<sup>33</sup> *Almond Milk*, MERRIAM-WEBSTER, <https://www.merriam-webster.com/dictionary/almond%20milk> [<https://perma.cc/E34F-X84A>]; see also Joshua Rapp Learn, *People Went Crazy for Almond Milk in the Middle Ages*, DISCOVER (Feb. 9, 2021), <https://www.discovermagazine.com/planet-earth/people-went-crazy-for-almond-milk-in-the-middle-ages> [<https://perma.cc/5TDG-5QYK>] (noting that almond milk was likely a fixture of European cooking as early as the 1200s, and that by the 14th Century it was “included in most European cookbooks”).

one of the oldest English-language cookbooks.<sup>34</sup> Horchata, a milky nut- or rice-based drink, dates to the 8th Century,<sup>35</sup> though it can trace its origins even farther back to a North African drink from approximately 2,400 B.C.<sup>36</sup> Nut milk is also a traditional food of the Wabanaki Confederacy in what is now the northeastern United States.<sup>37</sup> These common or usual names are now regularly seen nationwide on grocery store shelves and coffee shop menus. For example, Dunkin’ Donuts<sup>38</sup> and Panera Bread<sup>39</sup> advertise their use of “almond milk,” Starbucks touts almond, coconut, oat, and soy milk menu options,<sup>40</sup> Tim Hortons offers almond, coconut, and oat milk at its U.S. locations,<sup>41</sup> Peet’s Coffee<sup>42</sup> and Dutch Bros. Coffee<sup>43</sup> both promote “oat milk” versions of their signature latte drinks, Biggby Coffee<sup>44</sup> and The Coffee Bean & Tea Leaf both offer oat milk, soy milk, almond milk, and coconut milk alternatives.<sup>45</sup>

FDA itself has long used the term “milk” to refer to plant-based milk products without an inkling of confusion. This further illustrates how established the word “milk” is as part of the common or usual name for plant-based milk products. As one federal court noted, “the FDA regularly uses the term soymilk in its public statements.”<sup>46</sup> This includes FDA enforcement reports that repeatedly refer to “soy milk” and “coconut milk,” among other terms. Elsewhere, FDA has defined “soymilk” as “a [t]raditional food[] prepared from soybeans.”<sup>47</sup> The agency has also frequently explained to the public that fortified “soy beverages (soymilk)” provide both calcium and vitamin D, two nutrients “of concern for most Americans,” and that “[a]lmond, rice, coconut, and

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<sup>34</sup> SAMUEL PEGGE, *THE FORME OF CURY: A ROLL OF ANCIENT ENGLISH COOKERY COMPILED* (2005), <https://archive.org/stream/theformeofcury08102gut/7cury10.txt> [<https://perma.cc/WK82-G7AP>] (compilation of ancient English cookery, spelling term alternately as “almaund mylke,” and “almaunde mylke”).

<sup>35</sup> See Ligaya Malones, *A Brief History of Horchata*, SALT & WIND TRAVEL, <https://saltandwind.com/best-horchata-guide-southern-california/> [<https://perma.cc/L35U-6A8E>].

<sup>36</sup> See Dana Givens, *Where Does Horchata Come From Anyway?*, MSN (Aug. 26, 2022), <https://www.msn.com/en-us/foodanddrink/foodnews/the-surprising-origins-of-horchata/ar-BB11tZEm> [<https://perma.cc/6W8J-R6QS>].

<sup>37</sup> Avery Yale Kamila, *Vegan Kitchen: Americans Have Been Enjoying Nut Milk and Nut Butter for at Least 4 Centuries*, PORTLAND PRESS HERALD (Nov. 8, 2020), <https://www.pressherald.com/2020/11/08/vegan-kitchen-americans-have-been-enjoying-nut-milk-and-nut-butter-for-at-least-4-centuries/> [<https://perma.cc/5PLN-VV2N>] (nuts were “ground in a mortar with water to make a flavorful nut ‘milk’ to add to various dishes” or turned into a “nut butter”).

<sup>38</sup> Press Release, Dunkin’ Brands, *You’ve Asked and We’ve Heard: Almondmilk is Now at Dunkin’!* (Sept. 3, 2014) [<https://perma.cc/YF6D-AVCN>].

<sup>39</sup> See *Madagascar Vanilla Almond Cold Brew*, PANERA BREAD, <https://www.panerabread.com/en-us/menu/products/madagascar-vanilla-almond-cold-brew.html> [<https://perma.cc/7NW7-FV9T>].

<sup>40</sup> See Menu, STARBUCKS, <https://www.starbucks.com/menu> (select “Hot Coffees” then “Cappuccino” to see a dropdown showing Almond, Coconut, Oatmilk, and Soy options).

<sup>41</sup> See Menu, TIM HORTONS, <https://www.timhortons.com/menu> [<https://perma.cc/78HM-H5UR>].

<sup>42</sup> See, e.g., *Original Cold Brew Oat Latte*, PEET’S COFFEE, <https://www.peets.com/products/original-cold-brew-oat-latte> [<https://perma.cc/Z2PR-2KK9>].

<sup>43</sup> See Bob Miller, *Dutch Bros Pours New Sugar N Spice Oat Milk Latte As Part Of 2022 Holiday Drinks Menu*, CHEW BOOM (Nov. 3, 2022), <https://www.chewboom.com/2022/11/03/dutch-bros-pours-new-sugar-n-spice-oat-milk-latte-as-part-of-2022-holiday-drinks-menu/> [<https://perma.cc/8BNA-ZDE4>].

<sup>44</sup> See *Allergen Information for Products*, BIGGBY COFFEE, <https://media.biggy.com/wp-content/uploads/2017/01/BIGGBYAllergenGuide.pdf> [<https://perma.cc/N5FZ-MYWU>].

<sup>45</sup> See *Delicious Non-Dairy Options at The Coffee Bean & Tea Leaf This Holiday Season*, THE COFFEE BEAN & TEA LEAF (Nov. 15, 2019), <https://www.coffeebean.com/blog/our-community/delicious-non-dairy-options-coffee-bean-tea-leaf-holiday-season> [<https://perma.cc/M6XL-4UVM>].

<sup>46</sup> *Ang*, 2013 WL 6492353, at \*3.

