



July 31, 2023

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA–2023–D–0451; Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements; Draft Guidance for Industry

The Center for Science in the Public Interest (CSPI) appreciates the opportunity to comment on the Food and Drug Administration (FDA) Draft Guidance for Industry on the Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements.¹ We urge the agency to ensure that any actions taken to clarify the labeling of plant-based milk alternatives prioritize public health, and to adopt a mandatory labeling disclosure requirement to inform consumers about nutritional differences between plant-based and dairy milks, as we first commented in 2019.²

In brief, CSPI recommended then—and continues to recommend today—that the FDA *require* a front-of-package disclosure on plant-based milk alternatives that do not provide similar levels of certain *key nutrients* as the levels typically found in dairy milks.³ Our recommended approach would alleviate consumer confusion about whether plant-based milks are as nutritious as dairy milk⁴ by clearly disclosing when they fall short in key nutrients, and it would promote public health by encouraging fortification with those key nutrients. Our intent is not to discourage the use of plant-based milks, nor to restrict the term “milk” to dairy alone, but rather to promote the availability of nutritionally adequate plant-based products for people who must avoid dairy milk or simply choose to avoid it. The approach described in the agency’s draft guidance incorporates certain elements of CSPI’s recommendations; however, we offer the following critiques to improve its impact:

- CSPI agrees that the term “milk” should be allowed on plant-based milk alternatives, but disclosures regarding nutrient differences should be mandatory rather than voluntary.
- CSPI urges FDA to consider ways to encourage adequate fortification of plant-based milks in this guidance.
- Disclosures regarding nutrient differences should apply to all plant-based products that are marketed as replacements for milk, not only those named “milk.”
- FDA should prioritize key nutrients for disclosure to reduce the burden on—and hence increase compliance by—plant-based milk manufacturers and consumers.
- Neither voluntary nor mandatory disclosures violate the First Amendment.

I. CSPI agrees that the term “milk” should be allowed on plant-based milk alternatives, but disclosures regarding nutrient differences should be mandatory rather than voluntary.

If disclosures regarding nutrient differences (“Contains lower amounts of [nutrient names(s)] than milk”) are only voluntary, consumers will not know whether the *absence* of a disclosure statement means that a plant-based milk/beverage is (a) a good choice that is equivalent in key nutrients to dairy milk, or (b) not equivalent in key nutrients to dairy milk, but produced by a company that has chosen not to follow the voluntary guidance. Indeed, it is hard to see why a plant-based milk manufacturer would want to avail themselves of such a disclosure. Thus, this proposal is unlikely to alleviate much consumer confusion about the nutrient content of various plant-based milks; in fact, it could fuel more confusion.

II. The FDA should consider ways to encourage adequate fortification of plant-based milks in this guidance.

To prioritize public health, the FDA should consider encouraging fortification—to prevent deficiencies or suboptimal nutrient intakes that could result from a heavy reliance on unfortified plant-based milks—to be one of the goals of this guidance. People may avoid dairy milk for a variety of reasons. For example, they may be allergic to milk, have lactose intolerance, view it as a healthier alternative, or seek more environmentally sustainable products.⁵ Furthermore, plant-based milks can have certain nutritional advantages over dairy milk. For example, as CSPI has advised consumers in our publication, *Nutrition Action*, many plant-based milks (such as soy, almond, or oat milks) are typically lower in saturated fat and higher in healthy fat than 2 percent or full-fat dairy milks because their fat comes from nuts or predominantly unsaturated oils (soybean, canola, sunflower, etc.).⁶ And some plant-based milks (such as soy) naturally contain more of certain beneficial nutrients noted in the FDA’s draft guidance (such as magnesium) than dairy milks.⁷ Choosing *adequately fortified* plant-based milks can therefore have additional health benefits that stem from their core plant ingredients.

Furthermore, encouraging fortification is another reason to support a mandatory rather than voluntary disclosure on plant-based milks. If manufacturers can forgo a voluntary disclosure, there are very few, if any, incentives—aside from the threat of private litigation—for manufacturers to take on the costs and effort required to fortify their products. Why fortify (to shorten or remove disclosures) when it is easier to simply not disclose? That represents a missed opportunity to promote public health with adequate fortification of plant-based milks.

III. Disclosures regarding nutrient differences should apply to all plant-based products that are marketed as replacements for milk, not only those named “milk.”

