



# National Milk Producers Federation

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Agri-Mark, Inc.  
Associated Milk Producers Inc.  
Bongards' Creameries  
Cooperative Milk Producers Association  
Dairy Farmers of America, Inc.  
Ellsworth Cooperative Creamery  
FarmFirst Dairy Cooperative  
First District Assoc.  
Foremost Farms USA  
Land O'Lakes, Inc.  
Lone Star Milk Producers  
Maryland & Virginia Milk Producers Cooperative Association  
Michigan Milk Producers Association  
Mid-West Dairyman's Company  
Mount Joy Farmers Cooperative Association  
Northwest Dairy Assoc.  
Oneida-Madison Milk Producers Cooperative Association  
Prairie Farms Dairy, Inc.  
Premier Milk Inc.  
Scioto Cooperative Milk Producers' Association  
Select Milk Producers, Inc.  
Southeast Milk, Inc.  
St. Albans Cooperative Creamery, Inc.  
Tillamook County Creamery Association  
United Dairyman of Arizona  
Upstate Niagara Cooperative, Inc.

January 28, 2019

Dockets Management Staff (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

## **Re: Docket No. FDA-2018-N-3522, Use of the Names of Dairy Foods in the Labeling of Plant-Based Products**

We appreciate the opportunity the U.S. Food and Drug Administration has provided the public to offer information on an important issue for consumers in the food marketplace: the integrity of standards of identity. As products evolve and marketing competition pushes companies to stretch food labeling regulations to their limits – and beyond – it is increasingly important that the FDA intervene to re-establish first principles defining what a product is and what it is not. Nowhere is this more apparent than in dairy labeling, where imitation food items are proliferating that are in clear violation of federal standards of identity, to the detriment of consumers' nutrition and public health.

We at the National Milk Producers Federation, the trade association representing the nation's cooperative dairy producers, are eager to assist in a constructive, definitive resolution of this unfortunate situation. We applaud the FDA's request for information, which we hope will adequately address a problem that's been more than four decades in the making.

These comments are only one element of our response, and they are not meant to be exhaustive. They do, however, outline our concerns and detail the current situation, one of consumer confusion over nutritional content and unfair competition based on misinformation. Clear, accurate labeling is a fundamental matter of truth and transparency for consumers. In light of the rampant labeling abuse by plant-based dairy imitators, it is critical that FDA reassert well-established standards of identity to guide all actors in the marketplace. We are eager to continue to be part of a productive solution going forward, and we appreciate the agency's attention to this matter.

Our comments today are a capstone to the numerous filings we have already made in this docket as we strive to provide FDA with relevant information. We hope this will assist FDA in understanding the importance of standards of

identity in the marketplace and the imperative of enforcing the rules it has promulgated.

Also included in those filings are results from three separate consumer studies by IPSOS, a global market research and consulting firm. Cumulatively, the studies paint a clear picture of rampant consumer confusion in the marketplace over the nutritional contribution of milk versus plant-based imitators, as well as consumer sentiment that use of dairy terms by plant-based products is inappropriate.

To further the agency's understanding, NMPF will file a citizen petition with FDA in the coming weeks calling for prompt enforcement actions against misbranded plant-based dairy imitators, as well as for the FDA to amend its regulations to codify its longstanding and well-tailored food labeling policies. These policies permit imitation and substitute foods to use standardized dairy names only under limited, defined conditions that directly advance the government's substantial consumer-protection and public-health protection interests in a well-tailored manner. The citizen petition will also extensively address any alleged 1<sup>st</sup> Amendment issues and establish a clear path forward for the agency.

After nearly 40 years of asking the FDA repeatedly to enforce its rules and regulations regarding imitation dairy products in the marketplace, the NMPF is thankful that the agency has finally acknowledged the seriousness of this issue and is considering it with deliberation and thoughtfulness. But even during the era when our responses from the agency ran along the lines of "it is not a priority," we gained information that may be useful for present consideration. For example: In 1980, NMPF attempted to compel FDA, in federal court, to act against imitation cheese products. While NMPF was unsuccessful in getting the courts to compel FDA to enforce its rules, we did gain clarity in that the courts felt that imitation labeling provisions at 21 CFR 101.3(e) were valid. Those provisions remain valid today, and the failure to enforce them in earlier times has undoubtedly resulted in the present nomenclature nightmare we find in the marketplace.