<sup>47</sup> Biotechnology Notification File No. 000172, CFSAN Note to the File from Patrick Cournoyer, PhD, to Administrative Record, BNF No. 000172 (Apr. 25, 2022), <https://www.fda.gov/media/158266/download> [<https://perma.cc/2KZ4-ZX2N>].

hemp milks” also provide calcium.<sup>48</sup> Additionally, FDA regularly mentions “soy milk” or other nondairy milks in rulemaking materials. For example, the agency repeatedly referenced “soy milk” or “soymilk” in a 2017 proposed rule,<sup>49</sup> a 1998 proposed rule,<sup>50</sup> and a 1993 final rule.<sup>51</sup> FDA has also used the term “soymilk” in at least seven warning letters, to describe the substance that investigators observed on visits to various soy food facilities.<sup>52</sup>

FDA’s parent agency, the Department of Health and Human Services (HHS), also uses terms such as “soymilk” and “almond milk.” In the current Dietary Guidelines, HHS and the United States Department of Agriculture (USDA) explain that “fortified soy beverages” are “commonly known as ‘soymilk.’”<sup>53</sup> In numerous places, the Guidelines also simply state “soymilk” and “[a]lmond milk” without further explanation.<sup>54</sup> Furthermore, the same Guidelines reference “products sold as ‘milks’ but made from plants (e.g., almond, rice, coconut, and hemp ‘milks’).”<sup>55</sup> HHS and USDA have also put out healthy eating guides, recipes, and other documents making reference to “almond milk,” “coconut milk,” and other plant-based milks.<sup>56</sup>

ALDF commends FDA for confirming this common usage and stating in its Draft Guidance that as non-standardized foods, plant-based milks are to be labeled with their clear and widely understood common or usual names—including names like soymilk and almond milk.<sup>57</sup>

## **II. FDA’s Voluntary Nutrient Statement is unsupported and must be stricken from the guidance.**

Though FDA recognizes that use of the word “milk” is not misleading, the agency has recommended that plant-based milk producers include a statement on their labels negatively comparing their products to animal-based milk.<sup>58</sup> FDA’s recommended imposition of a “voluntary” nutrient statement<sup>59</sup> on plant-based milk labels is discriminatory and treats similar situations differently in a way that harms plant-based milk producers while benefiting their direct competitors.

The consensus from health scientists is that plant-based milk is healthier than animal-based milk due to its lower levels of cholesterol and saturated fats as well as higher levels of necessary

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<sup>48</sup> USDA, HHS, DIETARY GUIDELINES FOR AMERICANS 2020-2025, [https://www.dietaryguidelines.gov/sites/default/files/2020-12/Dietary\\_Guidelines\\_for\\_Americans\\_2020-2025.pdf](https://www.dietaryguidelines.gov/sites/default/files/2020-12/Dietary_Guidelines_for_Americans_2020-2025.pdf) [<https://perma.cc/5Z2Z-PNVJ>].

<sup>49</sup> Food Labeling: Health Claims; Soy Protein and Coronary Heart Disease, 82 Fed. Reg. 50324 (Oct. 31, 2017).

<sup>50</sup> Food Labeling: Health Claims; Soy Protein and Coronary Heart Disease, 63 Fed. Reg. 62977 (Nov. 10, 1998).

<sup>51</sup> Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2302 (Jan. 6, 1993).

<sup>52</sup> See, e.g., FDA, Warning Letter to Fong Kee Tofu Company (Mar. 7, 2012); FDA, Warning Letter to Lifesoy, Inc. (Aug. 8, 2008).

<sup>53</sup> DIETARY GUIDELINES FOR AMERICANS 2020-2025, *supra* note 48.

<sup>54</sup> *Id.*

<sup>55</sup> *Id.*

<sup>56</sup> See, e.g., HHS, Healthy Eating for an Active Lifestyle (2013); *Simple Green Smoothie*, USDA MYPLATE, <https://www.myplate.gov/recipes/supplemental-nutrition-assistance-program-snap/simple-green-smoothie> [<https://perma.cc/94MB-Y6ZT>].

<sup>57</sup> See FDA Draft Guidance on Plant-Based Milk, at 7-8.

<sup>58</sup> See *id.* at 15-16 (recommending that plant-based milk producers include statements such as “contains lower amounts of [nutrient] than milk” on their product label).

<sup>59</sup> Despite FDA’s characterization of the statement as “voluntary,” this guidance will have real world effects. See *infra* II.e.

fiber, unsaturated fats, vitamins, minerals, and antioxidants.<sup>60</sup> Even the popular understanding that milk is beneficial for bone health has been controverted by recent studies.<sup>61</sup> Consumers know this. In fact, health and wellness is a leading motivator for consumers to switch to plant-based milk—thus, consumers clearly do not expect different products to have the same nutrition. As FDA has long held, the ingredient list and a nutrition facts panel (NFP) communicate all relevant and necessary nutritional information. Recommending new negative comparisons would only act to harm a growing industry on behalf of its direct competitor. Accordingly, FDA’s recommended nutrient statement is arbitrary, capricious, and not in accordance with the agency’s statutory duty to prevent false or misleading labeling.

**a. FDA’s Voluntary Nutrient Statement treats similar situations differently by prescribing additional nutrient label requirements for plant-based products but not for animal-based products.**

In pushing derogatory comparison statements only on plant-based milk producers, FDA is acting arbitrarily, capriciously, and not in accordance with law.<sup>62</sup> There are numerous other similarly situated examples where FDA has not required or recommended substitute products to make comparative nutrient statements on their packaging.<sup>63</sup> For example, white bread contains less fiber, protein, or nutrients like iron and manganese than wheat bread.<sup>64</sup> Similarly, fruit snacks contain a much smaller share of fiber, potassium, and vitamins than real fruit and are instead loaded with added sugar and artificial coloring.<sup>65</sup> Rice is higher in calories and lower in fiber, choline, and vitamin C when compared to cauliflower rice.<sup>66</sup> White rice is missing out on several key nutrients compared to brown rice.<sup>67</sup> Traditional wheat-based pasta has half the protein and a quarter of the fiber yet has more carbohydrates than chickpea-based pasta.<sup>68</sup> However, FDA has not recommended that any of

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<sup>60</sup> See, e.g., Exhibit 11, Elif Feyza Aydar et al., *Plant-based Milk Substitutes: Bioactive Compounds, Conventional and Novel Processes, Bioavailability Studies, and Health Effects*, 70 J. FUNCTIONAL FOODS 103975 (2020); see also *infra* II.b.

