



# National Milk Producers Federation

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July 30, 2023

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
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**RE: Docket No. FDA-2023-D-0451, Labeling of Plant-based Milk Alternatives and Voluntary Nutrient Statements; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request**

Dear Sir or Madam:

The National Milk Producers Federation (NMPF) offers these comments in response to the proposed guidance entitled “Labeling of Plant-based Milk Alternatives (PBMA) and Voluntary Nutrient Statements” published in the *Federal Register* on February 23, 2023. NMPF was organized in 1916 to provide a forum for dairy producers and the cooperatives they own to participate in public policy discussions. NMPF advocates policies to Congress, U.S. and foreign government agencies, industry organizations, the news media, and the public.

The Food and Drug Administration (FDA) seeks information relating to and feedback on its draft guidance on Labeling of Plant-based Milk Alternatives and Voluntary Nutrient Statements. The information request invites comment on:

- The voluntary nutrient statement recommendations provided in section III.2 of the draft guidance. We acknowledge that the labeling of some plant-based milk alternatives may have space constraints that limit listing of multiple nutrients in the voluntary nutrient statement. Therefore, we are interested in comments about the placement of and possible space constraints for the voluntary nutrient statement on product labels.
- FDA is recommending nutrient disclosure statements on the labels of plant-based milk alternatives that contain less of the following nutrients compared to milk: calcium, protein, vitamin A, vitamin D, magnesium, phosphorus, potassium, riboflavin, and vitamin B12. We chose these specific nutrients because the Dietary Guidelines for Americans identifies the Dairy Group as being a key contributor of those nutrients and to align with the nutritional standards set by the U.S. Department of Agriculture’s (USDA) Food and Nutrition Service

Agri-Mark, Inc.  
Associated Milk Producers Inc.  
Bongards' Creameries  
Burnett Dairy Cooperative  
California Dairies, Inc.  
Cayuga Marketing  
Cooperative Milk Producers Association  
Dairy Farmers of America, Inc.  
Ellsworth Cooperative Creamery  
FarmFirst Dairy Cooperative  
First District Association  
Foremost Farms USA  
Land O'Lakes, Inc.  
Lone Star Milk Producers  
Maryland & Virginia Milk Producers Cooperative Association  
Michigan Milk Producers Association  
Mount Joy Farmers Cooperative Association  
Northwest Dairy Association  
Oneida-Madison Milk Producers Cooperative Association  
Prairie Farms Dairy, Inc.  
Scioto Cooperative Milk Producers' Association  
Southeast Milk, Inc.  
Tillamook County Creamery Association  
United Dairymen of Arizona  
Upstate Niagara Cooperative, Inc.

for fluid milk substitutes served in the National School Lunch Program, School Breakfast Program, and Child and Adult Care Food Program (USDA criteria) (see 7 CFR 210.10(d)(3), 220.8(d), and 226.20(g)(3)).

- For the purpose of this draft guidance, are the USDA criteria that identify minimum levels of nutrients for fluid milk substitutes the most appropriate criteria to use? If yes, why? If not, what criteria (i.e., nutrients and nutrient levels, minimums versus ranges of nutrient levels, etc.) should we consider and why? Please provide information, research, and data to help us understand your reasoning.

We will address specific questions raised by the FDA in the recent Federal Register notice, address a number of legal issues and share some background information. We also would like to remind FDA that NMPF, at considerable time and expense, filed a Citizen Petition to address the Plant-Based Milk Alternative labeling problem on February 21, 2019. In that Petition, NMPF asked FDA to:

- Enforce existing “imitation” labeling requirements against nutritionally inferior non-dairy substitutes for standardized dairy foods that are named and positioned as forms of “milk,” “yogurt,” “cheese,” “ice cream,” or “butter,” yet fail to provide the “imitation” disclosure statement that is required under the Act and FDA implementing regulations; and
- Amend section 101.3(e) of FDA regulations to codify in more detailed form longstanding FDA policies that permit the name of a standardized dairy food (*e.g.*, “milk,” “yogurt,” “cheese,” “ice cream,” “butter”) to be used in the statement of identity of a non-dairy substitute for the standardized food only under limited and defined conditions. [**See Attachment A**]

Before we go further, NMPF wants to be very clear: NMPF has never asked for an outright ban on the use of dairy terminology on imitation, substitute, or alternative plant-based foods. We have always acknowledged a complete ban would be impermissible under the First Amendment -- advocates of plant-based products that assert that “Big Dairy” wants an outright ban simply do not have their facts right. NMPF has instead consistently asked for everyone to follow the rules and provide transparency and fair factual disclosure to consumers to assist them in making informed purchasing decisions. Current regulations have long permitted the use of the name of a food being imitated, such as “Imitation Vanilla Extract” or “Imitation Crab Meat.” It can and has been done for decades.

Further, NMPF has never advanced the notion that consumers were confused about what the PBMA product was, or whether it contained real dairy or not: We focused on how consumers do not understand the nutritional inferiority of PBMA. We have however pointed out that some PBMA-funded research did show a degree of

consumer confusion over what was in a particular PBMA product. But the real issue is -- and must be -- about nutrition.

Finally, much of the information shared in the background is extracted from the Citizen Petition, a complete copy of which was filed separately in this docket.

## **I. PBMA Nutritional Inferiority Matters - Serious Public Health Consequences are Associated with the Misbranding Violations**

### **A. Public Health Consequences**

It is long overdue that FDA finally recognizes that most if not all PBMA are not nutritionally equivalent to real milk. The difference becomes even starker when one considers protein quality in addition to protein quantity. Consumers need to understand that -- especially parents when selecting foods for their growing children.

The harm associated with naming food products in violation of FDCA and FDA regulations is not purely hypothetical or academic. As discussed in the Citizen Petition NMPF filed with FDA, existing regulations are grounded in important consumer and public health protection objectives that “discourage the gradual nutritional degradation of the American diet through the introduction of products that replace traditional products but are nutritionally inferior to them.” These public health goals are directly at stake here. Specifically, because non-dairy substitutes are almost uniformly nutritionally inferior to the standardized dairy products they resemble and for which they substitute, consumers unknowingly reduce consumption of nutrients vital to a healthy diet based on the false assumption that the non-dairy substitute is nutritionally equivalent to the reference standardized dairy food. Notably, the risk applies whether or not a consumer understands that the non-dairy substitute food is not comprised in whole or in part of the reference standardized dairy food. At the same time, even surveys funded by the PBMA industry have found that a significant proportion of consumers either affirmatively believe or do not know whether nondairy substitutes contain dairy. For example, an Oct. 2018 industry funded survey conducted by the International Food Information Council Foundation (IFICF) found that between 7 and 9 percent of consumers believe that non-dairy, plant-based beverages contain cow’s milk and between 16 and 20 percent of consumers report not knowing whether they contain cow’s milk. While the study was touted as finding “a low level of consumer confusion over nomenclature and basic differences” between non-dairy substitutes and their standardized dairy counterparts, longstanding Federal Trade Commission precedent holds that a threshold of 10-20 percent of consumers is sufficient to establish deception from an implied claim. More fundamentally, the survey failed to ask consumers about their perception of the nutritional and performance characteristics of non-dairy substitutes compared to their reference standardized dairy counterparts.