Many plant-based products that bear names like “almond drink” or “beverage” (Figure 1) are clearly marketed as replacements for milk because—like products named “almond milk” or “soy milk”—they feature imagery of a milky liquid on their principal display panel, they bear names very similar to “milk” that signals their intent (like malk, mylk, m*lk, or m!lk), they are stocked and sold alongside other milk alternatives, they come in packages that resemble milk cartons, or

they are marketed for uses that mimic milk’s (e.g., “Pour it over your cereal, add to your favorite recipe, or enjoy it cold by the glassful.”⁸). The average consumer is likely to treat these products as milks and cannot be expected to know that the FDA’s nutrient disclosure guidance only applies to products named “milk.” As noted, to eliminate this source of consumer confusion under the current FDA proposal, the FDA should broaden the scope of this guidance to include any plant-based products that are marketed as replacements for milk, regardless of whether their name contains “milk.”

Figure 1. Plant-based “milk” and other products that are all marketed as similar to milk.



Sources:

- <https://silk.com/plant-based-products/almondmilk/unsweet-vanilla-organic-almondmilk/>
- <https://www.bluediamond.com/brand/almond-breeze/almondmilk/original>
- <https://www.traderjoes.com/home/products/pdp/organic-unsweetened-almond-beverage-064957>
- <https://www.dreamplantbased.com/product/almond-dream-unsweetened-almond-drink/>
- <https://malkorganics.com/>

Furthermore, under the current proposal, manufacturers could comply with this guidance by simply changing their product names from “milk” to “beverage” or “drink,” thus eluding even a voluntary obligation to inform consumers about nutrient shortcomings or any incentive to engage in fortification to change the product’s nutrient profile. Tying the guidance to the use of “milk” means that label designs could simply downplay the statement of identity (e.g., “milk” or “beverage” or “drink”) while emphasizing the characterizing plant ingredient (e.g., “almond” or “oat”), as some leading brands already do.⁹ This simple name-change option not only leaves

consumers in the dark without informative nutrient disclosures, it also undermines an incentive to engage in fortification that could promote public health.

IV. FDA should prioritize key nutrients for disclosure to reduce the burden on plant milk manufacturers and consumers, as well as increase voluntary compliance.

Although mandatory nutrient disclosures would be far more effective than voluntary disclosures, regardless of the approach that FDA adopts, CSPI recommends that FDA prioritize key nutrients for disclosure. The list of nutrient levels that necessitate disclosure in the FDA’s draft guidance comes from the U.S. Department of Agriculture Food and Nutrition Service’s criteria that a fluid milk substitute must contain a minimum amount of calcium, protein, vitamin A, vitamin D, magnesium, phosphorus, potassium, riboflavin, and vitamin B-12 to be part of a reimbursable meal in the National School Lunch Program, School Breakfast Program, and Child and Adult Care Food Program.¹⁰ However, this list of nine nutrients, which is based on statutory obligations and broad criteria,¹¹ could result in lengthy disclosures. Lengthy disclosures that crowd product labels are likely to be less prominent on product labels than shorter disclosures, if they are used at all. Shorter disclosures are more likely to be adopted by manufacturers, especially when such disclosures are voluntary.

To encourage the use of disclosures, we recommend that FDA develop a set of general principles to prioritize a shorter list of key nutrients that are most critical to public health. In 2019, CSPI suggested a set of such principles, which led to our urging that FDA prioritize vitamin D, calcium, potassium, protein, and vitamin B-12 for disclosure while allowing the voluntary disclosure of vitamin A, riboflavin, and magnesium levels below that of dairy. We refer the agency to our 2019 comment for a complete discussion of those principles and supporting evidence.¹² In brief, CSPI recommended that FDA select key nutrients required for disclosure when their levels in plant-based products are below that of dairy by considering the following six general principles:

- Whether the nutrient is a “shortfall nutrient”; that is, one under-consumed by a significant proportion of the general population or among vulnerable subgroups, per the Dietary Guidelines Advisory Committee (DGAC),
- Whether the nutrient shortfall is associated with a health outcome; that is, nutrients of “public health concern,” per the DGAC,
- Whether dairy milk contributes a substantial proportion of the nutrient to overall intakes at current consumption levels per nationally representative survey data (e.g., NHANES),
- Whether dairy milk provides a good or excellent source of the nutrient,
- Whether consumers expect milk to be a good source of the nutrient,¹³ and
- Whether fortification with the nutrient and at certain thresholds could pose potential harms.