In these, as well as in the additional NMPF and dairy-organization filings already mentioned, the industry has shown:

- **Consumers are being misled about the nutritional content of plant-based imitators relative to real dairy products, creating marketplace confusion and inappropriately blurring well-defined standards of identity.**

Data from an IPSOS survey completed last August suggests that among consumers who exclusively purchase plant-based beverages, most view them as healthier and more nutritious than milk. Nearly two-thirds (65%) thought plant-based beverages were nutritious, but only 32% said milk was nutritious. Large majorities of respondents in all buyer categories viewed almond beverage as having as much as or more protein than milk (77%); at least as many vitamins and minerals (78%); and at least as many “key nutrients (e.g., calcium, potassium)” (68%).<sup>1</sup>

The reality is starkly different: According to the USDA Nutrient Database, a 1-cup (8-ounce) serving of unsweetened almond beverage has 2 grams of protein compared to 8 grams in a serving of milk. Milk exceeds the content of almond beverage for riboflavin, vitamin B6, phosphorus, pantothenic acid, niacin and vitamin B12. (Through fortification – not naturally-occurring – some almond beverages contain more calcium, thiamin and vitamin E.)

- That confusion creates a public health issue by causing harm to our nation’s children and, potentially, other consumers – a concern also raised by FDA commissioner Scott Gottlieb.
- The U.S. Dietary Guidelines for Americans (DGA) do not recognize plant-based beverages (except for soy) to be part of the dairy category because of their nutritional inferiority.
- Only 20 percent of all consumers said plant-based beverages should be labeled milk because the DGA do not recommend imitators as a substitute for dairy milk; even when limited to buyers of plant-based drinks, support for mislabeling rose to only 41 percent.<sup>2</sup>

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<sup>1</sup> Dairy Management Inc. (Oct. 24, 2018) *Consumer Perceptions: Dairy and Plant-Based Milk Alternatives*. Retrieved from <https://www.usdairy.com/trends-and-initiatives/community-focus>

<sup>2</sup> Dairy Management Inc. (Jan. 14, 2019) *Consumer Perceptions: Dairy and Plant-Based Milks Phase II*. Retrieved from <https://www.usdairy.com/trends-and-initiatives/community-focus>

- Pediatricians, dieticians and other health professionals, here and in other countries, recognize the public health harm created by misinformation about plant-based products.
  - Some 25% of consumers are confused about whether there is cow's milk in the plant-based beverages they purchase.<sup>3</sup>
- **FDA inaction has allowed marketplace confusion to fester while state and international bodies fill the breach.**
    - NMPF has diligently encouraged FDA to act for over 40 years.
    - During that time the problem has escalated. For example, as recently as 2010 there were several hundred plant-based beverage SKU's, but now there are over 1,200.
    - The internationally-recognized Codex Alimentarius is very clear that the use of dairy terms is for dairy products, not dairy imitators or substitutes.
    - State legislatures are acting where FDA has failed to enforce its rules.
- **NMPF supports marketplace clarity and free speech.**
    - NMPF supports clarity in regulations that would explicitly include milk from other animal species.
    - Despite obfuscatory efforts by opponents of our quest to end consumer deception in dairy labeling, NMPF does not take issue with products that do not purport to be a dairy substitute – for example, we do not object to the term “peanut butter,” as that food product does not purport to be a substitute for butter. Similarly, we do not take issue with canned coconut milk (used for cooking and sold in the canned goods section of the store) but we do take issue with coconut milk sold in dairy-like packaging and merchandised in the dairy case where it is intended to be used as a direct substitute for cow's milk.
    - FDA's enforcement of standards of identity does not violate the 1<sup>st</sup> Amendment.

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<sup>3</sup> Food Insight (Oct. 11, 2018) What's in a Name? Survey Explores Consumers Comprehension of Milk and Non-Dairy Alternatives. Retrieved from <https://foodinsight.org/whats-in-a-name-survey-explores-consumers-comprehension-of-milk-and-non-dairy-alternatives/>

- Consumer packaged goods companies do not get to choose what laws they follow and what they can ignore – a situation that can only result in chaos.
- The public is waking up to the fact that the plant-based food industry's marketing efforts rely heavily on false and misleading labeling.

### **FDA Needs to Educate Plant-Based Food Manufacturers on Compliance**

Compliance with proper labeling of imitation and substitute food products is not very complicated. FDA clearly explained how it should be done in a January 6, 1993, 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.<sup>4</sup>

Simply put, if the modified food uses a standardized dairy term and is nutritionally inferior as described in 21 CFR 101.3 (e)(4), as most if not all such plant-based foods are, it must bear the word "imitation." If the food is not nutritionally inferior, it must bear the word "substitute" or "alternative." If traditional dairy marketers are expected to follow these simple rules as indicated by the mozzarella example above, it is a fundamental matter of basic fairness and justice that everyone be compelled to achieve similar compliance.

