National Milk Producers Federation

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Dear Dr. Lenkel,

This letter is submitted on behalf of the National Milk Producers Federation (NMPF), which is based in Arlington, Virginia, and was founded in 1916 to provide a forum for U.S. dairy farmers and the dairy cooperatives they own to participate in public policy discussions. For more than 100 years, NMPF has been engaged in public policy matters[1] to advance the well-being of the U.S. dairy farmers, the dairy cooperatives they own, and the consuming public. The members of NMPF's farmer-owned dairy cooperatives produce roughly two-thirds of all U.S. milk, making NMPF the voice of dairy producers on Capitol Hill and with governmental agencies, including the Food and Drug Administration (FDA).

In NMPF's Citizen Petition filed with FDA on Feb. 21, 2019, NMPF asked FDA to take enforcement and regulatory actions to stop the continued proliferation and marketing of unlawfully labeled nutritionally inferior non-dairy substitutes for standardized dairy foods that are misrepresented to be "milks" or forms of other standardized dairy foods.

The NMPF Citizen Petition asks FDA to enforce FDCA requirements for labeling nutritionally inferior substitutes for standardized dairy foods, including the "imitation" disclosure requirement mandated under FDCA section 403(c). The petition also asks FDA to promote labeling compliance in the category of non-dairy substitutes for standardized dairy foods by codifying established requirements in more specific detail through modest amendments to section 101.3(e) of existing FDA food labeling regulations. But, as with numerous previous attempts to get FDA to act, FDA has done nothing.

We therefore request your immediate assistance in breaking through the persistent FDA logjam that keeps the agency from taking enforcement and regulatory actions that are necessary to stop the continued proliferation and marketing of unlawfully labeled nutritionally inferior non-dairy ("plant-based") dairy food substitutes. *These imitation dairy foods fail to bear the "imitation" disclosure statement required by FDCA section*

[1] NMPF address policies concerning milk pricing, domestic and international market development, agriculture credit and taxation, environmental issues, food safety and health, animal welfare, product standards and labeling, and research and biotechnology.

403(c) and are identified with product names (e.g., "Almond Milk," "Rice Milk," "Oat Milk," "Hemp Milk," "Almondmilk Yogurt," etc.) that do not comply with the "common or usual name" requirements applicable to these nutritionally inferior dairy food substitutes under FDCA section 403(i) and related provisions (FDCA sections 403(a) and 201(n)). For reasons explained in the extensive Statement of Grounds in the NMPF Citizen Petition summarized in the discussion below, the requested FDA actions are authorized under the applicable FDCA provisions and well-supported by the First Amendment standards addressing the government's authority to regulate the content of commercial speech, including disclosure requirements affecting food labeling. The requested FDA actions also are necessary to uphold the agency's mandate to protect consumer health and the public health more generally. The unlawfully labeled foods at issue are duplicitously designed, formulated, packaged, labeled, and marketed in a manner aimed at encouraging consumers to substitute nutritionally inferior plant-based imitation dairy foods (e.g., "milks") for standardized dairy foods, encouraging dietary practices at odds with the Dietary Guidelines for Americans and potentially damaging the nutritional health of consumers and public health more generally.

As producers responsible for the bulk of all U.S. milk, NMPF members make vital contributions to the integrity, authenticity and nutritional quality of the U.S. milk supply and the many consumer food products that contain milk or dairy ingredients. NMPF members also have substantial interests in FDA regulatory and enforcement policies relating to the ingredients and composition of foods represented as forms of "milk" or containing ingredients represented to be forms of "milk" or foods or ingredients that are made from "milk." In this regard, NMPF has substantial interests in FDA regulatory and enforcement policies governing the composition and labeling of "milk," "yogurt," "cheese," "ice cream," "butter" and other dairy foods subject to FDA standards of identity. NMPF also has substantial interests in FDA regulatory and enforcement policies governing the labeling of nonstandardized foods that are designed to resemble and function as substitutes for a corresponding referenced standardized dairy food ("milk," "yogurt," "cheese," "ice cream," "butter," etc.) to ensure that both dairy-based substitutes and non-dairy "plant-based" substitutes are held responsible for compliance with FDCA requirements that apply to these substitutes regardless of dairy-based or non-dairy ingredients.