Even if consumers did understand that non-dairy substitutes do not contain the reference standardized dairy food misleadingly used in their names, FDA regulatory requirements governing food standards and names of foods are grounded not only in preventing consumer deception but also protecting consumer and public health by establishing nutritional, quality, and compositional benchmarks. This is especially important here, because non-dairy substitutes are marketed as healthy, nutritious alternatives to their dairy counterparts and are labeled with explicit references to the traditional standardized dairy food.

Studies confirm that consumers wrongly assume that non-dairy, plant-based substitutes are nutritionally equivalent or even superior to their dairy counterparts. According to a 2018 survey by IPSOS, a global market research and consulting firm, 62% of plant-based beverage buyers cite nutrition as important to their purchase decision. Additionally, more than 70% of consumers thought plant-based, non-dairy substitutes have the same or more protein than dairy milk. However, an actual comparison of nutritional profiles shows that most types of non-dairy substitutes are almost uniformly nutritionally inferior to their nutrient-dense dairy counterparts. To evaluate, in August 2017, NMPF surveyed non-dairy substitute beverages sold in grocery stores in the Washington, D.C. metropolitan area, and then compared the nutrition facts panels of these products with that of 1% milk, including the thirteen essential nutrients for which milk is the number one source in children's diets. The results are summarized in **Attachment B** which showed that of the 244 beverages examined:

- None of these products are nutritionally equivalent to real milk or deliver those nine essential nutrients in the same proportions as dairy milk;
- Many of these products lack key essential nutrients provided by milk such as protein and Vitamin D; and
- Unlike real milk's consistent nutrient profile, extremely wide variation existed both within and among the various categories of non-dairy, plant-based beverages.

The inconsistency between consumer perception and reality of the nutritional profiles of dairy and plant-based substitutes has potentially grave consequences, given the important role that dairy plays in contributing to human nutritional needs. Many scientists, doctors, and even some in the non-dairy substitute industry have recognized the risks to individual health and public health that are presented by the proliferation of these misbranded imitation products. The most recent Dietary Guidelines for Americans addressed the nutritional inferiority issue by grouping products separately and explaining that "[o]ther 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 and fortified soy beverages.” In addition, a 2023 study compared the nutritional content of 237 PBMA with dairy milk, finding that the amounts of nutrients varied across brand and type and that few plant-based milk alternatives matched levels of protein, calcium and vitamin D in dairy milk. The researcher, Dr. Abigail Johnson, a professor in nutrition and human health at the University of Minnesota, presented her research at the American Society of Nutrition's flagship meeting, on July 24.<sup>1</sup>

While health experts and industry executives know that non-dairy substitutes are generally nutritionally inferior to their dairy counterparts, consumers are not so well informed, and misleading labels reinforce the false perception that nutritionally inferior imitations are equivalent or even superior to their dairy counterparts. Indeed, there have been a number of reports of health incidents such as malnutrition associated with replacement of dairy beverages with nutritionally inferior imitations. These potentially grave public health consequences are precisely why the FDCA and FDA regulations require truthful and non-misleading common or usual names and require nutritionally inferior substitutes to be labeled as “imitation” products.

## **B. Nutrient Absorption**

While we appreciate FDA recognizing the need to proclaim the nutritional differences between plant-based milk alternatives and milk on the labels, we do feel FDA has missed a large piece of the puzzle. The amount of a nutrient a beverage contains is important, but the body's ability to use that nutrient is important as well.

Using calcium as an example, let's explore the difference in absorption levels between calcium consumed in dairy products versus calcium consumed through calcium fortified products. Dairy products are one the main natural sources of dietary calcium in the United States which is driven by their high level of natural, absorbable calcium. However, for other food products fortified with calcium, depending on the type of calcium it is fortified with, lower levels of absorbable calcium are available. For example, the amount of calcium absorbed from a fortified soy drink depends on if it contains calcium carbonate or tricalcium phosphate. As stated in Shkemi 2022, “to be considered a suitable source of calcium, it is important that foods not only contain it in adequate quantities, but also that the calcium is also sufficiently bioavailable.”<sup>2</sup>

In addition, the type of vitamin D products are being fortified with can also impact nutritional benefits. Dairy products are typically fortified with vitamin D3 which is much more inclined to raise blood levels of vitamin D, whereas many PBMA are

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<sup>1</sup> <https://www.newsweek.com/scientists-analyzed-plant-based-milk-substitute-cow-milk-dairy-1814307>.

<sup>2</sup> Shkemi, B., & Huppertz, T. (2021). Calcium Absorption from Food Products: Food Matrix Effects. *Nutrients*, 14(1), 180. <https://doi.org/10.3390/nu14010180>

fortified with plant-based vitamin D2 which is not nearly as effective in raising blood levels. This is yet another example where FDA should not rely on the quantity of the nutrient only when other factors are clearly in play.

## **II. NMPF Response to Addressing FDA's Specific Invited Questions**

- Most PBMA packages have plenty of space for additional disclosures. The vast majority of PBMA products in the marketplace are packaged in quart or half-gallon containers. In fact, with respect to soy beverages, 92.6% are sold in half-gallon cartons and another 4.4% are sold in quart sizes for a total of 97% being in packaging with ample room for disclosure. NMPF would also assert that there is room on smaller SKU's as well and what holds for soy products likely holds for the other PMBA products. See the attached "Spreadsheet A" from Circana Group, L.P. for additional information on soy PBMA SKU's. There is no reason to believe that those sized packages do not contain ample space to provide the nutritional inferiority disclosure. NMPF is strongly opposed to hiding such disclosure on the back of the package, where most consumers simply do not have the time or inclination to search for such information. It is abundantly clear that consumers are misinformed, and any requests to move the disclosure to anything but front-of-pack is an attempt to be non-transparent and continue to mislead consumers.
- FDA's recommendation for nutrient disclosure statements on the labels of plant-based milk alternatives that contain less of the following nutrients compared to milk: calcium, protein, vitamin A, vitamin D, magnesium, phosphorus, potassium, riboflavin, and vitamin B12 is a great start. However, dairy is in fact a good or excellent source of 13 nutrients which include: protein, calcium, phosphorus, vitamin A, vitamin D, riboflavin (B2), niacin (B3), pantothenic acid (B5) and cobalamin (B12), iodine, potassium, selenium and zinc. It is, as FDA suggests, consistent with the Dietary Guidelines for Americans as well as the nutrition standards set by the U.S. Department of Agriculture's (USDA) Food and Nutrition Service for fluid milk substitutes served in the National School Lunch Program, School Breakfast Program, and Child and Adult Care Food Program (USDA criteria) (see 7 CFR 210.10(d)(3), 220.8(d), and 226.20(g)(3)). In addition, NMPF strongly feels FDA misses the mark with respect to protein, making equivalency depend solely on protein quantity. This is very short-sighted, as not all proteins are equal. In fact, dairy proteins are of the highest quality and contain all the essential amino acids required for a healthy diet. Plant proteins are of significantly less quality. NMPF tried to address this when it asked for modifications to 21 CFR 103 in our Petition specific we suggested the following addition:

(vi) For the purposes of section 101.3(e)(6), nutritional inferiority shall be defined as provided in section 101.3(e)(4) except that nutritional inferiority shall also take into account the protein quality value of the non-dairy substitute food based on the protein digestibility-corrected amino acid score method set forth in section 101.9(c)(7).

