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April 21, 2023

Robert M. Califf M.D.
Commissioner, U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

RE: Docket No. FDA-2023-D-0451, Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements: Guidance for Industry; Request for Comments

Dear Commissioner Califf,

The New York Farm Bureau (NYFB), New York State's largest general farm organization, submits the following comments to the U.S. Food and Drug Administration (FDA) regarding the draft guidance on the labeling of plant-based milk alternatives. It is imperative that FDA ensure consumers have accurate information about the food products they consume. NYFB calls on FDA to vigorously enforce food standards regarding the labeling of dairy substitute products and prohibit the misleading labeling of nut- and plant-based beverage products as "milk" or other common dairy terms.

The dairy industry plays a key role in the New York State economy and in 2018, the value of milk production totaled over \$2.7 billion¹, which makes up almost half of the value of New York agricultural production, which totaled over \$5.7 billion in 2017². With approximately 3,600 dairy farms, New York State is the fifth highest producer of milk in the country and produced 15 billion pounds of fluid milk in 2020³. However, New York has also faced a loss of over 1,712 farms from 2010 to 2020⁴. There are multiple factors that play into the hardships that the New York dairy industry faces, one of which is competing with cooler space in grocery stores and the proper identification of what is and isn't milk.

The draft guidance (pages three and four) says: "FDA seeks to improve dietary patterns in the United States to help reduce the burden of nutrition-related chronic diseases and advance health equity. We are committed to accomplishing this by promoting healthy starts through improved

¹ New York State Dairy Statistics 2020 Annual Summary. New York State Milk Control Dairy Services Division Records :

<https://agriculture.ny.gov/system/files/documents/2021/10/2020dairystatisticsannualsummary.pdf>

² A Profile of Agriculture in New York State, Office of the New York State Comptroller

<https://www.osc.state.ny.us/sites/default/files/reports/documents/pdf/2020-02/agriculture-report-2019.pdf>

³<https://agriculture.ny.gov/system/files/documents/2021/10/2020dairystatisticsannualsummary.pdf>

⁴<https://agriculture.ny.gov/system/files/documents/2021/10/2020dairystatisticsannualsummary.pdf>

maternal, infant, and child health, creating a healthier food supply for all, and empowering consumers with more informative and accessible labeling to choose healthier diets.” In response to previous requests for related comments, the draft guidance further states, “the comments, other research reviewed, and our analysis of the data suggest a potential public health concern related to the substitution of milk with plant-based milk alternatives that contain lower amounts of certain nutrients than found in milk.” The implied permissance of the term “milk” on any non-lacteal secretion-based products strongly contradicts the mission defined by FDA and the conclusions of FDA’s own information-gathering efforts.

Milk is a food product with an established standard of identity (SOI) defined in 21 CFR 131.110 as: “the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows.” Standards of identity were first established in 1939 to address economic adulteration in the marketplace. FDA provides⁵ their own historical example of marketplace adulteration describing that certain products were represented as “jams” containing fruit, but the products contained little fruit (e.g., the SOI for fruit preserves and jams requires that products represented as jam contain a minimum amount of fruit) so therefore these items were not permitted to be represented as jams. Like the SOI for jams, FDA notes, “products that purport to be or are represented as milk are required to conform to the definition and standard, and their labels must bear the name ‘milk.’ Products that do not purport to be and are not represented as milk are not subject to these requirements.” Plant-based alternatives of milk are not milk, they are made from plant materials. Under the Federal Food, Drug and Cosmetic Act, they may not be offered for sale as “milk.” Even with these clear directives, FDA makes the false claim that plant-based alternatives of milk do not purport to be milk, nor are they represented as milk, therefore they are exempt from requirements.