NMPF has urged FDA repeatedly to enforce both its standards of identity for dairy foods and the labeling requirements that apply to nonstandardized foods designed to resemble and function as substitutes for such standardized foods. While the agency has continued to hold standardized dairy foods, nonstandardized dairy foods and nonstandardized dairy-containing substitute foods accountable for compliance with FDCA requirements, in recent years FDA has failed to hold nonstandardized non-dairy plant-based substitute foods accountable for food labeling compliance. NMPF has conveyed to FDA its particular concern that FDA's departure from its historical enforcement policies not only flouts FDCA requirements but has obvious adverse implications for the nutritional health of consumers and public health while falling short

of the requirements of the Administrative Procedure Act (APA). FDA's departure has contributed to the proliferation of unlawfully labeled, nutritionally inferior non-dairy substitutes that not only fail to comply with the applicable "imitation" dairy food disclosure requirement, but are misrepresented as "milk," "yogurt," "cheese," "ice cream," and "butter" by misappropriating common or usual names for dairy foods to name imitation dairy foods.

FDA's unjustified departure in recent years from well-established law and the longstanding agency policy to require non-dairy and dairy-based substitutes to comply with these FDCA requirements is contributing to the rising tide of unlawfully labeled nutritionally inferior non-dairy substitutes that are flooding the U.S. marketplace and consuming retail shelf space inside refrigerated cases alongside the standardized milk, yogurt, cheese, ice cream, and butter. These non-dairy foods are positioned as "plant-based" dairy foods to be used as substitutes for standardized milk, yogurt, cheese, ice cream, and butter; but as the extensive evidence NMPF has provided to the agency shows, virtually all of these non-dairy foods are nutritionally inferior to the reference standardized dairy food they are positioned to replace. As such, these non-dairy foods are prohibited from using the "common or usual name" of the reference standardized dairy food (e.g., "milk") in the name of the food (e.g., "Almond Milk"), except as part of the imitation disclosure requirement that is mandatory under FDCA section 403(c) and related FDA regulations discussed further below (e.g., "IMITATION MILK"). By continuing to allow these unlawfully labeled non-dairy substitutes to be labeled and positioned in ways that encourage consumers to make food choices that have foreseeable potential detrimental effects on the nutritional adequacy of a consumer's diet and nutritional health, FDA is unconscionably fueling the proliferation of unlawfully labeled nutritionally inferior non-dairy substitutes in ways that ultimately fail to support the public health, the integrity and nutritional quality of the foods that comprise the U.S. food supply. This action or, more appropriately, *inaction,* clearly fails to uphold FDA's public-health mission.

These non-dairy foods are being labeled in ways that disregard the "imitation" dairy food disclosure requirement and the well-established policy evidenced by section 101.67 which restricts the use of the common or usual name of a standardized dairy food (e.g., "butter") to name a nonstandardized substitute that is nutritionally equivalent – not inferior to – the reference standardized food, and that complies with the ingredient specifications of the standard of identity, with only small deviations, such that the use of the standardized name (e.g., "butter") as a part of the name for the nonstandardized substitute (e.g., "Reduced Fat Butter") accurately characterizes the nature of the food. As discussed further below, the failure of these nutritionally inferior non-dairy substitutes to comply with these requirements renders them misbranded, economically adulterated and thus prohibited under FDCA section 301.

In addition to these flagrant violations, these imitation dairy foods employ statements of identity that fall short of the most basic requirements for naming nonstandardized foods.