NMPF believes that FDA should amend the proposed equivalence determination to specifically address the inferiority of plant-based proteins.

- USDA put considerable effort into determining the minimum levels of nutrients that should be required for fluid milk substitutes. Those requirements have stood a considerable test of time, though as mentioned above protein quality should be considered as well. But, as mentioned above milk has 13 essential nutrients including iodine, which is also deficient in many American diets.

### **FDA's Draft Guidance Violates the Administrative Procedures Act (APA) and the US Constitution**

While FDA's guidance takes a step in the right direction by recommending that PBMA companies voluntarily disclose the nutritional inferiority of their products, FDA's draft guidance fails on two important legal grounds. First, the draft guidance rewrites and contradicts FDA's existing regulation on misbranding and imitation labeling at 21 CFR 101.3 (c) and second it violates the U.S. Constitution as Congress itself drafted the misbranded and imitation labeling requirements and misbranding provisions in the Federal Food, Drug and Cosmetic Act (FDCA) codified at 21 U.S.C 343 (c) and 21 U.S.C. 343 (g).

Specifically, 21 CFR 101.3 (e) states:

(e) Under the provisions of section 403(c) of the Federal Food, Drug, and Cosmetic Act, a food shall be deemed to be misbranded if it is an imitation of another food unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.

(1) A food shall be deemed to be an imitation and thus subject to the requirements of section 403(c) of the act if it is a substitute for and resembles another food but is nutritionally inferior to that food.

And Congress stated at 21 U.S.C. §343 - Misbranded food:

"A food shall be deemed to be misbranded-

(a) ...

(b) ...

(c) Imitation of another food

If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated."

The violation under the APA stems from the fact that FDA is rewriting a regulation using a guidance document. This is a blatant violation of the notice and comment process which provides stakeholders with a clear and transparent manner in which to share information and perspectives during the regulatory promulgation process. The complete disregard for the APA is, to say the least, alarming-- but, we also need to look at where the authority to regulate imitation food products came from. Congress declared how an imitation food should be labeled - stating in clear and precise language that a food is misbranded if it imitates another food unless it bears the word "imitation" immediately prior to the name of the food being imitated. As stated above, plant-based milk alternatives epitomize imitation. They have tried to capture the dairy industry's health halo, the look and feel of the actual product, the packaging, and the placement in stores. They in no uncertain terms purport to be milk. Anyone who says that plant-based milk alternatives are not imitations of real dairy products is exceptionally naïve or simply dead wrong.

FDA has not reinterpreted, amended, or extended the Congressional language and mandate; it has chosen to contradict it and substitute its judgment over that of Congress. This is a clear example of a regulatory Agency, which is in the Executive branch, deciding its decision making is superior to that of Congress, our Legislative branch, and re-legislating settled law without Congressional involvement. This is an egregious violation of the separation of powers.

While NMPF does not believe that the FDA intended to violate the APA, nor the U.S. Constitution, it will have done precisely that should this guidance be issued in final form. If FDA wants to eliminate the misbranding and imitation provisions of the FDCA, it must be done through consultation with its counsel and Congress and the proper proves of having Congress remove them. Once this first step is taken and only then can it embark upon notice and comment rulemaking as provided for under the APA to eliminate the provision at 21 CFR 101.3 (c).

### **III. The Hauntingly Familiar Case of American Academy of Pediatrics v. Food and Drug Administration - Case No.: PWG-18-883**

In March 2018, the American Academy of Pediatrics (AAP) filed a lawsuit against FDA involving many analogous facts and FDA actions to the issues central here. AAP prevailed and the decision was not overturned on appeal. The two main claims in the litigation that were ultimately decided were the plaintiffs' assertions below:



- “Plaintiffs claim that the August 2017 FDA Guidance “is ultra vires and unconstitutional,” in violation of the APA, in that it “conflicts with the Tobacco Control Act; exceeds FDA’s statutory authority; and violates the Constitution’s Take Care clause, U.S. Const. art. II, § 3.” Compl. ¶ 94; see also id. ¶¶ 92–102 (Count I).
- They also claim that, because the August 2017 Guidance “is a ‘rule’ within the meaning of the APA,” the FDA violated the APA by issuing it without complying with the notice and comment requirements for rulemaking. Id. ¶¶ 105–07; see also id. ¶¶ 103–10 (Count II).”

As stated above, NMPF asserts that FDA’s PBMA Guidance which is the subject of these comments is also ultra vires and unconstitutional; in violation of the APA, in that it conflicts with the FDCA; exceeds FDA’s statutory authority; and violates the Constitution’s Article II Section 3 Take Care Clause which requires the executive branch ensure the laws of the United States are faithfully executed. The PBMA Guidance violates the APA because the guidance at issue here is attempting to be a rule and FDA issued it without complying with the notice and comment requirements for rulemaking.

The judge in the AAP case went to great lengths to explain why FDA’s Tobacco Act guidance was unlawful with a clear and concise explanation beginning on page 42 of the court’s decision. NMPF includes the court’s decision as **Attachment – AAP v. FDA Decision**. The court made it clear

“The power of an agency like the FDA “is ‘not the power to make law. Rather, it is “the power to adopt regulations to carry into effect the will of Congress be as expressed by the statute ... and moreover, “neither federal agencies [like the FDA] nor the courts can substitute their policy judgments for those of Congress.”

“Stated differently, the court’s “estimations, and the [agency’s] estimations, of desirable policy cannot alter the meaning of [a federal statute]. Thus, when the FDA takes action contrary to the FDCA, through that ultra vires action the FDA “exceed[s] the authority granted to it by Congress, and its . . . action cannot stand.”

The court also found that FDA’s alleged use of enforcement discretion was a red herring and that the blanket across the board determination not to enforce the statute was an abdication of its statutory responsibilities. The court ultimately said “In sum, the FDA’s action cannot fall within its enforcement discretion. Its action is inconsistent with the Tobacco Control Act and in excess of its statutory authority, and it cannot stand.”

NMPF asserts that FDA’s decades long decision to follow an across-the-board non-enforcement of existing rules and the FDCA is inconsistent with the FDCA and in excess of FDA’s authority and it cannot stand. We encourage FDA and its lawyers to revisit that court’s decision.