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<sup>4</sup> 58 Fed Reg 2431, 2433 January 6, 1993

With respect to nutritional inferiority, in addition to the parameters currently in 21 CFR 101.3(4), FDA should also consider protein quality and micronutrients. It is widely recognized that plant proteins are nutritionally inferior to animal proteins, so a proper assessment of nutritional inferiority should factor that into any assessment. NMPF will describe how protein quality is to be determined in the citizen petition we intend to file. With respect to micronutrients, such as but not limited to, lactoperoxidase, immunoglobins, metal-binding proteins, B2-microglodulin, osteopontin, glycoproteins, angiogenins, vitamin-binding proteins, glycoproteins and others, NMPF will submit additional details on micronutrients when FDA opens a docket for the dairy citizen petition as well.

### **Consumers Need Information About the Nutritional Inferiority of Plant-Based Imitators**

All fake dairy beverages start with a single major ingredient – water. Plant-based beverage manufacturers then add nut, grain or vegetable powders, emulsifiers, sweeteners, stabilizers and their ingredients until they have a product that purports to be a “milk.” Such beverages are not milk. Unlike milk, they are not found in nature in their highly processed liquid forms, but rather, they are concoctions of water with added ingredients. Long ago FDA took issue with nutritional fortification of nutritionally inadequate foods that held out to be healthy nutritionally-sound foods. FDA took action and issued what has been colloquially known as the “jelly bean rule.” In essence, one cannot take a jelly bean and inject it with nutrients and then advertise that it was a “good source of...”. The plant-based manufacturers are in essence doing precisely this. They start with water, add a concoction of powders and chemicals and then call it a “milk” – one of the most wholesome and nutritious food products known, a product that contains 9 essential nutrients and is an especially important source of nutrients in a child’s diet. Currently, plant-based food manufacturers are making implied nutrient content and health claims with no fear of retribution, a situation FDA must remedy.

Commissioner Gottlieb’s observation last summer was spot-on in that children are suffering from diseases such as kwashiorkor and rickets because the mis-used dairy terminology on plant-based imitation dairy products conveys a nutrition profile that is sorely lacking. He stated:

“One area that needs greater clarity – and which has been the subject of much discussion of late – is the wide variety of plant-based foods that are being positioned in the marketplace as substitutes for standardized dairy products. Many of these plant-based foods use traditional dairy terms (e.g., milk, yogurt, cheese) in the name of the product. For instance, we’ve seen a proliferation of products made from soy, almond or rice calling themselves milk. However, these alternative products are not the food that has been standardized under the name “milk” and which has been known to the American public as “milk” long before the 1938 Federal Food, Drug, and Cosmetic Act (FD&C Act) was established. In addition, some of these products can vary widely in their nutritional content – for instance in relation to inherent protein or in added vitamin content – when compared to traditional milk.

We intend to look at these differences in relation to potential public health consequences. There are reports that indicate this issue needs examination. For example, case reports show that feeding rice-based beverages to young children resulted in a disease called kwashiorkor, a form of severe protein malnutrition. There has also been a case report of a toddler being diagnosed with rickets, a disease caused by vitamin D deficiency, after parents used a soy-based alternative to cow’s milk. Because these dairy alternative products are often popularly referred to as “milk,” we intend to look at whether parents may erroneously assume that plant-based beverages’ nutritional contents are similar to those of cow’s milk, despite the fact that some of these products contain only a fraction of the protein or other nutrients found in cow’s milk.”<sup>5</sup>

NMPF looks forward to FDA exploring the probable health consequences for which these imitators of not only milk, but also other standardized dairy products, are responsible.

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<sup>5</sup> Statement from FDA Commissioner Scott Gottlieb, M.D., on the process FDA is undertaking for reviewing and modernizing the agency’s standards of identity for dairy products, July 26, 2018

### **Substitute and Alternative Foods Violate FDA's Nutrition Quality Guidelines for Foods**

FDA's Nutrition Quality Guidelines for Foods were updated and reissued on April 1, 2018. In the opening paragraph those guidelines state:

The fundamental objective of this subpart is to establish a uniform set of principles that will serve as **a model for the rational addition of nutrients to foods**. The achievement and maintenance of a desirable level of nutritional quality in the nation's food supply is an important public health objective. The addition of nutrients to specific foods can be an effective way of maintaining and improving the overall nutritional quality of the food supply. However, random fortification of foods could result in over or under fortification in consumer diets and create nutrient imbalances in the food supply. It could also result in deceptive or misleading claims for certain foods. **The Food and Drug Administration does not encourage indiscriminate addition of nutrients to foods, nor does it consider it appropriate to fortify fresh produce; meat, poultry, or fish products; sugars; or snack foods such as candies and carbonated beverages.** [Emphasis Added] <sup>6</sup>

As mentioned above, plant-based beverages start out as water. If the FDA does not encourage the fortification of fresh produce, meat, poultry or fish products, sugars or snack foods such as candies and carbonated beverages, it seems inconsistent that FDA would encourage the fortification of water to the point that it is passed off as milk. NMPF remains at a loss as to how FDA can support such a contradiction. These beverages are, in fact, fortified waters designed to mislead. If the fundamental objective of the April 1, 2018, Nutrition Quality Guidelines is to establish a uniform set of principles to serve as a model for the rational addition of nutrients to foods, allowing water to be mixed with characterizing ingredients and functional additives and subsequently fortifying it to the point it is passed off as milk is a failure of mission. The FDA needs to rethink, revise and reissue its policy. And most importantly, it needs to enforce it.