Despite the highly diverse plant varieties and plant derivatives used to make these products by means of any number of processing methods by different manufacturers, these foods are positioned as "plant-based" foods that are entitled to go on violating FDCA requirements because they have gotten away with it thus far. But as FDA well knows, the Plant Kingdom has been a well-known source of human sustenance for some time now; as a result, longstanding FDA regulations and enforcement precedents readily exposes the extent to which product names like "Almond Milk," "Rice Milk," "Oat Milk," "Hemp Milk" fail to comply with "common or usual name" requirements under FDCA sections 403(i) and 403(a)/201(n). To illustrate in comparison, FDA regulations in section 102.33 governing the common or usual names required for the plant-based food category known as "juice," make clear that to satisfy FDCA common or usual name requirements one must provide more information than simply naming a type of plant (e.g., "cashew") and adding the word "juice." Notably, the juice products must be named in compliance with section 102.33, *in addition to* complying with nutrition labeling, ingredient labeling and percentage juice declaration requirements. The status of these products as plant-based foods does nothing to amend FDCA requirements that apply to naming these foods.

The following pages will describe, in detail, nine important provisions in the FDCA which are necessary to comprehend before FDA can appropriately address how to properly label currently unlawfully labeled plant-based imitation dairy foods. Specifically:

I. That standards of identity for dairy foods are codified under established "common or usual name" for the respective dairy food

II. The requirements for naming standardized dairy foods and nonstandardized substitutes

III. The dairy standards of identity and FDCA requirements for naming substitutes

IV. That nonstandardized substitutes for standardized foods must be identified by common or usual name

V. The common or usual name of the reference standardized dairy food is prohibited for use in naming nutritionally inferior substitutes except when using "imitation"

VI. Unlawful product names for nonstandardized foods do not become lawful "common or usual names" simply through a history of use

VII. The persistent and proliferating use of unlawful product names for plant-based imitation dairy foods is encouraging consumers to adopt dietary practices that have foreseeable adverse consequences

VIII. First Amendment compelled commercial speech standards support FDA actions to require plant-based imitation dairy foods to comply with FDCA requirements

IX. FDA's failure to take action to enforce longstanding, well-documented requirements for naming nutritionally inferior substitute foods under the FDCA endangers public health and violates the Administrative Procedure Act in multiple ways

When these nine provisions are adequately considered together, it is clear that the current unlawful plant-based labeling practices must end, and long-time existing rules must be enforced. Doing so is the only fair, just, warranted and lawful solution to this decades-old problem.

I. Standards of Identity for Dairy Foods are Codified Under the Established "Common or Usual Name" for the Respective Dairy Food

Standards of identity frequently are mischaracterized as food labeling regulations designed to regulate the use of particular standardized terms. To the contrary, a standard of identity is designed to define a food that already is well-established in the marketplace and to set standards for ingredients and the composition of the finished product that align with the characteristics consumers have come to expect from the defined food. FDCA section 401 (entitled "Definitions and Standards for Food") provides that, "[w]henever in the judgment of [FDA] such action will promote honesty and fair dealing in the interest of consumers, he shall 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 . . .." (Emphasis added).

Foods that are subject to standards of identity must be identified by "common or usual name" in accordance with FDCA section 403(i) just as nonstandardized foods are required to be. The difference is this: Under FDCA section 401, when FDA proceeds to issue a standard of identity for a given food, it must do so "under its common or usual name so far as practicable . . .." The labeling provisions in FDA standards of identity regulations simply codify FDA's application of FDCA section 403(i) and related misbranding provisions (e.g., 403(a)/201(n)) in the context of a specific standardized food.

II. FDCA Requirements for Naming Standardized Dairy Foods and Nonstandardized Substitutes, Including Non-Dairy Substitutes

The FDCA regulatory framework for naming food products is well-established under a number of misbranding provisions adopted as part of the 1938 FDCA that, together with the interrelated adulteration provision in FDCA section 402(b) and the standards of identity provision in FDCA section 401, are designed to work together to prohibit the marketing of economically adulterated foods and labeling practices of the kind that have fueled the proliferation and passing off of such foods through misrepresentations concerning the identity of the food and the concealment of material information, including with respect to the nutritional inferiority of "imitation" foods.