#### IV. The Importance of Standards of Identity

Standards of Identity (SOIs) were developed to help protect consumers and promote honesty and fair dealing. SOIs have been established to ensure that the characteristics, ingredients and production processes of specific foods are consistent with what consumers expect.

Prior to the FDCA's enactment in 1938, the 1906 Act established definitions for adulteration and misbranding but failed to include a mechanism to compare foods to determine whether new products made in the semblance of traditional products were actually the same, whether the new products were wholly distinct, or whether they had been economically adulterated through dilution of valuable ingredients or other unlawful methods. Despite the fact that the 1906 Act had been intended to end such fraudulent practices, the limitations of the 1906 Act "actually contributed to the proliferation of cheap or debased foods that could be sold legally by reason of its so called 'distinctive name proviso,' [which] permitted the marketing of foods that would have been adulterated and misbranded if sold under the name of the food they purported to be by allowing their sale under meaningless 'distinctive' names such as 'Bred-Spread.'" As FDA would later explain:

The lack of a provision to establish mandatory standards under the 1906 act handicapped the Government in its attempts to maintain the integrity of the food supply by making it difficult for the Government to proceed ***against a debased food product, particularly a fabricated food*** ..... Eventually the government and the industry came to the conclusion that a new statute was needed to ensure the integrity of food by keeping economically adulterated foods off the market. This recognition resulted in inclusion of three key provisions (sections 401, 403, and 701 of the act) (21 U.S.C. 341, 343, and 371) for standardization of foods.

Notably, as evidence for the need for a new statute, the agency cited a case involving a food that did not purport to be a standardized food through its statement of identity but rather was labeled by a "meaningless distinctive" name – "Bred-Spred," a product resembling jam, but containing substantially less fruit than traditional fruit jams or preserves. This underscores that the FDCA food standard provisions were not intended solely to prevent consumer deception, which the agency was already authorized to address under the 1906 Act, but rather to protect the integrity of the food supply by establishing compositional and quality benchmarks for commonly consumed foods. To address this shortcoming, the FDCA directs the Secretary to "promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity" and to do so when it "will promote honesty and fair dealing in the interest of consumers." As a corollary, FDCA Section 403(c) provides that imitation foods must be labeled as

such to prevent misleading substitute products like “Bred-Spred” from simply being labeled through “meaningless distinctive” names.

Since the 1906 and 1938 acts, FDA has established standards of identity for many different types of foods. As a general matter, the requirements that are established under a standard of identity are designed to relate to the defining characteristics of the specific type of food. FDA explained this policy in the context of standardized dairy foods in 2005:

“Individual FDA food standards vary widely in their content. These variations have developed because of the different aspects of food technology that are responsible for providing the defining characteristics of a food. Some foods are defined and distinguished by their ingredients. The standards for these foods set specific limits on the levels of ingredients that may be used... . Other food standards focus on compositional characteristics of the food, rather than on the specific ingredients. For example, the standards of identity for milk products (part 131) list the minimum levels of milkfat and milk solids (excluding fat) that must be contained in these foods. Still other foods owe their distinctive characteristics to the manner in which they are produced, and the standards for these foods reflect this fact. For example, the standards of identity for cheese products (part 133) specify the manufacturing process, in addition to compositional characteristics, to distinguish one cheese from another.”

While the establishment of standards of identity to “promote honesty and fair dealing in the interest of consumers” in accordance with FDCA section 401 has always required standards to be designed in a manner that helps prevent consumer deception and helps ensure that standardized foods meet consumer expectations (*e.g.*, organoleptically, chemically (including nutritional composition), and in terms of performance characteristics), the establishment of standards of identity for basic foods that are important sources of essential nutrients in the overall diet, such as standardized dairy foods, also plays an important role in protecting and promoting consumer health and public health more generally. For example, because dairy foods are standardized, consumers are able to make informed purchase decisions that allow them to choose dairy foods that align with the recommendations of the Dietary Guidelines for Americans. The Dietary Guidelines currently recommend three daily servings of dairy products for Americans nine and older, 2.5 servings for children ages four through eight, and two servings for children ages two through three years old. Notably, the Dietary Guidelines distinguish dairy foods from plant-based dairy substitutes (except for fortified soy beverages) because the “overall nutritional content” of plant-based dairy substitutes “is not similar to dairy milk and fortified soy beverages.”

As such, standards of identity for dairy foods in particular have long been among the most important food standards, based on the widespread and frequent consumption of standardized dairy foods and the importance of the nutrient contributions that are made by standardized dairy foods to a healthy diet. Cheaper, nutritionally inferior non-dairy substitutes for standardized dairy foods began to emerge many years ago, prompting the Agency (and the states) to address consumer protection and public health issues in various ways. The Agency has sought to address these issues through various approaches, including by prohibiting confusingly similar names, prescribing imitation labeling, and promulgating new standards like that for margarine.

Additionally, in response to amendments to the FDCA under the Nutrition Labeling and Education Act of 1990 (“NLEA”) designed to authorize nutrient content claims for foods, including standardized foods, FDA adopted sections 130.10 and 101.67 to authorize nutritionally modified versions of standardized foods that are named using the standardized term combined with the FDA-approved nutrient content claim (*e.g.*, “low fat milk,” “fat-free ice cream,” “light butter”), provided a host of requirements are met. Section 101.30 establishes a generic standard of identity for standardized foods that have been modified to qualify for a nutrient content claim. The regulation advances the goals of Section 401 by permitting certain deviations from the formulation requirements of the reference standard for the traditional food to meet the nutritional criteria necessary to qualify for a nutrient content claim (which align with public health nutrition goals), but also by limiting these deviations to the “minimum necessary,” including by requiring authorized dairy ingredients to be used in substantial amounts, such that the modified food can still be fairly described as a standardized dairy food and be identified by using the name of the traditional reference standardized food in its statement of identity (*e.g.*, “low fat milk,” “fat-free ice cream,” *etc.*).

As FDA would later explain:

This one standard (§130.10) has provided enormous flexibility in the manufacture of foods that deviate from the traditional standards and in providing many healthful and informatively labeled food products to consumers. It has also eliminated the need for use of complex alternative names for foods, as well as the need for industry to request establishment of new standards or TMPs [temporary marketing permits] to deviate from existing standards to make new foods to meet consumers’ needs and desires.

## **V. Establishment of Common and Usual Names**

Under FDCA section 403(i)(1), a food product must be identified by “common or usual name ..... if any there be.” FDCA section 403(b) prohibits a food from being “offered for sale under the name of another food,” and section 403(c) prohibits a food that “is an imitation of another food, unless its label bears .....

‘imitation’ and, immediately thereafter, the name of the food imitated.” FDCA section 403(a) further prohibits a food for which labeling is “false or misleading in any particular.”