<sup>61</sup> See, e.g., Exhibit 12, Karl Michaëlsson et al., *Milk Intake and Risk of Mortality and Fracture in Women and Men: Cohort Studies*, 349 BMJ (2014); Exhibit 13, Marilyn Tseng et al., *Dairy, Calcium, and Vitamin D Intakes and Prostate Cancer Risk in the National Health and Nutrition Examination Epidemiologic Follow-up Study Cohort*, 81(5) AM. J. CLINICAL NUTRITION 1147 (2005); see also David S. Ludwig & Walter C. Willett, *Three Daily Servings of Reduced Fat Milk: An Evidence-Based Recommendation?*, 167(9) JAMA PEDIATRICS 788 (2013).

<sup>62</sup> Agency action is arbitrary and capricious if it exhibits internally inconsistent reasoning, *Nw. Corp. v. F.E.R.C.*, 884 F.3d 1176, 1179 (D.C. Cir. 2018), or fails to offer sufficient reasons for why it treats similar situations differently. *County of Los Angeles v. Shalala*, 192 F.3d 1005, 1022 (D.C. Cir. 1999); *Transactive Corp. v. United States*, 91 F.3d 232, 237 (D.C. Cir. 1996).

<sup>63</sup> Moreover, in some food categories, consumers do demonstrate confusion, yet FDA is taking no action to recommend negative comparative nutrient statements beyond the NFP for those products. For example, in a large consumer survey about the nutritional content of cereal bars, only 9% of respondents correctly chose the healthiest option. See Attest, U.S. Food & Beverage Digest—Wellness Foods Issue (2022), <https://www.askattest.com/our-research/us-fb-digest-wellness-foods-issue> [<https://perma.cc/7PKV-3DB4>]. Contrast this with the research FDA cites here, in which most consumers demonstrate a high level of understanding differences in calcium, fat, protein, and vitamins found in plant-based versus animal-based milk. See *infra* II.c.

<sup>64</sup> Rachel Ajmera, *Is Bread Bad for You? Nutrition Facts and More*, HEALTHLINE (Oct. 23, 2018), <https://www.healthline.com/nutrition/is-bread-bad-for-you> [<https://perma.cc/CLH3-BJJU>].

<sup>65</sup> See Toby Amidor, *Fruit Snacks: Are They Healthy?*, FOOD NETWORK, <https://www.foodnetwork.com/healthyeats/2012/08/fruit-snacks-are-they-healthy> [<https://perma.cc/8E28-DV6L>].

<sup>66</sup> See Miho Hatanaka, *How Cauliflower Rice Benefits Your Health*, HEALTHLINE (Apr. 17, 2020), <https://www.healthline.com/nutrition/cauliflower-rice-calories> [<https://perma.cc/2ALV-KWPW>].

<sup>67</sup> See Cory Whelan, *Brown Rice vs. White Rice: Which Is Better for You?*, HEALTHLINE (SEPT. 29, 2018), <https://www.healthline.com/health/food-nutrition/brown-rice-vs-white-rice> [<https://perma.cc/R3BC-3MY6>].

<sup>68</sup> See Alexandra Sifferlin, *What is the Best Non-Pasta Pasta?*, TIME (Aug. 22, 2017), <https://time.com/4906359/healthy-pasta-noodles/> [<https://perma.cc/Z3YH-ZVMH>].



these products include voluntary nutrient statements. To treat plant-based milk differently than all these other similarly situated substitute products is discriminatory as well as arbitrary and capricious. FDA justifies this discrimination by citing to alleged consumer confusion. But even to the extent some consumers could be confused, which evidence shows is not the case,<sup>69</sup> this is simply not enough to diverge so drastically from the agency's practices.<sup>70</sup>

Here, FDA is not recommending that animal-based milk include a similar disclaimer for the myriad of ways it is nutritionally inferior to plant-based milk, nor is the agency imposing similar guidance on other substitute food products. Instead, FDA is applying this selectively in only one instance and in only one direction. The agency's proposed Voluntary Nutrient Statement is not like anything the agency has ever included in a guidance document before, as here it applies sector-wide and *only* applies to plant-based milk alternatives. FDA is not simultaneously recommending that animal-based milk add nutrient statements to its labeling—for example, disclosure that “this milk has 35 mg more cholesterol, 4.5 g more saturated fat, and 60 more calories per cup when compared to soymilk.” Instead, the agency has opted to discourage the purchase of plant-based dairy products by recommending plant-based producers voluntarily compare their products unfavorably with marketplace competitors. This will have real world impacts and will serve the market interests of animal-based dairy producers while being punitive against plant-based competitors.

In addition to discriminating against plant-based milk producers, FDA's recommendations here are internally inconsistent and unnecessary. If the concern is that consumers will not be able to understand that nutritional differences between cows' milk and other milk products,<sup>71</sup> then similar comparative nutrient statement recommendations should be applied to non-cow animal-based dairy products. For example, goats' milk has more calcium and protein than cow milk, but also more calories and fat.<sup>72</sup> Logically, if FDA's alleged consumer education purpose is legitimate, then goats' milk should also be subject to voluntary comparative nutrient disclosures. The agency's reasoning for ignoring these other cases, that non-cow animal-based milk accounts for a relatively small market share,<sup>73</sup> is not a legitimate reason to discriminate and only further supports the finding that FDA is acting to protect the dominant market player from its primary competitor. FDA's decision not to apply negative nutrient comparison statements to any product other than plant-based milk demonstrates the internal inconsistency and arbitrariness of this guidance.

To further compound the unnecessary nature of this guidance, FDA already regulates comparative nutrition statements.<sup>74</sup> FDA regulations govern the use of voluntary relative nutrition claims, including claims of “less” or “more” of a nutrient than a reference food.<sup>75</sup> Producers wanting to make “less” or “fewer” claims on their label can do so as long as the reference food is in the same product category and can generally be substituted for the marketed product.<sup>76</sup> Thus, if plant-based milk producers voluntarily wanted to represent that their product contains less cholesterol, fewer calories, or some other positive comparison to animal-based milk, they could do so under existing

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<sup>69</sup> See *infra* II.c.