Under FDCA section 402(b), a food is deemed to be adulterated

> "(1) if any valuable constituent has been in whole or part omitted or abstracted therefrom; or
> (2) if any substance has been substituted wholly or in part therefor; or
> (3) if damage or inferiority has been concealed in any manner; or
> (4) if any substance has been added thereto or mixed or packed therewith so as to increase it bulk or weight, or reduced its quality or strength, or make it appear better or of greater value than it is."

The misbranding provisions concerning the naming of foods complement the ban on economically adulterated foods through labeling requirements that require foods to be identified by "common or usual name" under FDCA section 403(i) in a manner that accurately describes the food and discloses differences from other foods. In addition, under FDCA section 403(c) nutritionally inferior imitations of standardized dairy foods (e.g., "milk") must bear the imitation disclosure statement (e.g., "IMITATION MILK"). FDCA section 403(g) also prohibits a food that "purports to be or is represented as a food for which a definition and standard of identity has been prescribed by [FDA] regulations as provided under [FDCA] section 401," unless the labeled food complies with the standard. FDCA section 403(b) additionally prohibits a food from being "offered for sale under the name of another food," and section 403(a) prohibits foods from being identified in labeling in a manner that is "false or misleading in any particular way." FDA section 201(n) further provides that the determination of whether a food is misbranded because its labeling is misleading and requires FDA to take into account "not only the representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling . . . fails to reveal facts material in the light of such representations or material with respect to the consequences which may result from the use of the article to which the labeling . . . related under the conditions of use prescribed in the labeling . . . thereof or under such conditions of use as are customary or usual."

III. Dairy Standards of Identity and FDCA Requirements for Naming Substitutes for Standardized Dairy Foods Are Designed to Combat Economic Adulteration and Product Naming Practices that Fail to Distinguish Inferior Imitation Foods

FDCA section 401 was adopted as part of the 1938 FDCA, and like the adulteration provision in FDCA section 402(b) and the complementary misbranding provisions in FDCA section 403 discussed above, it is responsive to weaknesses in the 1906 Pure Food and Drug Act that had impeded FDA's ability to take action against economically adulterated foods. The 1906 Act had been intended to address the growing problem of economic adulteration of manufactured foods and the substitution of these inferior foods in the diet as industrialization made consumers less able to rely on homemade foods and more dependent on manufactured foods. Unfortunately, loopholes in the 1906 Act made matters worse, contributing to the proliferation of cheap, debased manufactured foods while failing to provide FDA with the regulatory and enforcement tools needed to combat the problem, including the absence of standards of identity for basic foods such as milk and butter that would allow these foods to be distinguished from economically adulterated inferior substitutes.

The proliferation of economically adulterated manufactured foods under the 1906 Act helped to inspire the standard of identity for "butter," which was established by statute in 1923 (21 U.S.C. 321a) and defines "butter" to mean "the food product usually known as butter, and which is made exclusively from milk or cream, or both, with or without common salt, and with or without additional coloring matter, and containing not less than 80 per centum by weight of milk fat, all tolerances having been allowed for." The butter standard helped to inspire the adoption of section 401 in the 1938 FDCA, which replaced the 1906 Act.

FDA regulations establishing standards of identity for dairy foods under FDCA section 401 establish specifications for ingredients and minimum levels of food components in the finished food that are measurable, enabling FDA to determine whether a food that resembles "milk" and is labeled as "milk" qualifies as "milk," or instead is an economically adulterated and misbranded knock-off.