FDA regulations governing the statement of identity required on food labels implement and expand upon these statutory requirements. Section 101.3(b)(2) provides that, when the name of the food is not assigned by law or regulation, the “common or usual name of the food” must be used when one exists. When an established common or usual name does not exist for a product, section 101.3(b)(3) requires that the statement of identity name the food using “[a]n appropriately descriptive term, or when the nature of the food is obvious, a fanciful name commonly used by the public for such food.” In this regard, section 102.5(a) further specifies:

*The common or usual name of a food, which may be a coined term, shall accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients. The name shall be uniform among all identical or similar products and may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name. Each class or subclass of food shall be given its own common or usual name that states, in clear terms, what it is in a way that distinguishes it from different foods.*

Curiously, there is no provision in section 102.5(a) which allows for the creation of a common or usual name by an extended and continuous violation of existing labeling rules. Congress did not say, “Ignore the rules long enough and you can get away with it permanently,” in the statute. By analogy, telling a police officer who pulls you over for speeding, that “I always speed, been speeding for decades and I never got a ticket before” is not likely to get one out of that infraction. Scofflaws should not be rewarded. That is not how a functional society works.

## **VI. The Proliferation of Misbranded Non-Dairy Substitutes Misappropriating Standardized Dairy Terms**

Non-dairy, plant-based foods formulated and labeled to substitute for and resemble standardized dairy products have been on the market for some time, but they are increasingly labeled and marketed as nutritionally equivalent or even superior substitutes, even though they are almost uniformly nutritionally inferior to their standardized dairy counterparts. In addition to new and more brazen labeling campaigns, these non-dairy substitutes are now derived from a vast and nutritionally diverse array of plant-derived ingredients (e.g., hemp, oat, pea, pecan, rice, quinoa, cashew, hazelnut, pistachio, flax), and include random combinations thereof (e.g., “coconut hemp milk”). Additionally, manufacturers of non-dairy substitutes have also expanded their offerings to target replacement of additional

dairy products subject to standards of identity, such as yogurt and ice cream. These products are intentionally formulated with added colors, flavors, and other additives to resemble dairy products, and are labeled through use of the standardized dairy term reserved for the product they are intended to substitute for and resemble, notwithstanding that they do not contain that food as a primary or even subsidiary ingredient. NMPF respectfully submits that FDA's failure to enforce existing regulations and policies against these non-dairy substitutes has emboldened the industry and contributed to the current disarray of non-dairy substitutes purporting to be something they are not.

**Attachment C** provides examples of products that are named to capitalize on the healthy halo associated with dairy foods through use of standardized dairy terms in the statement of identity, notwithstanding that the non-dairy substitute does not contain the reference dairy food in any amount. These products are unmistakably manufactured, labeled, and marketed to resemble dairy products and thus constitute "substitute" products subject to "imitation" labeling requirements if nutritionally inferior under section 101.3(e) of FDA regulations. Some labeling for these products is more egregious than others – with terms such as "non-dairy" or "vegan" haphazardly and inconsistently thrown about. Whether or not these modifiers are included on the labels, these products are misbranded because they are held out as nutritionally equivalent substitutes, violating FDCA and FDA implementing regulations and degrading public health. Importantly, and contrary to the assertion of some in the non-dairy, substitute foods industry, these misleading names are not accepted or used consistently internationally, or even here in the United States. Indeed, as shown in Attachment C, certain non-dairy substitutes manufactured and sold in the United States by Trader Joe's, Quaker Oats, Pacific Foods, and Kirkland are already labeled to comply with longstanding FDA regulations and precedent and refrain from referencing the standardized food they substitute for and resemble as part of the statement of identity. These products affirm that enforcing and codifying existing FDA precedent will not stifle these products or deter selling and marketing non-dairy substitutes.

In addition to those manufacturers of certain non-dairy substitutes already complying with the relevant law and precedent in the United States, other manufacturers who do not use compliant statements of identity here use different product names such as "soy beverage" or "almond drink" in Canada, the United Kingdom, and the European Union to comply with applicable legal requirements and avoid enforcement. The European Court of Justice recently considered this precise issue and found that "the relevant legislation reserves the term 'milk' only for milk of animal origin [and] ... reserves designations like 'cream,' 'butter,' 'cheese,' and 'yoghurt' solely for milk products, that is products derived from milk." The Court further explained "that the addition of descriptive or clarifying additions indicating the plant origin of the product concerned ... has no influence on that prohibition [and] ... cannot completely exclude the likelihood of confusion on the part of

consumers.” The same legal requirements and public policy rationale applies in the United States.

These products marketed and sold in the United States and elsewhere around the world that comply with existing FDA regulations and policy demonstrate that manufacturers of non-dairy substitutes could easily revise their labels to avoid using standardized food terms in the statement of identity in a misleading fashion. Yet some in the non-dairy substitute industry continue to audaciously attempt to frame the issue as one of embracing versus stifling innovation and consumer choice. This could not be farther from the case. NMPF recognizes that there are consumers who prefer to include non-dairy substitutes in their diet in addition to or in lieu of their standardized dairy counterparts. NMPF does not seek to prevent these products from being marketed and sold; it rather asks that FDA ensure that the products are labeled consistent with longstanding law and prevent labeling that falsely suggests the products are nutritionally equivalent substitutes of the same basic nature and properties as dairy counterparts that have been central to American nutrition for centuries.

## **VII. Clarification: If it Does Not Purport to be a Dairy Product, It Can Use a Dairy Term**

A great deal of confusion seems to exist among plant-based food companies, their trade associations, and advocates regarding non-dairy products that legitimately use dairy terminology. They seem to think that non-dairy non-imitator’s use of dairy terminology somehow establishes and validates PBMA’s assertions that they too can use dairy terminology on their PBMA and other foods, but that is not what the law says.

### **21 U.S. Code § 343 - Misbranded food**

A food shall be deemed to be misbranded—

....

#### **(g) Representation as to definition and standard of identity**

If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 341 of this title, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

#### **Merriam-Webster definition: Purport (verb)**

1: to have the often specious appearance of being, intending, or claiming (something implied or inferred)<sup>3</sup>

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<sup>3</sup> <https://www.merriam-webster.com/dictionary/purport>

Admittedly an awkward definition at best. But when one looks at the context as used in the statute it should be very clear as Congress states: “If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed.” PBMA do purport and represent themselves to be real milk, PBMA do represent themselves as being like real milk. They are concocted to look like milk (a white liquid), their viscosity is similar, the packaging is similar, the store placement is in the dairy section, and yes, most PBMA companies probably paid fees to retailers, called “slotting allowances,” to be placed in the refrigerated section next to milk. Further, the use of PBMA’s are clearly established to be exactly the same as real milk, leaving no doubt whatsoever that they do present themselves, speciously as real milk.

In stark contrast, peanut butter, milk of magnesia, cocoa butter, canned coconut milk and many other products using dairy terminology clearly do not purport to be a dairy product. Their packaging, placement in stores, and intended uses are not similar to real dairy products and consumers are not being misled into thinking so. The dairy industry has never taken issue with these products using dairy terminology, because such products are doing so in compliance with Congressional law and FDA regulations. This is quite different than PBMA’s practices as indicated by then WhiteWave CEO Steven Demos when he said over two decades ago in 2001:

“We also had to figure out how to get this product category to market. Dairy milk is a staple food that we consider a fundamental part of the scenery in a supermarket. Why not position fresh soymilk to be as close as possible?”