<sup>70</sup> See *infra* II.d.

<sup>71</sup> See FDA Draft Guidance on Plant-Based Milk, at 15.

<sup>72</sup> See Michael Metzger, *Goat Milk Versus Cow Milk: A Comparison*, MICH. STATE U. (July 22, 2022), <https://www.canr.msu.edu/news/goat-milk-versus-cow-milk-a-comparison> [<https://perma.cc/9Y4M-FJND>].

<sup>73</sup> See FDA Draft Guidance on Plant-Based Milk, at 2.

<sup>74</sup> 21 C.F.R. §§ 101.13(j), 101.54(e).

<sup>75</sup> *Id.* § 101.13(j).

<sup>76</sup> *Id.*

FDA regulations. Conversely, if cows' milk or other animal-based milk producers wanted to represent that their product has "more" protein when compared to a specific plant-based milk, they can readily do so under the regulation governing "more" claims.<sup>77</sup>

Historically, regulations providing for voluntary comparative statements have only applied when companies want to highlight ways their products are *better* than substitute products. FDA's past guidance on voluntary labeling statements has similarly been limited to positive, voluntary distinctions that producers choose to highlight, such as producers labeling their food as not derived from genetically engineered sources.<sup>78</sup> Here, FDA is deviating from this longtime practice by prescribing that plant-based milk companies include statements highlighting ways their product is *worse* than a substitute. This new and selective application of comparative nutrient statements is discriminatory against plant-based milk companies, it is wholly unnecessary given the existing regulatory regime establishing rules for voluntary comparative statements. Furthermore, this recommendation is arbitrary and capricious for treating similar situations differently without adequate explanation and violates FDA's statutory mandate to prevent misbranded labels by misleading consumers that plant-based milk is less healthy than animal-based milk.

**b. FDA's Voluntary Nutrient Statement is contrary to the evidence showing that plant-based milk is the gold standard for health.**

There is significant scientific consensus that plant-based dairy products can offer health benefits when compared to animal-based dairy products. Traditional dairy products, such as cows' milk, have been associated with numerous maladies ranging from bone fractures, cardiovascular disease, and cancer.<sup>79</sup> Conversely, plant-based milk contains none of the harmful cholesterol of traditional dairy milk and does contain healthy fiber, unsaturated fats, vitamins, minerals, and antioxidants. Thus, it contravenes FDA's statutory mandate to prevent misleading and false labeling for the agency to request nutrients statements that imply a nutritionally inferior product is healthier.

Animal-based dairy products such as cows' milk have been associated with serious health concerns. For example, several studies have linked consumption of cows' milk with higher rates of bone fractures as well as cardiovascular and cancer mortality.<sup>80</sup> Population-level studies have found a correlation between cows' milk consumption and rates of hip fracture.<sup>81</sup> Clinical trials have partially replicated these findings. As one meta-analysis of five trials noted, "the risk of hip fracture was greater among persons who received calcium supplements than among those who received placebo."<sup>82</sup> Higher cows' milk consumption during teenage years has also been associated with an increased risk of hip fractures later in life.<sup>83</sup> Internationally, "consumption of dairy products is

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<sup>77</sup> *Id.* § 101.54(e).

<sup>78</sup> *E.g.*, Voluntary Labeling Indicating Whether Food Has or Has Not Been Derived From Genetically Engineered Atlantic Salmon; Draft Guidance for Industry, 80 Fed. Reg. 73193 (Nov. 24, 2015); Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived From Genetically Engineered Plants; Guidance for Industry, 80 Fed. Reg. 73194 (Nov. 24, 2015).

<sup>79</sup> *See supra*, note 61.

<sup>80</sup> *Id.*

<sup>81</sup> *See* Exhibit 14, Walter C. Willett & David S. Ludwig, *Milk and Health*, 382 NEW ENG. J. MED. 644 (2020) (noting that a high rate of cows' milk consumption is linked to higher rates of hip fracture, and conversely that "low dairy consumption is clearly compatible with low rates of hip fracture").

<sup>82</sup> *Id.*

<sup>83</sup> *See* Exhibit 4, Feskanich et al.

strongly correlated with rates of breast cancer, prostate cancer, and other cancers.”<sup>84</sup> Prospective cohort studies linked cows’ milk consumption to the most aggressive and fatal forms of prostate cancer.<sup>85</sup>

Animal-based milk is also much higher in sugar than plant-based alternatives. Cows’ milk, for example, has twelve grams of sugar per cup.<sup>86</sup> That holds true across whole milk, 2%, and skim varieties.<sup>87</sup> Most plant-based milk, conversely, has less than one or two grams of sugar per cup.<sup>88</sup> Americans are already consuming more than 300% the recommended daily amount of added sugar,<sup>89</sup> and suffering the health consequences—from type 2 diabetes to cardiovascular disease.<sup>90</sup> Switching away from animal-based milks and their higher sugar content, cancer risk, and link to cardiovascular disease towards plant-based alternatives that contain necessary fiber is a healthy substitute to make.

Additionally, many of the alleged health benefits from consuming cows’ milk, such as assertions that it reduces weight gain or lowers blood pressure, remain unsubstantiated or have been debunked.<sup>91</sup> Cows’ milk is, however, high in saturated fats and cholesterol.<sup>92</sup> For this reason, “[h]eavy consumption of animal-based foods causes cardiovascular disease and an increase in cholesterol.”<sup>93</sup>

Plant-based milk, on the other hand, has fewer calories and less fat than animal-based milk.<sup>94</sup> The fat that plant-based milk does have is healthier—for example, almond, cashew, macadamia, soy, hemp, and flax milks all have more heart-healthy unsaturated fats than cows’ milk.<sup>95</sup> Many prominent plant-based milks, like almond, rice, and oat milk, have no saturated fat at all.<sup>96</sup> As plant-based milks are made from nuts, legumes, and other nutraceutical foods, they “contain dietary fiber, vitamins, minerals, and antioxidants.”<sup>97</sup> Cholesterol, which is unnecessary and which Americans

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<sup>84</sup> Exhibit 14, Willett & Ludwig.

<sup>85</sup> *Id.*

<sup>86</sup> Anne Danahy, *How Much Sugar is in Milk?*, HEALTHLINE (Dec. 10, 2019), <https://www.healthline.com/nutrition/sugar-in-milk> [<https://perma.cc/X69B-B9B4>].