Nut- and plant-based beverages are marketed as milk, and sold in the milk case, right alongside traditional milk. These imitation products are not segregated or separated into another area of a grocery store; instead, they are sold in the refrigerated dairy section, often on the very same shelf and in the very same case as actual milk. This can create confusion when consumers – who often rely on product indicators such as the name on the front of the label, rather than the technical information on the back of the label — are in the grocery store deciding to purchase milk or a non-dairy substitute. Packaging on these alternatives often display rich white colors, replicate the specific texture of liquid milk splashing, and often use pasture, cow, cow spot or other milk-adjacent imagery. Combined, the physical location, use of imagery, and use of dairy terms demonstrates an intent to convince the consumer there is no fundamental difference between products. These products are positioned and advertised as direct substitutes for milk. If a product is attempting to garner market share based on a suggested replication of quality, characteristics and use of a certain product, they are purporting to be that product. Plant-based milk alternatives are purporting to be milk in a consumers’ basket, but as they do not contain any milk as defined by FDA’s SOI, they cannot utilize the term. If these items are not attempting to represent the qualities that define milk, there should be no concern with dropping the term.

FDA appears to suggest plant-based alternatives may qualify for flexibility under their current classification as “non-standardized foods,” a category of foods that do not have an established definition or SOI. In these cases, food items must utilize common or usual names known to the

⁵ Standards of Identity for Food: <https://www.fda.gov/food/food-labeling-nutrition/standards-identity-food>

American public without being misleading. Given that plant-based alternatives have only surpassed 10% market share in the past 10 years, claiming that “milk” is an organically common or usual name for this wide range of diverse products is unreasonable. Had FDA enforced existing SOIs, substitute products would not have been able to piggyback off consumer trust in milk for market share and recognition. Additionally, the enforced ban of dairy terms on imitation products in other developed economies like Canada, the United Kingdom and the European Union counters any argument of common or usual acceptance of the terms from a global perspective. In the draft guidance, FDA uses a consumer survey statistic indicating about 75% of respondents understood plant-based alternatives of milks do not contain milk as a reason to allow flexibility with the term. Observed from a more appropriate perspective, one out of four grocery store shoppers is confused as to whether these alternatives contain milk or think they do contain milk. Twenty-five percent is a massive segment of consumers (83 million people in the United States) to be confused or misled. Consumers in communities with less access to quality education and associated lower incomes are often more susceptible to misleading marketing tactics. Consumers who buy plant-based milk alternatives thinking they contain or are milk could jeopardize the health of their families. Product label speech is limited in situations where the use of specific terms is inherently false, such as advertising plant-based alternative beverages as milk.

FDA confirms that labeling plant-based beverages as “milk” confuses consumers from a nutritional equivalency standpoint. The agency notes on page six of the draft guidance, “several consumer studies submitted in response to the notice indicate that consumers, including consumers who purchase plant-based milk alternatives, do not understand the nutritional differences between milk and plant-based milk alternatives.” Among consumers, milk and dairy have a clear and important nutritive connotation with growth and development. As expected, this is because milk is the primary and often sole substance mammals live on during the beginning stages of postnatal life. This includes large quantities of calcium, protein, vitamin A, vitamin D, magnesium, phosphorus, potassium, riboflavin and vitamin B-12, as well as zinc, choline and selenium – all essential nutrients difficult to replace in a healthy dietary pattern that does not include dairy products⁶.

The nutritional components of milk are essential to its definition. Non-dairy products labeled as milk that lack the foundational nutritive components of milk can be misleading and harmful. Consumers know the healthiness of dairy labels such as “milk” and may infer that any product bearing this term possesses the same or an equivalent nutritional profile. In many other cases, consumers have been led to believe plant-based alternatives are healthier. As the draft guidance describes: “the research also suggests that a majority of consumers who purchase plant-based milk alternatives state they do so because they believe the products are healthier than milk.” These conclusions demonstrate the dangers of utilizing the term “milk” on non-milk products.

⁶ U.S. Department of Agriculture, Agricultural Research Service, Dietary Guidelines Advisory Committee, Scientific Report of the 2020 Dietary Guidelines Advisory Committee: Advisory Report to the Secretary of Agriculture and the Secretary of Health and Human Services. Washington, DC (2020). Available by visiting: <https://www.dietaryguidelines.gov/2020-advisory-committee-report>

Based on U.S. dietary guidelines⁷, approximately 90% of the U.S. population does not meet the recommended consumption of dairy products. The guidelines clarify the distinction in nutrition properties of alternatives to dairy as “other products sold as ‘milks’ but made from plants (e.g., almond, rice, coconut, and hemp ‘milks’) may contain calcium and be consumed as a source of calcium, but they are not included as part of the dairy group because their overall nutritional content is **not similar to dairy milk.**” Associated analyses⁸ have demonstrated that even when consumers can find alternative sources for essential nutrients found in milk, like calcium, the number of potential alternatives to provide a sufficient concentration of a vitamin or mineral “would provide too many calories and/or be a too large amount to consume daily.”