While successful in bringing this product category to market he also ignored a major federal statute and FDA regulations, arguably setting the tone for the entire PBMA industry while the FDA sat back and did nothing. The dairy industry has consistently asked for decades that the PBMA companies be required to follow the same rules as everyone else but no enforcement has been taken. The result of which has been consumer confusion over the nutritional quality of PBMA leading to malnourishment.

## **VIII. NMPF Citizen Petition**

### **A. Enforcement of Existing and Modified Rules Falls Well Within the Confines of Acceptable First Amendment Limitations**

The enforcement of existing “imitation” labeling requirements established under FDCA section 403(c) against nutritionally inferior non-dairy substitutes for standardized dairy foods that are named and positioned as forms of “milk,” “yogurt,” “cheese,” “ice cream,” or “butter,” yet fail to provide the “imitation” disclosure statement that is required by the Act and section 101.3(e) of FDA regulations is consistent with the First Amendment.



While the Supreme Court has struck down bans of constitutionally protected commercial speech and other restrictions over the years that fundamentally undermine free speech rights, the Court has distinguished more limited regulatory schemes that require the disclosure of factual and uncontroversial information concerning a product or service because such disclosure requirements “trench much more narrowly on an advertiser’s interests than do flat prohibitions on speech.” Importantly, the disclosure requirements addressed in our petition would apply only to those manufacturers of non-dairy foods that have chosen to take a number of affirmative steps to manufacture and label a non-dairy food in such a manner that it substitutes for and resembles a referenced standardized dairy food (*e.g.*, milk) and identifies the non-dairy substitute through the use of a standardized dairy term reserved for the reference standardized dairy food substituted for and resembled. Moreover, for the reasons discussed above, when the “imitation” labeling would be required, it would function to explicitly distinguish the non-dairy substitute from the reference standardized dairy food in a manner that is factually accurate and uncontroversial.

In addition, under both current section 101.3(e) and related FDA policies, and section 101.3(e) as amended by our petition, “Imitation” and “Substitute”/“Alternative” labeling disclosures can be readily avoided. Specifically, under current regulations, the “Imitation” disclosure is not required for non-dairy substitutes that are nutritionally equivalent to the reference standardized dairy food when they are identified using a distinctive name that complies with sections 101.3 and 102.5 and makes no use of a standardized dairy term (*e.g.*, “milk”) in the statement of identity of the non-dairy substitute (*e.g.*, “Rice Beverage”). Similarly, under related FDA policies, the use of the “Substitute”/“Alternative” labeling disclosure can be readily avoided for a nutritionally equivalent non-dairy substitute that complies with sections 101.3 and 102.5 and makes no use of a standardized dairy term (*e.g.*, “milk”) in the statement of identity of the non-dairy substitute (*e.g.*, “Soy Beverage”). It is only when a manufacturer formulates and labels its non-dairy substitute food in a manner that causes the non-dairy food not only to substitute for and resemble a reference standardized dairy food (*e.g.*, milk), but also to be identified in a manner that appropriates the name of the reference standardized food (*e.g.*, “Hempmilk”), that the “imitation” disclosure is required for nutritionally inferior substitutes, and the “substitute” or “alternative” disclosure is required for substitutes that are not nutritionally inferior. Examples of permissible approaches under current law include:

- “Hempmilk – Imitation Milk”; and
- “Hemp Beverage” (no imitation, substitute, or alternative labeling disclosure required, regardless of nutritional inferiority compared to a dairy alternative).

Under essentially the same conditions, “imitation” and “substitute”/“alternative” disclosures would also be avoided under new proposed section 101.3(e)(6), which places existing requirements under section 101.3(e) into the specific context of non-dairy substitutes for standardized dairy foods, and explicitly specifies requirements that already apply under FDCA sections 403(a) and 201(n) to prevent consumer deception and applies them in such a way that would permit “substitute”/“alternative” labeling for nutritionally inferior products in lieu of current shorthand “imitation” labeling under certain circumstances.

Specifically, new proposed section in the NMPF petition, section 101.3(e)(6)(iii)-(vi) would specify that the “imitation” disclosure requirement would not apply to either nutritionally inferior or nutritionally equivalent non-dairy substitutes for standardized dairy foods that do not represent in the labeling of the non-dairy substitute that they are a form of “milk,” “yogurt,” “cheese,” “ice cream,” or another standardized dairy food, including through the use of a standardized dairy term in the statement of identity (*e.g.*, “Oat Beverage” rather than “Oat Milk”). In addition, for nutritionally inferior non-dairy substitutes, no representation could be made in labeling that suggests that the nutritionally inferior non-dairy substitute is nutritionally equivalent or superior to the reference standardized dairy food.

For both nutritionally inferior and nutritionally equivalent non-dairy substitutes, the product labeling would be required to disclose material differences in the performance characteristics of the non-dairy substitute as compared to the reference standardized dairy food (*e.g.*, not suitable for frying) – a disclosure requirement that already is specified under FDCA sections 403(a) and 201(n). For nutritionally inferior non-dairy substitutes for standardized dairy foods that are not labeled with the “imitation” disclosure statement, the “nutritional inferiority” of the substitute would be required to be disclosed on product labels and in labeling in a prominent and conspicuous manner, in accordance with the requirements of FDCA sections 403(a) and 201(n), which prohibit false and misleading labeling and require the disclosure of material facts.

In addition to the use of reference standardized foods when appropriately qualified through “imitation,” “substitute,” or “alternative” disclosures, under new proposed section 101.3(e)(6)(v), use of a standardized dairy term (*e.g.*, “milk”) would be authorized for non-dairy substitutes that satisfy the requirements necessary to avoid the imitation labeling disclosure in the context of an *optional* “substitute”/“alternative” disclosure statement. Examples:

- “Rice Beverage” or “Rice Beverage – Milk Substitute”; and
- “Coconut-Hemp Drink” or “Coconut-Hemp Drink – Milk Alternative.”

The enforcement and regulatory actions requested by our Petition are carefully tailored to advance FDA’s indisputably substantial and longstanding interests in preventing consumer deception, protecting consumer health, and in the aggregate,

thereby also protecting public health. The enforcement initiative requested by the Petition does not ask the agency to enforce a ban on constitutionally protected truthful and non-misleading speech. The Petition instead asks FDA to undertake enforcement actions against misbranded products that by their very nature violate no less than three core misbranding provisions of the Act – FDCA sections 201(n), 403(a) and 403(c) – and are labeled in a false and misleading manner. False and misleading commercial speech is not entitled to First Amendment protection, and where the misleading nature of the targeted non-dairy substitute food can be remedied through factual disclosures that are already mandatory under the Act (*e.g.*, “Imitation [Milk],” “not suitable for frying”), such disclosure requirements easily satisfy the requirements of *Central Hudson*, *Zauderer*, and progeny.