<sup>87</sup> *Id.*

<sup>88</sup> See Exhibit 15, *Should You Switch to Plant-based Milk?*, UCLA HEALTH (Jan. 24, 2022), <https://www.uclahealth.org/news/should-you-switch-to-plant-based-milk>; see also U. FLA., PLANT-BASED BEVERAGES VS COW’S MILK, [https://animal.ifas.ufl.edu/media/animalifasufledu/dairy-website/docs/Plant-based-beverages-vs-cows-milk-\(2\).pdf](https://animal.ifas.ufl.edu/media/animalifasufledu/dairy-website/docs/Plant-based-beverages-vs-cows-milk-(2).pdf) [<https://perma.cc/9AMW-4XMJ>].

<sup>89</sup> Samir Faruque et al., *The Dose Makes the Poison: Sugar and Obesity in the United States – A Review*, 69(3) POL. J. NUTRITION SCI. 219 (2019).

<sup>90</sup> See *Sugar: How Much is Too Much?*, NEWYORK-PRESBYTERIAN/WEILL CORNELL MEDICAL CENTER HEALTHMATTERS, <https://healthmatters.nyp.org/how-much-sugar-is-too-much/> [<https://perma.cc/U6UY-Q996>]; see also Brian Krans, *America’s Deadly Sugar Addiction has Reached Epidemic Levels*, HEALTHLINE (Aug. 16, 2019), <https://www.healthline.com/health/sugar/americas-deadly-sugar-addiction> [<https://perma.cc/N4LB-99CC>].

<sup>91</sup> See Exhibit 14, Willett & Ludwig.

<sup>92</sup> See Exhibit 11, Aydar et al.

<sup>93</sup> *Id.*

<sup>94</sup> Exhibit 15, *Should You Switch to Plant-based Milk?* (“Compared to one cup of whole-fat cows’ milk, most plant-based milks have 37% to 75% less fat. Many varieties of non-dairy milk, including almond, rice, coconut, hemp and cashew milk, are lower in calories than dairy milk.”).

<sup>95</sup> Exhibit 16, *Plant-based Milks Have Benefits for the Heart and the Planet*, HARVARD T.H. CHAN SCH. OF PUB. HEALTH (2022), <https://www.hsph.harvard.edu/news/hsph-in-the-news/plant-based-milks-heart-planet-health/>.

<sup>96</sup> See Exhibit 17, Amy Kraft, *How Do Different Milks Affect Your Cholesterol Levels?*, EVERYDAY HEALTH (June 9, 2022), <https://www.everydayhealth.com/high-cholesterol/diet/best-worst-types-milk-your-heart/#:~:text=Almond%20Milk%3A%20No%20Cholesterol%2C%20but%20Low%20in%20Protein&text=Unsweetened%20almond%20milk%20contains%20between,it%20also%20contains%20no%20cholesterol.>

<sup>97</sup> Exhibit 11, Aydar et al.

consume too much of already, is only found in animal-based foods, while necessary fiber is only found in plant-based foods.<sup>98</sup> Plant-based foods like nuts and seeds have been observed to reduce the risk of neurodegenerative disorders such as Alzheimer’s disease.<sup>99</sup> As a team of researchers concluded in a recent study of plant-based milk and its health effects, the presence of “phenolic compounds, unsaturated fatty acids, antioxidant activity, and bioactive compounds such as phyosterols and isoflavones make plant-based milk substitutes an excellent choice.”<sup>100</sup>

The scientific consensus is clear: animal-based milks carry several big health risks, and the switch to plant-based milk is the healthier option. Thus, any requirement that only one of these products (especially the healthier of the two) include a nutrient statement highlighting a select nutrient area it may be comparatively lacking in, runs counter to the evidence before FDA and is irreconcilable with the agency’s statutory mandate to prevent misleading labeling.

**c. FDA’s Voluntary Nutrient Statement is contrary to the evidence that consumers do not expect different products to have the same nutrition.**

FDA’s justification for the Voluntary Nutrient Statement is that some consumers are confused. Evidence clearly shows this is simply not the case. Consumers understand that plant-based dairy products with names like “almond milk” or “oat milk” are not made with cows’ milk.<sup>101</sup> Similarly, consumers do not expect these different products, which consumers are easily able to differentiate between, to have the same nutritional profile as each other. There is no reliable evidence that suggests consumers expect plant-based and animal-based products to have the same nutritional profile. Much of the evidence that FDA cites in favor of this Voluntary Nutrient Statement directly contradicts the need for such a disclosure. Further, federal courts have repeatedly made clear that even “an unsophisticated consumer[] would not assume that two distinct products have the same nutritional content.”<sup>102</sup>

Research from the University of Oklahoma found that consumers were “generally accurate at identifying nutritional differences between plant-based and animal-based milk and cheese products.”<sup>103</sup> Further research by Comax Flavors found that 48% of consumers buy plant-based dairy products because they enjoy their flavor.<sup>104</sup> The Comax study found that consumers considered health, wellness, sustainability, and animal welfare as key to explaining why consumers purchased plant-based dairy products.<sup>105</sup>

This conclusion—that consumers are not confused about the nutritional differences between plant-based and animal-based milk—is further supported by several of the studies FDA

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<sup>98</sup> See Exhibit 18, Diane Quagliani & Patricia Felt-Gunderson, *Closing America’s Fiber Intake Gap*, 11(1) AM. J. LIFESTYLE MED. 80 (2017); USDA, HHS, Dietary Guidelines 2015-2020, at 32, [https://health.gov/sites/default/files/2019-09/2015-2020\\_Dietary\\_Guidelines.pdf](https://health.gov/sites/default/files/2019-09/2015-2020_Dietary_Guidelines.pdf) [<https://perma.cc/Y7PT-6QH9>].

<sup>99</sup> See Exhibit 19, Francesca Pistollato et al., *Nutritional Patterns Associated With the Maintenance of Neurocognitive Functions and the Risk of Dementia and Alzheimer’s Disease: A Focus on Human Studies*, 131 PHARMACOLOGICAL RSCH. 32 (2018).

<sup>100</sup> Exhibit 11, Aydar et al.

<sup>101</sup> See *supra* 1.b.