The nature and extent to which a substitute food deviates from the ingredient and finished product specifications established in a dairy standard of identity also has implications for the nutritional quality of the food and whether the substitute is nutritionally inferior to the standardized food. By establishing ingredient and finished product specifications that ultimately require the nutritive components of milk to meet or exceed minimum thresholds, (e.g., milk fat, milk solids not fat) (as opposed to water and additives that contribute few, if any, essential nutrients), these specifications help to ensure that the composition and nutritional quality of dairy foods comply with a given

standard of identity. In addition, when substitute foods are formulated to resemble the standardized food with respect to significant organoleptic or functional performance properties but are formulated in ways that depart significantly from the dairy ingredient and finished product specifications in the absence of compensating fortification, the substitute food is likely to be nutritionally inferior to the standardized food. In other words, while the specifications provided in the dairy standards of identity on their face are not identified as nutritional specifications, they function as nutritional specifications. In addition, the consistency in the baseline composition of each type of standardized dairy food has enabled standardized dairy foods, including milk, to be fortified with Vitamin D, thus contributing to the significant nutritional health gains for consumers and public health more generally that have been made through the dramatically reduced risk of rickets and the promotion of healthy bones and teeth that is associated with adequate consumption of Vitamin D and calcium (for which standardized milk is naturally an excellent source).

Standards of identity for "milk" and other standardized dairy foods equip FDA for effective enforcement and regulatory action against "race-to-the-bottom" innovations that result in nutritionally inferior imitations of the kind now raging in the marketplace. They also help foster nutritionally enhanced substitutes for standardized foods (e.g., sugar-reduced, protein enriched, omega-fatty acid fortified low fat milk; high calcium yogurt; low saturated fat ice cream; reduced fat butter, etc.), including non-dairy substitutes (e.g., soy beverages fortified to avoid nutritional inferiority with reference standardized dairy foods).

For FDA to effectively stem the proliferation of unlawfully labeled nutritionally inferior substitutes for standardized dairy foods, the agency must return to its longstanding policy to require all substitutes for standardized dairy foods to comply with FDCA requirements and hold non-dairy substitutes fully accountable for compliance with FDCA requirements.

IV. Nonstandardized Substitutes for Standardized Dairy Foods Must Be Identified by Common or Usual Name

Nonstandardized foods, including both dairy-based and non-dairy plant-based substitutes, must be identified by "common or usual name, if any be," in accordance with FDCA section 403(i)(1).The ingredients of a nonstandardized food also must be identified on the label by "common or usual name" under FDCA section 403(i)(2).

FDA regulations governing the "statement of identity" and "ingredient statement" further specify the requirements for identifying foods and food ingredients by "common or usual name." With respect to the statement of identity, section 101.3(b)(1) provides that, when the name of a food is "specified in or required by any applicable Federal law or regulation," as in the cases of the standards of identity for "milk," "yogurt," "cheese,"

and “ice cream,” which are established by regulation, and for “butter,” which is established by statute, the common or usual name that has been codified in the applicable regulatory or statutory provision must be used to identify a food that complies with the specifications provided in the standard of identity. Likewise, a nonstandardized food which does not comply with the requirements of a standard of identity is prohibited from being identified by the common or usual name of a standardized food. FDCA section 403(g) prohibits a food that does not comply with the requirements of an FDA dairy standard of identity regulation from being labeled in a manner that “purports to be or is represented as a food” for which a “definition and standard of identity has been prescribed by regulation.” Similarly, with respect to the “butter” standard of identity established by statute, FDCA section 403(b) provides a comparable prohibition against offering a nonstandardized food for sale “under the name of another food.” FDA regulations in section 101.4 governing the designation of ingredients are consistent, specifying that ingredients must be identified by their “common or usual name,” including ingredients that comply with standards of identity.

FDA statement of identity regulations in section 101.3(b)(2) specify 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 in the statement of identity 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.”

FDA regulations in section 102.5 provide general principles governing the common or usual name of a food. Section 102.5(a) provides that the “common or usual name of a food, which may be a coined term, shall accurately identify and 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.”