The enforcement and regulatory actions requested by our Petition are readily justified on First Amendment grounds and are easily distinguishable from the commercial speech bans that have been invalidated by the Supreme Court, including those considered in *Central Hudson*, *Bolger*, *R.M.J.*, *Bates* and *Western States*. Instead, they resemble the many instances in which courts have upheld disclosure requirements that seek to provide consumers with useful factual and uncontroversial information related to a product or service. And to the extent that the actions requested in our Petition are asserted to have the potential to be conceptualized as effectuating a speech ban with respect to the use of standardized dairy terms to name non-dairy substitutes, this would be at odds with the facts and applicable case law. The actions requested are more accurately cast as disclosure requirements – permitting the use of standardized dairy terms under conditions in which they are qualified by descriptors (*e.g.*, “imitation,” “substitute”/“alternative”) that are factual and uncontroversial – conditions that have been found to easily pass First Amendment muster. The Supreme Court’s rationale in *Zauderer* applies equally here: the actions requested do not “attempt to prevent ... conveying information to the public; [they] only require[] them to provide somewhat more information than they might otherwise be inclined to present.”

## **B. Summary of the Petition’s Request to Modification to Existing Rules**

In addition to enforcement, our petition asked FDA to adopt amendments to section 21 CFR 101.3(e) to codify in more detailed form longstanding FDA policies that permit the name of a standardized dairy food (*e.g.*, “milk,” “yogurt,” “cheese,” “ice cream,” “butter”) to be used in the statement of identity of a non-dairy substitute for the reference standardized food only under limited and defined conditions. The Petition is much broader than this PBMA issue and extends to all plant-based foods that use dairy terminology. That is appropriate as the plant-based imitators are increasingly usurping dairy terminology for a variety of products and FDA is in the promulgation process of a guidance document to address that issue that goes beyond PBMA. See Attachment A for those modifications.

The requested amendments would codify requirements that already exist under FDCA sections 403(a), 403(c) and 201(n) and related FDA regulations (*e.g.*, section 101.3) and policies in the specific context of non-dairy substitutes for standardized dairy foods in new section 101.3(e)(6), entitled “Non- Dairy Foods that Substitute for and Resemble Standardized Dairy Foods.”

This provision would apply to non-dairy foods that substitute for and resemble standardized dairy foods including milk, yogurt, cheese, ice cream and butter products, and would codify distinct requirements for nutritionally inferior and nutritionally equivalent non-dairy substitutes for standardized dairy foods. In both cases, new section 101.3(e)(6) would prohibit claims that are already prohibited by FDCA sections 403(a) and 201(n), and to specify disclosures that are already required under FDCA sections 403(c) and/or sections 403(a) and 201(n).

More specifically, new section 101.3(e)(6)(iii) would apply to non-dairy substitute foods that are nutritionally inferior to the reference standardized dairy food they substitute for and resemble. The provision is designed to align generally with the imitation labeling requirements for nutritionally inferior substitute foods that currently apply under section 101.3(e)(1), with one key difference. Under the new provision, imitation labeling under FDCA section 403(c) would not be required for a nutritionally inferior non-dairy substitute food that adheres to certain labeling practices designed to prevent consumer deception, including prominent and conspicuous disclosure of the nutritional inferiority of the nutritionally inferior non-dairy substitute food as compared to the reference standardized dairy food. Ultimately, under the new provision, nutritionally inferior non-dairy substitute foods could either be identified with the legally defined term, “imitation” (*e.g.*, “imitation milk”), to disclose the nutritional inferiority of the non-dairy substitute as compared to the reference standardized dairy food, or alternatively, the substitute food could be labeled to disclose the material facts that are represented by the “imitation” disclosure – that is, the facts that the non-dairy substitute is nutritionally inferior and materially different from the standardized food (*i.e.*, is likely to have material performance limitations) that must be disclosed to consumers (*e.g.*, “not suitable for frying”) – in accordance with existing FDA policies.

In addition, to avoid “imitation” labeling requirements under FDCA section 403(c), the nutritionally inferior non-dairy substitute food would be required to be labeled in a manner that makes no express or implied representation that suggests that the non-dairy food is a form of milk, cheese, ice cream, butter or any other dairy food that is governed by a standard of identity, except as expressly permitted. In this regard, representations made in the name of a nutritionally inferior non-dairy substitute food would be considered, specifically including the use of a standardized dairy term (*e.g.*, “milk”) in the statement of identity for the substitute food. Under new section 101.3(e)(6)(v), a nutritionally inferior substitute food would be permitted to use a standardized dairy term in its statement of identity provided the material fact that the food is a substitute or alternative to the reference

standardized dairy food, and not the standardized dairy food itself, is disclosed (*e.g.*, “Milk Substitute;” “Milk Alternative”). In addition, to avoid imitation labeling requirements, the labeling for the nutritionally inferior non-dairy substitute food would not be permitted to make any express or implied representation (falsely) suggesting that the substitute food is nutritionally equivalent or superior to the reference standardized dairy food, or (falsely) suggesting that consuming the nutritionally inferior substitute in lieu of the reference standardized dairy food would either have positive or insignificant nutritional consequences for consumers.

Similarly, new section 101.3(e)(6)(iv) would apply to non-dairy substitute foods that are not nutritionally inferior to the reference standardized dairy food they substitute for and resemble. The provision aligns generally with the requirements that already apply to nutritionally equivalent substitute foods under section 101.3(e)(2) and related provisions, for which compliance is essential to qualify for the exemption from “imitation” status and related labeling requirements.

Under new section 101.3(e)(6)(iv), to avoid triggering imitation requirements under FDCA section 403(c), non-dairy substitute foods that are not nutritionally inferior would not only be required to comply with existing section 101.3(e)(2), but would also be required to be labeled and advertised in a manner that makes no express or implied representation (falsely) suggesting that the non-dairy food is a form of milk, cheese, ice cream, butter or any other standardized dairy food. In this regard, representations made in the name of the non-dairy substitute food would be considered, including the use of a standardized dairy term (*e.g.*, “milk”) in the statement of identity of the non-dairy substitute food. Under new section 101.3(e)(6)(v), non-dairy substitutes for standardized dairy foods would be permitted to use a standardized dairy term to identify the food as a substitute or alternative to the reference standardized dairy food (*e.g.*, “Milk Substitute;” “Milk Alternative”). In addition, any material performance limitations of the non-dairy substitute as compared to the reference standardized dairy food would be required to be disclosed prominently and conspicuously on labels and in labeling, consistent with existing FDA requirements. These requirements are consistent with the requirements of the Act, and FDA policies and precedents, including those reflected in sections 130.10 and 101.67.