<sup>102</sup> *Miyoko’s Kitchen*, 2020 WL 8361994, at \*4; *Painter*, 2017 WL 4766510, at \*2; *Gitson*, 2015 WL 9121232, at \*1.

<sup>103</sup> Exhibit 6, Feltz & Feltz.

<sup>104</sup> Exhibit 2, NOT MILKING IT.

<sup>105</sup> *Id.*

itself cites to in justifying this recommendation.<sup>106</sup> For example, FDA cites to a 2017 study by the market research firm Mintel which found consumers believe animal-based dairy milk to be healthier.<sup>107</sup> This directly undercuts the agency’s argument that consumers believe plant-based milk to be healthier.<sup>108</sup> FDA also cites to several studies that show a high level of nuanced understanding of nutritional differences amongst consumers across products. An industry sponsored study found that consumers believed almond milk had less calcium than cow’s milk.<sup>109</sup> One online data analysis found consumers thought animal-based milk had more protein but also more fat.<sup>110</sup> That same study also found that consumers understood differences between plant-based milks, with many participants correctly identifying that almond milk has less protein than other plant-based milks.<sup>111</sup> Finally, FDA cites a focus group it commissioned in which participants “knew that plant-based milk alternatives can be lower than milk in protein and calcium.”<sup>112</sup> The FDA focus group also found that consumers thought “plant-based milk alternatives may be healthier than milk because they are lower in fat and cholesterol,”<sup>113</sup> all of which is true. Taken together, the studies cited by the agency do not support the recommended nutrient statement. Instead, they show that consumers already have a strong understanding of the nutritional differences between plant-based and animal-based milk, eliminating the need for such drastic measures as an unprecedented negative comparison statement.

Any concern that consumers expect different products to provide the same nutrition is further contradicted by the fact that traditional, animal-based dairy products vary widely in their nutritional content. For example, one brand’s vanilla yogurt offerings can range between 100 and 132 calories, 5 and 15 grams of protein, or 7 and 13 grams of sugar.<sup>114</sup> Similarly, different brands of skim milk can have drastically different levels of sugar, protein, and calcium.<sup>115</sup> Plant-based milks are also not a monolith. Some plant-based milks, like macadamia, soy, almond, and rice milk, have higher calcium levels than cows’ milk.<sup>116</sup> Others, like pea protein milk, have more potassium than cows’ milk.<sup>117</sup> As FDA has long-since held, consumers are able to obtain and understand this information from the nutrition facts panel and ingredients list without the need for additional disclosures.<sup>118</sup>

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<sup>106</sup> See Memorandum from Ewa Carlton et al., FDA, to Administrative File (Feb. 3, 2023), <https://www.regulations.gov/document/FDA-2023-D-0451-0004>.

<sup>107</sup> MINTEL, NON-DAIRY MILK (2017) (finding that “[a]mong all respondents, dairy milk appeared to be considered better than non-dairy milk in tastes good, nutritious, contains vitamins and minerals, natural, high protein, good for kids, and good to drink with a meal”).

<sup>108</sup> See FDA Draft Guidance on Plant-Based Milk, at 12 (“consumer studies indicate that . . . consumers do not understand the nutritional differences between plant-based milk alternatives and milk”).

<sup>109</sup> DAIRY MGMT. INC., CONSUMER PERSPECTIVE: PLANT-BASED BEVERAGES (2018).

<sup>110</sup> MOTIVEQUEST, PLANT-BASED BEHAVIORS & MOTIVATIONS: ONLINE ANTHROPOLOGY (2019).

<sup>111</sup> *Id.*

<sup>112</sup> WESTAT, FDA FOCUS GROUPS ON CONSUMER UNDERSTANDING AND BEHAVIORS RELATED TO PLANT-BASED MILK ALTERNATIVES (2019) (noting that consumers who knew plant-based milk may have lower protein or calcium “did not consider this an issue due to other benefits of plant-based milk alternatives”).

<sup>113</sup> *Id.*

<sup>114</sup> *Compare* Yoplait Vanilla Yogurt *with* Yoplait Greek Vanilla Yogurt.

<sup>115</sup> *Compare* Clover Skim Milk *with* Fairlife Skim Milk *and* Horizon Organic Skim Milk.

<sup>116</sup> See Exhibit 20, James F. Borin et al., *Plant-Based Milk Alternatives and Risk Factors for Kidney Stones and Chronic Kidney Disease*, 3 J. RENAL NUTRITION 363 (2022).

<sup>117</sup> See Exhibit 21, Sanae Ferreira, *Going Nuts About Milk? Here’s What You Need to Know About Plant-Based Milk Alternatives*, AM. SOC. NUTRITION (Jan. 25, 2019), <https://nutrition.org/going-nuts-about-milk-heres-what-you-need-to-know-about-plant-based-milk-alternatives/>.

<sup>118</sup> See *infra* II.d.

Rather than aid consumers, the recommended nutrient statement will likely lead to *more* consumer confusion, not less. Forcing a negative comparison on only one product and not its substitutes will have the effect of misleading consumers to believe that plant-based milks are less healthy than animal-based milks. This runs directly contrary to the evidence and to the agency’s statutory mandate to ensure that food labeling is not false or misleading.<sup>119</sup>

Plant-based milk is also not an “imitation” product. FDA regulations define “imitation” products as those that “substitute for and resembles another food but is nutritionally inferior to that food.”<sup>120</sup> The same regulation exempts food products that are (1) not nutritionally inferior, or (2) bear a common or usual name that is not false or misleading from any requirement to be labeled as “imitation” products.<sup>121</sup> Plant-based products clearly fall outside the FDA’s definition of imitation food products; they are not nutritionally inferior to cows’ milk,<sup>122</sup> nor do they bear a common or usual name that is misleading to consumers.<sup>123</sup>

Plant-based milks already include descriptive modifiers as part of their common or usual name—such as “almond milk,” “rice milk,” or “oat milk”—to make clear to consumers how the product is different from traditional animal-based dairy alternatives. Applying the “imitation” standard to plant-based milk would only serve to confuse consumers. FDA itself has noted that the imitation qualifier is a “derogatory term” used to protect “traditional food.”<sup>124</sup> Yet here, FDA is attempting to skirt the imitation standard (which does not apply to plant-based milk) by placing a derogatory negative comparison statement on plant-based milk labels.