Consistent with the requirements of FDCA sections 403(a) and 201(n), FDA regulations in section 102.5 require the common or usual name of a nonstandardized food to disclose material information concerning the amounts of characterizing ingredients when the labeling or appearance of a food may give the erroneous impression that ingredients are present in amounts greater than they are. Section 102.5(b) provides that the common or usual name of a food “shall include the percentage(s) of any characterizing ingredient(s) or components . . . when the labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient(s) or component(s) is present in an amount greater than is actually the case**.”** Section

102.5(c) further provides that the "common or usual name of a food shall include a statement of the presence or absence of any characterizing ingredient(s) or component(s) . . . when the presence or absence of such ingredient(s) or component(s) has a material bearing on price or consumer acceptance or when the labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient(s) or component(s) is present when it is not, and consumers may otherwise be misled about the presence or absence of the ingredient(s) or component(s) in the food. . . ."

In view of the wide variety of plant varieties, plant-derived ingredients, processing methods that are used to manufacture such "plant-based" imitation dairy foods, FDA regulations in section 102.5 indicate that the types of product names that are being used to identify these imitation dairy foods fail to comply with FDCA requirements in substantial ways (e.g., "Almond Milk," "Almondmilk Yogurt"), including through the failure to disclose material information concerning the actual nature of the food and its characterizing ingredients. For example, using a plant term like "almond," "rice," "oat," or "hemp" to refer to a purported characterizing ingredient to identify a food or food ingredient raises questions concerning the actual nature of the plant-derived ingredient(s) that are used in these products and the percentage contribution such plant-based ingredients contribute. For example, some imitation milk products can be made and consumed essentially as a puree such that resulting beverage may contain a whole plant part (e.g., seed) suspended in water. In contrast, other imitation milk products involve processing methods in which a plant part (e.g., bean, nut) is added to water but is removed from the water through filtration such that the finished beverage does not contain the whole food. The failure to disclose these material differences in the actual nature of the ingredient that is used, and its form is comparable to referring to grapeseed as grape and calling grape jelly grape jam. In addition, the percentage contribution a plant derived ingredient makes to an overall formulation has a great deal to do with how much of the product is comprised of water and other ingredients. Far more specific information is needed to accurately characterize these products and distinguish one from another. Notably, juice-containing beverages, which are subject to percentage juice disclosure requirements, are required to provide more specific information concerning the nature of the fruit and vegetable derived juice ingredients that comprise these products under section 102.33 of FDA regulations, discussed below.

V. The Common or Usual Name of the Reference Standardized Dairy Food is Prohibited for Use in Naming Nutritionally Inferior Substitutes Except as Part of the Mandatory "Imitation" Dairy Food Disclosure Requirement

Under longstanding FDA regulatory and enforcement policies, nonstandardized substitutes for standardized dairy foods have been prohibited from using the common or usual name of the reference standardized dairy food to name the substitute food except in limited and carefully tailored conditions. These conditions are designed to ensure that

the name of the standardized food ("milk," "yogurt," "cheese," "yogurt," "butter") is used under conditions that accurately characterize the food and discloses the manner that functions to accurately characterize the nonstandardized substitute food and is qualified to disclose the material differences between the standardized and nonstandardized food. As FDA has explained in the context of nonstandardized substitutes for standardized dairy foods:

> A food made in semblance of a [standardized dairy food] . . . will be deemed to be an imitation and thus subject to the [imitation labeling] requirements of [FDCA] section 403(c) . . . if it is nutritionally inferior to the [standardized dairy food] simulated. If it is not nutritionally inferior, it must bear a common or usual name that complies with the provisions of 21 C.F.R. 102.5 which is not false or misleading in any particular or, in the absence of an existing common or usual name, an appropriately descriptive name which is not false or misleading. The label may, in addition, bear a fanciful name that is not misleading.
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> **To ensure that the name of a substitute food is not misleading, the name should ordinarily not include the name of a product subject to a standard of identity unless (1) it complies with the standard of identity, or (2) it is nutritionally inferior[2] to the food simulated and is labeled with the term 'imitation.'** [**Emphasis added]** In some cases, it may be reasonable and appropriate to include the name of a standardize[d] food or other traditional food in the name of a substitute food in order to provide the consumer with an accurate description. *When this is done, the name of the food must be modified such that the nature of the substitute food is clearly described and is clearly distinguished from the food which it resembles and for which it is intended to substitute. The modification of the traditional or standardized food's name must be descriptive of all differences that are not apparent to the consumer. Thus, the procedure for naming these foods will depend on the nature of the substitute food and the manner and extent to which it differs from the food it simulates.*[3]