Indeed, the nutrient composition of many leading plant milks suggests that prioritizing vitamin D, calcium, potassium, protein, and vitamin B-12 would effectively shorten disclosures. For example, according to the FDA’s draft guidance, Blue Diamond Almond Breeze Original Almondmilk would need to disclose lower levels of six nutrients: protein, potassium, vitamin B-12, magnesium, phosphorus, and likely riboflavin.¹⁴ But according to CSPI’s recommended approach, the almond milk would only need to disclose lower levels of three key nutrients:

protein, potassium, and vitamin B-12. Likewise, according to the FDA’s draft guidance, Silk Unsweet Oatmilk would need to disclose lower levels of five nutrients: protein, potassium, riboflavin, and likely magnesium and phosphorus.¹⁵ But according to CSPI’s recommended approach, the oat milk would only need to disclose lower levels of two key nutrients: protein and potassium.

V. The draft guidance does not violate the First Amendment, either in its current voluntary form or as a mandatory regulation.

A. Voluntary Guidance

There has been at least one incorrect suggestion in the press coverage of the draft guidance that it would violate the First Amendment.¹⁶ The First Amendment’s Free Speech Clause is only at issue when the government mandatorily restricts or compels private speech.¹⁷ In its current voluntary form, FDA’s guidance does not restrict how beverage companies label their products, nor does it require them to label their products in a certain way. It only makes suggestions. In fact, the guidance is the government’s own speech, which is “exempt from First Amendment scrutiny.”¹⁸

B. Mandatory Guidance

Even if FDA mandates, through rulemaking under its authority to prevent false or misleading labeling,¹⁹ nutrient disclosures for plant-based milk and plant-based products marketed as milk replacements, it could design requirements that would not violate the First Amendment.

Zauderer v. Office of Disciplinary Counsel of Supreme Court, under which a compelled speech requirement does not violate the First Amendment if it is (1) strictly factual and uncontroversial, (2) reasonably related to a legitimate government interest, and (3) not unjustified or unduly burdensome.²⁰

Regarding the first prong of *Zauderer*, the Supreme Court has distinguished “factual and uncontroversial” information from opinion,²¹ and circuit courts have suggested that “factual and uncontroversial” means not subjective.²² Regarding “uncontroversial” specifically, circuit courts have interpreted it as referring to information that is nonideological²³ and factually accurate.²⁴ In 2009, the Second Circuit Court of Appeals upheld New York City’s chain restaurant menu calorie disclosure requirement (since preempted under the Patient Protection and Affordable Care Act’s national standard).²⁵ In that case, the New York State Restaurant Association conceded that calorie disclosures are factual and uncontroversial.²⁶

The nutrient disclosures at issue here are comparable to calorie disclosures. The draft guidance recommends disclosure of differences in calcium, protein, vitamin A, vitamin D, magnesium, phosphorus, potassium, riboflavin, and vitamin B12 compared to a reference product.²⁷ If FDA made the draft guidance’s nutrient disclosures mandatory, plant-based milks and plant-based products marketed as milk replacements but not named “milk” would need to carry statements comparing their nutrient content to that of milk. Such statements would be factual declarations based on nutritional analyses.

Zauderer's second prong, that the disclosure requirement reasonable relate to a legitimate government interest, is a low bar for the government to clear. In the New York City calorie disclosure case, the court found reducing consumer confusion and deception to be a legitimate government interest. Similarly, courts have upheld disclosure requirements where the government's interest was improving consumer knowledge related to chain restaurant food sodium content, the country-of-origin of meat products, and mercury in lightbulbs.²⁸ FDA's rationale for plant milk nutrient disclosures is to "provide consumers with additional nutrition information to help them understand certain nutritional differences between these products and milk and make informed dietary choices."²⁹ This government interest in better informing consumers satisfies *Zauderer*'s second prong.

Under *Zauderer*'s third prong, the government must point to evidence that the problem it is trying to address is "potentially real not purely hypothetical."³⁰ A disclosure does not need to all aspects of the problem.³¹ A requirement is not unduly burdensome when it does not extend further than reasonably necessary, and therefore does not risk "chilling" protected speech.³² An unjustified or unduly burdensome mandatory disclosure "drowns out" an advertiser's message and "effectively rules out the possibility" of advertising.³³ Circuit courts have found constitutional a tobacco warning occupying 50 percent of the back and front of cigarette packages³⁴ and mandatory solicitation statements applicable to loan lenders that are required to be in the same or larger font as other lender information.³⁵ The Ninth Circuit Court of Appeals, sitting *en banc*, invalidated a San Francisco sugar-sweetened beverages warning that would have occupied 20 percent of advertising space, but only because evidence cited by the City indicated that its goal could be accomplished by a warning half of that size.³⁶