Simply put, consumers are more than capable of understanding the nutritional differences between different products. Research confirms this, with consumers accurately identifying the nutritional differences between plant-based and animal-based milks. Even the research FDA itself cites in support of this guidance confirms that consumers already understanding nutritional differences. Thus, any additional nutrient statement beyond the nutrition facts and ingredients list would not serve the purpose of consumer education, rather, it would constitute an abandonment of longstanding FDA practice, would discriminate against and disadvantage plant-based milk in the marketplace, and likely lead to increased consumer confusion in violation of the agency’s statutory mandate.

**d. FDA’s Voluntary Nutrient Statement is contrary to FDA’s long-held position with respect to plant-based dairy products without explanation for this sudden departure.**

Consumers understand that different products have different nutrient contents, in part, because of longtime common and usual naming conventions<sup>125</sup> as well as the clarity of nutritional labeling already on food packaging. FDA requires that all food products contain an ingredient list

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<sup>119</sup> 21 U.S.C. § 343(a).

<sup>120</sup> 21 C.F.R. § 101.3(e)(1).

<sup>121</sup> *Id.* § 101.3(e)(2).

<sup>122</sup> *See supra* II.a.

<sup>123</sup> *See supra* I.

<sup>124</sup> *Food Standards and the 1906 Act*, FDA, <https://www.fda.gov/about-fda/histories-product-regulation/food-standards-and1906-act> [<https://perma.cc/Z9KB-FMX2>].

<sup>125</sup> *See supra* I.

and NFP on their packaging.<sup>126</sup> The ingredient list must contain all required ingredients in descending order of predominance by weight.<sup>127</sup> The NFP must include nutrition information such as calories, fat, sodium, carbohydrates, and protein per serving, displayed in the typeface and size dictated by FDA.<sup>128</sup> Plant-based milks already fully comply with these rules. FDA's history of nonenforcement against plant-based milk companies confirms that they comply with all applicable rules and are not misleading to consumers.

Moreover, FDA has long since taken the position that the NFP and the ingredient list are sufficient for consumers to make informed decisions. In the FDA's own words, "consumer confidence and trust in the nutrition facts panel needs to be nurtured rather than challenged by the introduction of new terms and concepts."<sup>129</sup> The agency continues to emphasize consumers use and understanding of the NFP, especially given how long it has been around.<sup>130</sup> For example, in response to comments expressing concerns about trans fats, FDA responded that it would add a line to the NFP to include trans fats,<sup>131</sup> further expressing the agency's support for using the NFP to communicate nutrient information rather than adding new nutrient disclosures in some format less understood by consumers. Academic studies have further confirmed that "[c]onsumers are fairly sophisticated in their ability to use Nutrition Fact panel information to draw conclusions."<sup>132</sup> Recommending an additional nutrient disclosure, even one that is characterized as voluntary, will have real world effects and directly cuts against FDA's longtime policy of developing consumer trust in the NFP and ingredient list.

**e. FDA's Voluntary Nutrient Statement will have real repercussions for industry.**

Despite its characterization as "voluntary," FDA's recommended nutrient statement negatively comparing plant-based milk to its market competitors will, if finalized, have a very real effect on the market for plant-based dairy products. FDA is well aware that its Guidance for Industry documents are taken seriously and are generally adhered to by industry. In part, this is because courts have used FDA's Guidance for Industry as persuasive authority<sup>133</sup> and have in some

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<sup>126</sup> 21 C.F.R. §§ 101.2, 101.4, 101.9.

<sup>127</sup> *Id.* § 101.4(a).

<sup>128</sup> *Id.* § 101.9.

<sup>129</sup> Food Labeling: Nutrient Content Claims Pertaining to the Available Fat Content of Food, 61 Fed. Reg. 67243 (Dec. 20, 1996).

<sup>130</sup> *See, e.g.*, Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. 71155 (Dec. 1, 2014) ("Because the Nutrition Facts label on packaged foods has been required for nearly 20 years, and the Nutrition Facts uses 2,000 calories as a reference amount, consumers are already familiar with this single reference amount for daily calorie consumption for individuals 4 years of age and older.").

<sup>131</sup> Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims, 67 Fed. Reg. 69171 (Nov. 15, 2002).

<sup>132</sup> Exhibit 22, Ratapol Teratavat et al., *Consumer Understanding and Use of Health Information on Product Labels: Marketing Implications for Functional Food* (Am. Agric. Econ. Ass'n Ann. Meeting, Selected Paper, 2004) (summarizing experimental study findings and noting that consumers "are somewhat wary of health claims, preferring instead to trust specific nutritional information when it is available").

<sup>133</sup> *E.g.*, *Ignaciuinos v. Boehringer Ingelheim Pharm. Inc.*, 8 F.4th 98, 104 (2d Cir. 2021).

cases found such guidance to be practically binding upon industry in spite of the agency's use of boilerplate 'non-binding' language.<sup>134</sup>

Furthermore, if this comparative nutrient statement were to be truly voluntary, it seems unlikely any plant-based company would ever choose to negatively compare itself to a direct competitor. As FDA is not in the business of making recommendations it believes will never be adopted and given the persuasive power of Guidance for Industry documents, the Voluntary Nutrient Statement will have tangible effects in the marketplace. Plant-based companies will act to comply with the guidelines, and this new additional disclosure that goes beyond the NFP and ingredient list will confuse and detract consumers from purchasing plant-based milk, discriminately hurting one sector while protecting its competitor.

### Conclusion

Plant-based milk has a long history, is in wide use today, and is well understood by consumers. FDA is right to acknowledge that plant-based milks common and usual names, including terms like "almond milk," "soymilk," "oat milk," and "coconut milk," are not confusing and are the best names for these products. However, further recommended labeling disclosures that negatively compare plant-based milk to animal-based alternatives would not serve consumers but merely discriminate against a rising sector on behalf of legacy industry.

Compared to animal-based milk, plant-based milk has many health and wellness benefits such as lower risk of cardiovascular disease. Concerns about health are a leading reason motivating consumers to change their consumption behavior. It would be arbitrary, capricious, and not in accordance with law for FDA to single out plant-based milk with this unprecedented new label disclosure that departs from FDA's long-held position. For the foregoing reasons, FDA must amend its Guidance for Industry to remove any recommendation that plant-based milk producers include a Voluntary Nutrient Statement on their product label.