Though detailed, the draft FDA guidance does not go far enough to describe the nutritional disparities of plant-based alternatives to milk. A study⁹ published in the British Journal of Nutrition commented, “when plant-based milk is considered, it is significant to realize that, even though nuts and cereals are rich in terms of protein, dietary fiber, fatty acids, vitamins, and phytochemicals, plant-based milk substitutes include smaller amounts of these beneficial bioactive compounds which are lost during processing.” The research reported that after being peeled or processed, many nuts and seeds lose between 50% and 90% of their beneficial bioactive compounds by the time a beverage is produced. Bioavailability, or the proportion of a nutrient that can actually be absorbed or utilized by the human body, also remains a barrier for plant-based alternatives to milk. A 2020 analysis¹⁰ concluded that though plant-based substitutes may be rich in terms of antioxidant activity that would be beneficial to the immune system, antinutrients negatively impact the ability of the body to use those antioxidants. Further, the study finds “a low bioavailability of mineral and vitamin content, and the added sugar present a dilemma for the consumption of plant-based milk substitutes when compared to cow’s milk.”

The World Health Organization has reported¹¹ that “added sugar used to sweeten plant-based milk substitutes and increase market acceptance has a detrimental impact on oral health.” A 2019 study¹² in the Journal of Dentistry compared soy beverages to milk in terms of tooth enamel mineral content. The authors warn about the risk to dental health from the low bioavailable calcium content of soy beverages: “as a consequence of having a smaller amount of bioavailable

⁷ U.S. Department of Health and Human Services and U.S. Department of Agriculture. Dietary Guidelines for Americans (2020-2025). Available by visiting <https://www.dietaryguidelines.gov/>

⁸ U.S. Department of Agriculture, Agricultural Research Service, Dietary Guidelines Advisory Committee, Scientific Report of the 2015 Dietary Guidelines Advisory Committee: Advisory Report to the Secretary of Health and Human Services and the Secretary of Agriculture. Appendix E-3.6: Dairy Group and Alternatives, Washington, DC (2015). Available by visiting: <https://health.gov/sites/default/files/2019-09/15-Appendix-E-3.pdf>

⁹ Cesaretin Alasalvar and Bradley W. Bolling, Review of nut phytochemicals, fat-soluble bioactives, antioxidant components and health effects, British Journal of Nutrition, Volume 113, Issue 2, 2015, pp. S68-S78 <https://doi.org/10.1017/S0007114514003729>

¹⁰ Elif Feyza Aydar, Sena Tutuncu, Beraat Ozelcik, Plant-based milk substitutes: Bioactive compounds, conventional and novel processes, bioavailability studies, and health effects, Journal of Functional Foods, Volume 70, 2020, 103975, ISSN 1756-4646, <https://doi.org/10.1016/j.jff.2020.103975>

¹¹ World Health Organization (2016, September 26). Risks to oral health and intervention. Oral Health; World Health Organization. https://www.who.int/oral_health/action/risks/en/

¹² P. Shen, G.D. Walker, Y. Yuan, C. Reynolds, D.P. Stanton, J.R. Fernando, E.C. Reynolds, Effects of soy and bovine milk beverages on enamel mineral content in a randomized, double-blind in situ clinical study Journal of Dentistry (2019), 10.1016/j.jdent.2019.06.007

minerals, soy drinks demineralize the lesion while dairy milk remineralizes the lesion because dairy milk has a higher level of bioavailable calcium.” Similar to barriers in dental health, substituting plant-based products for milk has implications on broader bone mineral density throughout the body. A 2019 Nutrition Review study¹³ concluded that diets lacking dairy products had significantly lower bone mineral densities at the femoral neck, lumbar spine and whole body. Lower bone mineral densities correspond to increased rates of fractures and highlights the absolute need for “careful, detailed, and long-term planning” of diets lacking dairy products in order to reduce the risk of negative effects on bone health.