To satisfy *Zauderer*'s third prong, FDA could point to evidence of consumer confusion or lack of knowledge about the nutritional differences between plant milks and dairy milk. FDA's existing summary of research on consumer perceptions and understanding of plant-based milk alternatives includes a nationally representative survey of 1,003 adult U.S. residents in which 27 percent said that plant-based milks have *more* of those nutrients than cow's milk, 25 percent said that plant-based milks have the same amount of protein, calcium, vitamin A, and potassium as cow's milk, and 20 percent did not know whether plant-based milks are nutritionally equivalent to cow's milk.³⁷ Such evidence shows that mandatory nutrient disclosures are justified. FDA would also be able to design nutrient disclosures that are not unduly burdensome in that they would be small enough to still allow ample room on a container for a beverage company's messaging. Nutrient disclosures, which are simply a few lines of text, would take up much less than 20 percent of a beverage container.

VI. Conclusion

To alleviate consumer confusion and promote public health, CSPI urges the FDA to adopt, through rulemaking, a mandatory labeling disclosure requirement for low levels of key nutrients in plant-based "milk" and plant-based "drinks," "beverages," and other products that are similarly marketed as replacements for milk.

If FDA proceeds with a voluntary approach, we recommend that the agency allow shorter disclosures to encourage their adoption and recommend disclosure for all products marketed as plant-based milk alternatives, not only those that use the term "milk."

¹ U.S. Food and Drug Administration. Draft Guidance for Industry: Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements. February 2023. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-labeling-plant-based-milk-alternatives-and-voluntary-nutrient-statements>

² Comment from the Center for Science in the Public Interest. January 28, 2019.

<https://cspinet.org/sites/default/files/attachment/CSPI%20Dairy%20Alternatives%20Comment.pdf>

³ *Id.*

⁴ U.S. Food and Drug Administration Consumer Studies Branch. Memorandum. Summary of Consumer Research Reports on Consumers' Perceptions and Understanding of Plant-Based Milk Alternatives. February 3, 2023.

<https://www.regulations.gov/document?D=FDA-2023-D-0451-0004>. Note: Although FDA's consumer research summary includes studies commissioned, conducted, or funded by companies with an interest in dairy or plant-based products, it also includes studies that find evidence of consumer confusion from non-industry sources, such as Consumer Reports and the FDA's own focus groups.

⁵ Producing dairy milk in North America releases more greenhouse gases and uses more land than oat, soy, almond, or rice milk, though almond and rice milk require more water, based on data in *Science* 360: 987, 2018 (with additional calculations by author J. Poore). See Lindsay Moyer and Marlena Koch. Don't Have a Cow? The Latest in Plant Milks. April 2023. <https://www.cspinet.org/media/12864>

⁶ Lindsay Moyer and Marlena Koch. Don't Have a Cow? The Latest in Plant Milks. April 2023.

<https://www.cspinet.org/media/12864>

⁷ *Id.*

⁸ Sunopta Grains and Foods Inc. Almond Dream Unsweetened Almond Drink. 2023.

<https://www.dreamplantbased.com/product/almond-dream-unsweetened-almond-drink/>

⁹ See, for example, Silk Unsweet Oat, with "Oatmilk" in small, faint type in the lower left corner: Whitewave Services, Inc. Silk Unsweet Oatmilk. 2023. <https://silk.com/plant-based-products/oatmilk/unsweet-oatmilk>.

¹⁰ 7 CFR § 210.10 (d)(3), § 220.8(d), § 226.20(g)(3)

¹¹ U.S. Food and Drug Administration. Draft Guidance for Industry: Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements. February 2023. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-labeling-plant-based-milk-alternatives-and-voluntary-nutrient-statements>

¹² Comment from the Center for Science in the Public Interest. January 28, 2019.

<https://cspinet.org/sites/default/files/attachment/CSPI%20Dairy%20Alternatives%20Comment.pdf>

¹³ Consumers are also likely to expect cheese and yogurt to provide many nutrients found in milk, such as calcium and protein, yet many plant-based products are unfortified and contain little, if any, protein. However, the scope of the FDA's draft guidance is limited to plant-based "milk" products because the agency concluded that plant-based milks that contain lower levels of nutrients than dairy milk pose a potential public health concern.