Sincerely,

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<sup>134</sup> E.g., *Am. Acad. of Pediatrics v. F.D.A.*, 379 F. Supp. 3d 461, 488 (D. Md. 2019).



## Exhibit List

Exhibit No.	Item
<i>Volume I</i>	
1	<i>U.S. Retail Market Data for the Plant-based Industry</i> , GOOD FOOD INST., <a href="https://gfi.org/marketresearch/#overview">https://gfi.org/marketresearch/#overview</a> .
2	COMAX FLAVOR, NOT MILKING IT (2017).
3	R. G. Cumming & R. J. Klineberg, <i>Case-Control Study of Risk Factors for Hip Fractures in the Elderly</i> , 139(5) <i>Am. J. Epidemiology</i> 493 (1994).
4	Diane Feskanich et al., <i>Milk Consumption During Teenage Years and Risk of Hip Fractures in Older Adults</i> , 168(1) 54 <i>JAMA PEDIATRICS</i> (2014).
5	<i>More Than 75% of Commenters Tell FDA: Allow Plant-Based Alternatives to Use Dairy Terms</i> , PLANT BASED FOOD ASS'N (Apr. 22, 2019), <a href="https://www.plantbasedfoods.org/commenters-tell-fda-allow-plant-based-alternatives-to-use-dairy-terms/">https://www.plantbasedfoods.org/commenters-tell-fda-allow-plant-based-alternatives-to-use-dairy-terms/</a> .
6	Silke Feltz & Adam Feltz, <i>Consumer Accuracy at Identifying Plant-based and Animal-based Milk Items</i> , 4(1) <i>FOOD ETHICS</i> 19 (2019).
7	Expert Declaration on Miyoko's Labeling Conventions, Dr. Adam Feltz, Dr. Silke Feltz, <i>Miyoko's Kitchen v. Ross</i> , No. 20-CV-00893-RS, 2021 WL 4497867 (2021).
8	Shannon Campagna, PBFA Oral Remarks at FDA Hearing July 26, 2018.
9	Jared Gleckel, <i>Are Consumers Really Confused by Plant-Based Food Labels? An Empirical Study</i> , U. LOUISVILLE J. ANIMAL & ENVTL. L. (forthcoming).
10	KERI SZEJDA, GOOD FOOD INST., CONSUMER PERCEPTIONS OF INGREDIENT SOURCES (2018).
<i>Volume II</i>	
11	Elif Feyza Aydar et al., <i>Plant-based Milk Substitutes: Bioactive Compounds, Conventional and Novel Processes, Bioavailability Studies, and Health Effects</i> , 70 <i>J. FUNCTIONAL FOODS</i> 103975 (2020).
12	Karl Michaëlsson et al., <i>Milk Intake and Risk of Mortality and Fracture in Women and Men: Cohort Studies</i> , 349 <i>BMJ</i> (2014).
13	Marilyn Tseng et al., <i>Dairy, Calcium, and Vitamin D Intakes and Prostate Cancer Risk in the National Health and Nutrition Examination Epidemiologic Follow-up Study Cohort</i> , 81(5) <i>AM. J. CLINICAL NUTRITION</i> 1147 (2005).
14	Walter C. Willett & David S. Ludwig, <i>Milk and Health</i> , 382 <i>NEW ENG. J. MED.</i> 644 (2020).
15	<i>Should You Switch to Plant-based Milk?</i> , UCLA HEALTH (Jan. 24, 2022), <a href="https://www.uclahealth.org/news/should-you-switch-to-plant-based-milk">https://www.uclahealth.org/news/should-you-switch-to-plant-based-milk</a> .
16	<i>Plant-based Milks Have Benefits for the Heart and the Planet</i> , HARVARD T.H. CHAN SCH. OF PUB. HEALTH (2022), <a href="https://www.hsph.harvard.edu/news/hsph-in-the-news/plant-based-milks-heart-planet-health/">https://www.hsph.harvard.edu/news/hsph-in-the-news/plant-based-milks-heart-planet-health/</a> .

17	Amy Kraft, <i>How Do Different Milks Affect Your Cholesterol Levels?</i> , EVERYDAY HEALTH (June 9, 2022), <a href="https://www.everydayhealth.com/high-cholesterol/diet/best-worst-types-milk-your-heart/#:~:text=Almond%20Milk%3A%20No%20Cholesterol%2C%20but%20Low%20in%20Protein&amp;text=Unsweetened%20almond%20milk%20contains%20between,it%20also%20contains%20no%20cholesterol.">https://www.everydayhealth.com/high-cholesterol/diet/best-worst-types-milk-your-heart/#:~:text=Almond%20Milk%3A%20No%20Cholesterol%2C%20but%20Low%20in%20Protein&amp;text=Unsweetened%20almond%20milk%20contains%20between,it%20also%20contains%20no%20cholesterol.</a>
18	Diane Quagliani & Patricia Felt-Gunderson, <i>Closing America's Fiber Intake Gap</i> , 11(1) AM. J. LIFESTYLE MED. 80 (2017).
19	Francesca Pistollato et al., <i>Nutritional Patterns Associated With the Maintenance of Neurocognitive Functions and the Risk of Dementia and Alzheimer's Disease: A Focus on Human Studies</i> , 131 PHARMACOLOGICAL RSCH. 32 (2018).
20	James F. Borin et al., <i>Plant-Based Milk Alternatives and Risk Factors for Kidney Stones and Chronic Kidney Disease</i> , 3 J. RENAL NUTRITION 363 (2022).
21	Sanae Ferreira, <i>Going Nuts About Milk? Here's What You Need to Know About Plant-Based Milk Alternatives</i> , AM. SOC. NUTRITION (Jan. 25, 2019), <a href="https://nutrition.org/going-nuts-about-milk-heres-what-you-need-to-know-about-plant-based-milk-alternatives/">https://nutrition.org/going-nuts-about-milk-heres-what-you-need-to-know-about-plant-based-milk-alternatives/</a> .
22	Ratapol Teratavat et al., <i>Consumer Understanding and Use of Health Information on Product Labels: Marketing Implications for Functional Food</i> (Am. Agric. Econ. Ass'n Ann. Meeting, Selected Paper, 2004).