While minerals like calcium are often mentioned when considering milk, others, like iodine, though also vital, are not as commonly discussed. Dairy products like milk provide nearly 50% of total estimates of daily iodine intake from food for consumers in the United States¹⁴. Iodine is critical for the synthesis of thyroid hormone and for normal development, growth and metabolism. Low iodine intake in pregnant women has a significant negative impact on cognitive performance and neurological development in children¹⁵. Plant-based alternatives to milk are not nutritionally equivalent to milk and any marketing that makes or insinuates this claim, including use of the term “milk,” is dangerous, especially in terms of child development.

Various studies have shown the consequences of inappropriate consumption of plant beverages as alternatives to milk and milk formula in infants and children. Misleading health claims and marketing make families believe plant-based alternatives can be served to youth and garner the same health results. One study¹⁶ in the Archives of Pediatrics found frequent cases in protein-calorie malnutrition, severe hypocalcemia, hyponatremia, iron deficiency anemia, and vitamin D deficiency among infants who were given soya, rice and almond beverages. The authors concluded: “milk alternative beverages expose infants to severe nutritional deficiencies. Serious complications can occur. Early, exclusive, and extended use is riskier. These diseases are preventable, and parental education should be provided.” The authors went further to recommend statutory measures forbidding their use for infants. FDA currently has the statutory authority to enforce the SOI of milk, which would counter some of this substitution-induced medical risk, but is choosing not to do so. A study¹⁷ in the Journal of Pediatrics analyzed cases of hematuria and genitourinary symptoms directly linked to consumption of plant-based alternative products in place of milk. NYFB wholeheartedly supports a consumer’s right to access dairy-free products from an allergy, intolerance or personal dietary preference perspective. Misleading marketing that leads consumers to replace an intrinsically healthy product with an inferior product, however, is not appropriate, especially when the health of infants and children is at risk.

¹³ I. Iguacel, M.L. Miguel-Berges, A. Gómez-Bruton, L.A. Moreno, C. Julián, Veganism, vegetarianism, bone mineral density, and fracture risk: A systematic review and meta-analysis, *Nutr. Rev.*, 77 (2019), pp. 1-18, <https://doi.org/10.1093/nutrit/nuy04530>

¹⁴ Abt E., Spungen J., Pouillot R., Gamalo-Siebers M., Wirtz M. Update on dietary intake of perchlorate and iodine from U.S. Food and Drug Administration’s Total Diet Study: 2008–2012. *J. Expo. Sci. Environ. Epidemiol.* 2018;28:21–30. doi: 10.1038/jes.2016.78

¹⁵ K.W. Lee, D. Shin, M.S. Cho, W.O. Song, Food group intakes as determinants of iodine status among us adult population, *Nutrients*, 8 (2016), p. 325, <https://doi.org/10.3390/nu8060325>

¹⁶ Le Louer B, Lemale J, Garcette K, Orzechowski C, Chalvon A, Girardet JP, et al. Severe nutritional deficiencies in young infants with inappropriate plant milk consumption. *Archives of Pediatrics*, 2014;21(5):483–8

¹⁷ Ellis D, Lieb J. Hyperoxaluria and genitourinary disorders in children ingesting almond milk products. *The Journal of Pediatrics*. 2015;167(5):1155–8.

The FDA does attempt to buffer against nutrition confusion by suggesting use of voluntary nutrient statements on packaging. Unfortunately, a suggestion of voluntary nutrient statements is futile, since few companies would volunteer such packaging additions, leaving consumers with little additional information on the products they are purchasing. In the draft recommendation, the FDA provides a few examples of voluntary nutrient statements on a product label. In one example, the product is named “oat milk” and includes a nutrient statement that says, “contains a lower amount of potassium than milk.” How can a product have a lower nutritional content than what it labels itself? FDA explicitly chooses not to use the word “cow” in their example voluntary nutrient statement, as in “contains a lower amount of potassium than cow’s milk,” because they already have a formal standard of identity that defines what milk is. Using the word “cow” in front of milk would be redundant. Using the term “oat milk” implies an oat-flavored milk or blended milk similar to “strawberry milk” or “chocolate milk.” This labeling concept would be appropriate if the product was named “oat beverage” with the statement reading “contains a lower amount of potassium than milk.” In the FDA example, the portrayal and use of “milk” is even more confusing to consumers.