¹⁴ Blue Diamond Growers. Almondmilk Original. 2023. <https://www.bluediamond.com/brand/almond-breeze/almondmilk/original>. Note: Blue Diamond Almond Breeze Original Almondmilk does not list its riboflavin content on the Nutrition Facts label and is not required to do so. We assumed that a 240g serving of the USDA Food Data Central entry for refrigerated almondmilk is representative of the product's riboflavin content per 240 ml serving. See <https://fdc.nal.usda.gov/fdc-app.html#/food-details/2257045/nutrients>.

¹⁵ WhiteWave Services, Inc. Silk Unsweet Oatmilk. 2023. <https://silk.com/plant-based-products/oatmilk/unsweet-oatmilk>. Note: Silk Unsweet Oatmilk does not list its magnesium or phosphorus content on the Nutrition Facts label and is not required to do so. We assumed that a 240g serving of the USDA Food Data Central entry for refrigerated oatmilk is representative of the product's magnesium and phosphorus content per 240 ml serving. See <https://fdc.nal.usda.gov/fdc-app.html#/food-details/2257046/nutrients>.

¹⁶ Watson E. AgFunder. *FDA draft guidance on plant-based milk labeling ruffles industry feathers*. February 22, 2023. <https://agfundernews.com/fda-draft-guidance-on-plant-based-milk-labeling-ruffles-industry-feathers>. Accessed April 18, 2023.

¹⁷ *Central Hudson Gas & Elec. Corp v. Pub. Serv. Comm'n*, 447 U.S. 557 (1980); *Zauderer v. Office of Disc. Counsel of Supreme Court*, 471 U.S. 626 (1985).

¹⁸ See *Johanns v. Livestock Marketing Ass'n*, 544 U.S. 550, 553 (2005).

¹⁹ 21 U.S.C. § 343(a).

²⁰ *Zauderer*, 471 U.S. at 651.

²¹ *Id.*

²² *Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509 (6th Cir. 2012); *Entm't Software Ass'n v. Blagojevich*, 469 F.3d 641, 652 (7th Cir. 2006).

²³ *Am. Bev. Ass'n v. City and Cty of San Francisco*, 871 F.3d 884 (9th Cir. 2017).

²⁴ *Am. Meat Inst. v. United States Dep't of Agric.*, 760 F.3d 18, 29 (DC Cir. 2014).

²⁵ *National Rest. Ass'n v. New York City Dept. of Health & Mental Hygiene*, 148 A.D.3d 169 (2017).

²⁶ *N.Y. State Rest. Ass'n v. N.Y. City Bd. of Health*, 556 F.3d 114, 134 (2nd Cir. 2009).

²⁷ U.S. Food & Drug Admin., Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements: Guidance for Industry. Draft Guidance. 2023.

²⁸ *Nat'l Rest. Ass'n*, 148 A.D.3d 169; *Am. Meat Inst.*, 760 F.3d 18; *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104 (2nd Cir. 2001).

²⁹ U.S. Food & Drug Admin., Labeling of Plant-Based Milk Alternatives and Voluntary nutrient Statements: Guidance for Industry. Draft Guidance. 2023.

³⁰ *Nat'l Inst. of Family & Life Advocates v. Becerra*, 138 S. Ct. 2361, 2377 (2018).

³¹ *Zauderer*, 471 U.S. at 651, n. 14.

³² *NIFLA*, 138 S. Ct. at 2377.

³³ *NIFLA*, 138 S. Ct. at 2378.

³⁴ *Discount Tobacco City and Lottery, Inc.*, 674 F.3d 509.

³⁵ *Loan Payment Admin., LLC v. Hubanks*, 821 Fed. Appx. 687 (9th Cir. 2020).

³⁶ *Am. Bev. Ass'n v. City & Cty. of S.F.*, 916 F.3d 749, 757 (9th Cir. 2019) (“[E]xpress[ing] no view on the legality of a similar disclosure requirement that is better supported or less burdensome.” (quoting *NIFLA*, 138 S. Ct. at 2378)).

³⁷ See Plant-Based Milk Survey, 2018, commissioned by Consumer Reports and conducted by SSRS, in U.S. Food and Drug Administration Consumer Studies Branch. Memorandum. Summary of Consumer Research Reports on Consumers’ Perceptions and Understanding of Plant-Based Milk Alternatives. February 3, 2023. <https://www.regulations.gov/document?D=FDA-2023-D-0451-0004>. Note: Although FDA’s consumer research summary includes studies commissioned, conducted, or funded by companies with an interest in dairy or plant-based products, it also includes studies that find evidence of consumer confusion from non-industry sources, such as Consumer Reports and the FDA’s own focus groups.