In sum, our Petition asked FDA to adopt new section 101.3(e)(6) to codify existing requirements that prohibit false and misleading representations that already apply to non-dairy substitutes under the Act, and to make explicit the disclosure requirements that already apply to these substitute foods – specifically the disclosure of material facts to prevent consumer deception and requiring non-dairy substitutes to be identified in a manner that adequately distinguishes them from standardized dairy foods (*i.e.*, “Imitation [SOI Dairy Food],” [“Substitute [SOI Dairy Food],” “Alternative [SOI Dairy Food]”). The requested changes are carefully tailored to ensure that these disclosure requirements apply in limited contexts where the manufacturer of a non-dairy substitute food has affirmatively chosen to

manufacture and label a food that substitutes for and resembles a reference standardized dairy food and has chosen to employ the standardized dairy term in the name of the non-dairy substitute. Under our Petition, “Imitation” and “Alternative” or “Substitute” disclosure statements would not be required for non-dairy foods that do not substitute for and resemble standardized dairy foods, *or* that are identified using distinctive names that do not reference or incorporate standardized dairy terms and otherwise comply with sections 101.3 and 102.5 of FDA regulations. For example, a non-dairy beverage made from soy and other non-dairy ingredients and identified as a “Natural Soy Beverage” would not be required to comply with the disclosure requirements under either current section 101.3(e) or section 101.3(e) as amended as requested in the petition, even if the food otherwise resembles and substitutes for a standardized dairy food.

Notably, under new section 101.3(e)(6), the conditions under which “imitation” labeling would be legally required for non-dairy substitutes for standardized dairy foods would continue to be highly limited and would potentially be more limited than under existing regulations. As under current FDA regulations and policies, there would be no unavoidable requirement for the use of the terms “imitation,” “alternative,” or “substitute” to identify a non-dairy substitute for a standardized dairy food in view of the substantial freedom FDA policies give manufacturers in naming new foods under sections 101.3 and 102.5 of existing FDA regulations. In this regard, NMPF has observed that some non-dairy substitutes on the market already are labeled in a manner that avoids any reference to the standardized dairy food that they substitute for and resemble (*e.g.*, “Rice Beverage”) in accordance with FDA labeling policies under sections 101.3 and 102.5, and thus are not subject to “imitation,” “substitute,” and “alternative” disclosure requirements under existing law, or under the amendments proposed by NMPF.

The “imitation” labeling requirements the petition asks FDA to enforce would target misbranded products that fail to bear the mandatory “imitation” disclosure statement and that are labeled in a false and misleading manner. In the absence of compliance with the mandatory imitation labeling requirements, such non-dairy substitute foods are being identified in a manner that implies a false equivalence between the non-dairy substitute and its reference standardized dairy food, and potentially also, a broader false equivalence across all non-dairy products that substitute for and resemble a reference standardized dairy food (*e.g.*, milk) and are identified using a standardized dairy term that refers to that reference standardized dairy food (*e.g.*, across all non-dairy “milk” products). In short, NMPF asks FDA to undertake enforcement actions against non-dairy substitutes that are labeled in a false and misleading manner as a result of their lack of compliance with FDCA sections 201(n), 403(a), and 403(c). There is no question that such enforcement actions targeting false and misleading labeling are permitted on both statutory and First Amendment grounds.

The NMPF Petition also asks FDA to adopt amendments to section 101.3(e), including new section 101.3(e)(6), which would provide that nutritionally inferior non-dairy substitute foods would not be subject to “imitation” labeling requirements, provided that the non-dairy substitute food is named in a manner that does not represent it as being a form of a standardized dairy food (*e.g.*, by using a standardized dairy term in the name of the non-dairy substitute food without also disclosing that the product is a “substitute” or “alternative” to the standardized food), and the material differences between the non-dairy substitute and the reference standardized dairy food are disclosed in product labeling (*e.g.*, nutritional inferiority, performance limitations). In addition, the proposed amendments would make clear that non-dairy substitutes that are not nutritionally inferior would not be subject to “imitation” labeling requirements when they comply with existing regulations that require the food to be named in compliance with sections 101.3 and 102.5 of FDA regulations, and in addition, disclose any material limitations of the non-dairy substitute. Additionally, new section 101.3(e) would expressly permit non-dairy substitutes to use a reference standardized dairy term as part of the statement of identity provided the material fact that the food is a substitute or alternative to the reference standardized dairy food, and not the standardized dairy food itself, is disclosed (*e.g.*, “Milk Substitute;” “Milk Alternative”).

There is no question that such factual and uncontroversial disclosure requirements designed to prevent consumer deception and protect consumer health and public health can be adopted and enforced in view of the First Amendment standards that govern the regulation of commercial speech such as food labeling. Section A of the petition provides an overview of relevant case law from the Supreme Court’s recognition of First Amendment protection in *Central Hudson* to the D.C. Circuit’s recent important en banc decision in *American Meat Institute*. Section B of the petition explains how the effects on commercial speech contemplated by the Actions Requested fall well within established First Amendment confines.

## **Conclusion**

For the reasons discussed thus far, and for the benefit of consumers who have a right to factual information about the food products that they are interested in buying, we commend FDA for recognizing that consumers are being misled and that they need to better understand the nutritional inferiority of PBMA. Unfortunately, NMPF cannot condone FDA violating the Administrative Procedures Act, and arguably the U.S. Constitution, to convey that information to consumers rather than going through the proper legal process. In the end, FDA needs to enforce the existing standards of identity and should modify them in the manner suggested in NMPF’s Citizen Petition.

FDA’s proposed approach, though flawed for legal reasons, and NMPF’s approach in the petition are not that far apart. At the root of both is a concern for consumers and an appreciation for a marketplace that encourages transparency. However, given

FDA's acceptance and understanding of the reality of consumer confusion over actual nutritional content combined with the agency's need to respect and enforce its own standards of identity, the logical resolution of this issue is embodied in our Citizen Petition rather than this draft guidance. We strongly urge FDA's thorough examination of the petition and thoughtful reconsideration instead of making revisions to the proposed guidance.

Should FDA not choose to adopt NMPF's petition, the agency should clearly find a way, in compliance with the Administrative Procedure Act and Constitution, to make nutritional inferiority disclosures mandatory and have them prominently placed front-of-pack while expressly recognizing that anything otherwise would merely perpetuate consumer confusion. For decades, NMPF has been frustrated with FDA's unwillingness to enforce its own standards of identity for milk and milk products which continues today. We are encouraged by the agency's acceptance of the reality of consumer confusion regarding nutritional content.

In the absence of a full resolution of this issue that is focused on standards of identity – which NMPF will continue to work for via the DAIRY PRIDE Act and other vehicles – NMPF urges that any legally sound guidance, if such a thing is even possible, be focused on addressing consumer confusion and be forcefully implemented by the agency and taken seriously by the plant-based beverage community, so that we may at least improve consumers' understanding in the marketplace.

Sincerely,

A handwritten signature in black ink, appearing to read "Clay Detlefsen". The signature is fluid and cursive, with a prominent initial "C" and a long, sweeping underline.

Clay Detlefsen, Esq.  
Senior Vice President, Environmental and Regulatory Affairs & Staff Counsel