Section 101.67 of FDA regulations typifies FDA's longstanding policy to limit the conditions under which the common or usual name of a standardized food can be used to identify a nonstandardized food and underscores FDA's well-established policy to deem the food not only to be misbranded, but economically adulterated under FDCA section

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[2] Under FDA regulations implementing FDCA section 403(c) and related provisions in section 101.3(e) "nutritional inferiority" is any reduction in an essential nutrient in a substitute food compared to the food it resembles that amounts to two percent or more of the Daily Value for the nutrient on the basis of the "reference amount customarily consumed" ("RACC") that has been established for the food in 21 C.F.R. § 101.12(b).

[3] 48 Fed. Reg. 37666, 37667 (August 19, 1983)(emphases added).

402(b),when the common or usual name of a standardized food is used to identify a nonstandardized substitute food under conditions that are inconsistent with those typified in the section.[4] This regulation authorizes the use of the common or usual name for "butter," which is codified in the standard of identity in 21 U.S.C. 321a, to name a nonstandardized butter substitute that has been formulated to qualify for an FDA-approved (defined) nutrient content claim (e.g., "Reduced Fat") under limited conditions. These conditions require the nonstandardized butter substitute be identified using a common or usual name that includes the explicit nutrient content claim (e.g., "Reduced Fat Butter") to qualify "butter." The butter substitute also must be formulated to avoid nutritional inferiority to "butter" under section 101.3(e)(4) (e.g., through the addition of fat-soluble vitamins to compensate for vitamin losses attributable to reduced fat content). The butter substitute must also comply with the ingredient provisions of the standard of identity to the extent possible. Deviations meet the ingredient specifications of the standard of identity for butter are permitted only to achieve nutritional, organoleptic and functional performance characteristics that are comparable to standardized butter.

Notably, section 101.67(b) provides explicitly that "[d]eviations from the ingredient provisions" of the standard of identity "must be the minimum necessary to achieve similar performance characteristics as butter" produced under the standard of identity, "or the food will be deemed to be adulterated under section 402(b) of the Act."[5]

VI. Unlawful Product Names for Nonstandardized Foods Do Not Become Lawful "Common or Usual Names" Simply Through a History of Prolonged Use

While FDA regulations in section 102.5(d) recognize that common or usual names may be established through common usage, unlawful product names that fail to comply with FDCA requirements cannot be transformed into lawful "common or usual names" through a history of prolonged use. Ignorance of the law is rarely an excuse, and never excuses FDCA violations. FDA's failure to expend the resources necessary to compel compliance at an earlier time is no defense under the FDCA for persisting in the prohibited acts of introducing misbranded and economically adulterated plant-based imitation dairy foods into interstate commerce. To the contrary, FDA has responded to

[4] Compare 21 C.F.R. 130.10 (establishing comparable requirements for nutritionally modified versions of dairy foods subject to standards of identity regulations issued by FDA under FDCA section 401 (21 U.S.C. 341).

[5] FDCA section 402(b) provides that "a food shall be deemed to be adulterated . . . (1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is." Section 101.67(b) also requires significant differences from butter to be disclosed on the label of the butter substitute product.

persistent FDCA violations affecting a particular type of food product through stepped-up enforcement and rulemaking to prescribe the common or usual name requirements with greater specificity.

For example, FDA reined-in noncompliant labeling practices affecting the "plant-based" food category known as "juice" by issuing section 102.33, which specifies requirements for nonstandardized beverages that contain fruit or vegetable juice." Notably, while separate FDA regulations define the meaning of the term "juice" and specify brix criteria for a wide variety of fruits and vegetables for purposes of calculated and disclosing the mandatory percentage juice declaration for "foods purporting to be beverages that contain fruit or vegetable juice," it is obvious from the requirements that FDA has established in section 102.33 that combining a defined term such as "juice" with a reference to a type of plant (e.g., "Cashew," "Cranberry," "Tomato") is wholly inadequate to meet the requirement governing common or usual names for nonstandardized foods – even when such foods are required to declare the percentage juice content, Nutrition Facts, list each ingredient by common or usual name, and are permitted to include such voluntary claims as "non-dairy" on the label.