Nutritional content is one important consideration in this rule. However, as the FDA’s jam example demonstrates, a labelling standard, through clear definition and effective enforcement, assures consumers about a wide range of attributes of a product properly identified, including nutrition, nature of the source, composition, potential allergens, taste, texture, etc. This is why the distinction between jam and cheaper substitutes is important, regardless of nutritional comparison. Allowing flexibility in use of these terms nullifies any reason to have labeling enforcement generally and provides fuel to bad actors who may use this case as a reason to push for other wrongful use of terms.

When it comes to labeling these alternative beverages, FDA already has the rules on the books. Under the Federal Food, Drug, and Cosmetic Act, an imitation food is one that substitutes for and resembles another food and is nutritionally inferior to that food. FDA clearly explained these guidelines as far back as Jan. 6, 1993, in a Federal Register notice:

“A modified food that does use a traditional standardized term but that does not comply with the traditional standard of identity or with new § 130.10 must be labeled either as an ‘imitation,’ if it is nutritionally inferior, or as a ‘substitute,’ ‘alternative,’ or other appropriate term, if it is not nutritionally inferior, as specified in § 101.3(e) which will remain in effect. For example, a mozzarella cheese product made with skim milk and vegetable oil does not comply with the standard for mozzarella cheese (§ 133.155) or with new § 130.10(d)(2) and, therefore, must be labeled as ‘imitation mozzarella cheese’ if nutritionally inferior to mozzarella cheese or as ‘mozzarella cheese alternative’ or ‘mozzarella cheese substitute’ if it is not nutritionally inferior. For this reason, FDA concludes that there is no need to amend the definitions for ‘imitation’ or ‘substitute’ foods in § 101.3(e) at this time.”

In its draft guidance, FDA says consumers “generally” do not mistake plant-based alternatives to milk as milk and therefore will exempt these products from such regulation. This is baffling as they admit a fourth of consumers do not know the difference or they believe the substitutes contain milk (see above).

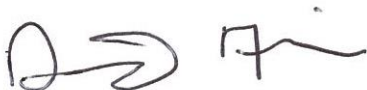
NYFB recommends FDA model their enforcement in a fashion similar to the labeling of imitation milk beverage products in other countries such as Canada, the European Union and the United Kingdom. These governments actively police and enforce mislabeling of misbranded nut- and plant-based beverages. Dairy terms such as “milk” are not allowed to be accompanied by clarifying or descriptive terms indicating the plant origin of the product. In fact, to comply with the rules set forth in other countries, U.S.-based companies must change their labels when their products are sold in these markets. For example, U.S.-labeled “almond milk” must be re-labeled “almond beverage” in Canada. Given that most of these companies already comply with labeling requirements of these countries, complying with existing FDA standards should not be a heavy or unreasonable burden. Additionally, enforcement of these labeling standards in other countries has not prevented these nut- and plant-based beverages from coexisting alongside real milk in the marketplace; rather they provide the consumer with accurate information about the product ingredients and dietary content.

The New York Farm Bureau believes that plant-based alternative milk products should adhere to current labelling laws and regulations and that consumers should be presented with accurate information on a product’s label so that they can make an informed choice about the wide range of attributes associated with milk and other dairy terms, including butter, ice cream, yogurt, etc. We ask that FDA amend their draft guidance to prohibit the use of “milk” or other dairy terms on non-dairy substitutes unless products follow proper use of imitation terminology, as defined by existing law. Allowing such changes runs the risk of undercutting the entire current FDA labelling framework for imitation products, to the detriment of farmers, honest processors, and all consumers. While we work to achieve these goals, it is absolutely critical that these efforts not result in changing the standards of identity for milk to include products beyond its established standard of identity, and in particular the nut- and plant-based beverages that are currently in violation of these standards of identity.

It is critical that the FDA act to rebrand non-dairy products and maintain the integrity of real dairy products not only for consumer confidence in milk and dairy products but to provide market and economic benefits for New York’s dairy farms.

NYFB thanks you for the opportunity to share these comments and appreciates your thoughtful consideration of this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "David Fisher". The signature is fluid and cursive, with a large initial "D" and "F".

David Fisher
President, New York Farm Bureau