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<sup>6</sup> <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=104.20>



### **Plant-Based Products Are Misbranded**

Under section 403(g) of the FD&C Act [Food, Drug, and Cosmetic Act], a food is misbranded if it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulation, **unless it conforms to such definition and standard.**

“Almond milk,” as an example, is a food purporting to be “a food for which a definition and standard of identity has been prescribed by regulation.” The standard of identity in question is for “milk.”

In comments it filed in this docket, one respondent attempts to assert that an almond beverage labeled as “almond milk” is appropriate and then asserts that “If Almond Milk was sold without ‘almond’ in its name and simply labeled as ‘milk,’ then there could be an issue.” They further assert that:

“Judge Vince Chhabria, a California federal district court judge, nicely captured this point when discussing whether soy milk was misbranded:

But the fact that the FDA has standardized milk does not categorically preclude a company from giving any food product a name that includes the word "milk." Rather, as the language of section 343(g) indicates, the standardization of milk simply means that a company cannot pass off a product as "milk" if it does not meet the regulatory definition of milk.”

The judge and the commenter are simply wrong. FDA in a June 29, 2011, warning letter sent to CytoSport, Inc., the marketer of a product that calls itself “Muscle Milk,” correctly stated the law:

Your “Chocolate Muscle Milk Protein Nutrition Shake” and “Vanilla Crème Muscle Milk Light Nutritional Shake” products are misbranded within the meaning of section 403(a)(1) of the Act [21 U.S.C. § 343(a)(1)] in that the labels are false or misleading. For example:

These product labels prominently feature the word “MILK,” however these products contain no milk [emphasis added.] The actual statements of identity, “Protein Nutrition Shake” and “Nutritional Shake” are in

significantly smaller and less prominent type than the words  
“MUSCLE MILK” on these product labels.

On March 7, 2012, FDA sent a warning letter to Fong Kee ToFu Company citing a number of violations it had identified. Among them:

Your Fresh Soy Milk Sweet product uses the term “milk” as part of the common or usual name. Milk is a standardized term 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. Therefore, we do not consider “soy milk” to be an appropriate common or usual name because your product does not contain milk. We consider “soy drink” or soy beverage” however as acceptable common or usual names for such products.”

Judge Chhabria and the commenter should have noted that the product must conform to the definition and standard. Judge Chhabria should have also followed the doctrine of primary jurisdiction. Primary jurisdiction is a doctrine whereby a court tends to favor allowing an agency an initial opportunity to decide an issue in a case in which the court and the agency have concurrent jurisdiction. He did not.

In contrast, in a similar case the judge in the United States District Court for the Eastern District of California did exactly that and issued a memorandum that stays the case “pending a determination from FDA on whether the defendant’s products must be labeled “imitation” under 21 CFR 101.3(e) or when it appears the FDA does not intend to address the matter.” Obviously with this docket, it is clear that FDA is trying to address this matter.

The FDA points out in its notice about this docket that the misbranding question also should examine where the product is sold in the store and the packaging of the product.

Dairy imitators (including imitations of the standardized products milk, creams, yogurt, cheese, ice cream and butter) are being sold in the same location of retail stores as dairy products, and their product names and their packaging clearly emulate traditional dairy products. These items are intentionally designed to mimic cow’s milk products in all ways possible, with similar

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packaging and location in the “dairy case.” It cannot be disputed that they purport to be dairy substitutes. Plant-based food manufacturers have done everything imaginable to capture the look and feel of dairy as well as the halo of nutrition, functionality, and good taste that dairy has long held throughout the world.

As noted above, NMPF takes no issue with “peanut butter,” “cocoa butter,” “coconut milk (canned, used for cooking),” “apple butter,” “head cheese,” “shea butter and body butter (cosmetic moisturizing lotions),” and many other products that use the names of dairy foods in their labeling as they are not intended to be consumed as a substitute for an existing dairy product. We do take issue with those products that do purport to be a substitute and do not follow the law or proper labeling regulations. To be clear, we do not take issue with plant-based beverages and foods being offered in the marketplace and we are happy to compete with them. But they need to be labeled properly and follow FDA’s rules and regulations.

We appreciate the opportunity to share our views on this important topic and look forward to a favorable resolution to this four-decade-old deception.

Sincerely,



Clay Detlefsen  
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Regulatory Affairs & Staff Counsel