It is noteworthy that the flagrant violations of FDCA requirements for naming nutritionally inferior substitutes are incredibly homogenous (i.e., plant name + common or usual name of reference standardized dairy food), given the huge differences in the plant varieties, plant-derived ingredients, formulations, processing methods used to make these imitation dairy foods. As section 102.33 illustrates, this approach to naming nonstandardized foods not only fails to provide adequate information concerning the nature of the labeled food and fails to distinguish the food from other foods as required by FDA regulations. Many factual details concerning the specific nature of the fruit and vegetable ingredients is required to comply with section 102.33. For example, is the juice made from concentrate or freshly squeezed? Is the juice modified in color, taste, or other organoleptic properties such that the original "juice" is no longer recognizable in the finished product? Is the juice present at levels requiring the product to be named as a fruit or vegetable "flavored juice drink"? By comparison, when one considers the distinctions in the processing methods that are used to make products identified as "Almond Milk," "Rice Milk," "Oat Milk," "Hemp Milk," it is obvious that these terms are inadequate. Moreover, as section 102.33 illustrates, the FDCA empowers FDA to ramp up the agency's enforcement and regulatory actions when noncompliance is widespread in a food category – including non-dairy, plant-based foods – in order to terminate unlawful practices.

VII. The Persistent and Proliferating Use of Unlawful Product Names for "Plant-Based" Imitation Dairy Foods and Related Positioning Strategies is Designed to Encourage Consumers to Adopt Dietary Practices that Have Foreseeable Potential Adverse Consequences for the Nutritional Health of Consumers and Public Health

For FDA to allow unlawfully labeled plant-based imitation dairy foods to continue to proliferate in the marketplace, unchecked by agency action to compel compliance with FDCA requirements, including through the enforcement of FDCA section 403(c) imitation disclosure requirement (e.g., "IMITATION MILK") cannot be justified under FDA's consumer and public health protection mandate in the FDCA.

The persistent and proliferating use of product names for "plant-based" imitation dairy foods (e.g., "Almond Milk," "Rice Milk," "Oat Milk," "Hemp Milk," etc.) combined with the failure to comply with the "imitation" disclosure requirement mandated by the plain language of FDCA section 403(c) not only are unlawful labeling practices, but are part of a more comprehensive strategy that is designed to encourage consumers to adopt dietary practices at odds with the Dietary Guidelines for Americans, with foreseeable potential adverse consequences for the nutritional health of consumers and the public health more generally.

Notably, these imitation dairy foods are formulated to resemble the reference standardized dairy foods for which they are positioned as substitutes in ways that consumers can observe (aesthetic, organoleptic and functional properties), but the formulation is designed to stop short of including the essential nutrients that would need to be added to achieve nutritional equivalence with the respective reference standardized dairy foods. These plant-based imitation dairy foods are functionally equivalent and nutritionally inferior by design and are then further positioned through unlawful labeling practices to encourage consumers to make dietary substitutions that replace real, nutrient rich dairy foods for nutritionally inferior imitations, undermining the nutritional adequacy of the consumer's diet on a serving-by-serving basis (e.g., using an imitation milk product instead of low fat milk on breakfast cereal, in a beverage (café latte)) and have foreseeable potential adverse consequences for the nutritional health of consumers, and ultimately also for public health.

Encouraging consumers to consume plant-based imitation dairy foods instead of standardized dairy foods is at odds with well-substantiated Dietary Guidelines recommendations urging Americans to consume nutrient-dense foods, including standardized milk, yogurt, and cheese on a daily basis (i.e., 3 cups of low-fat or non-fat milk (or dairy food cup-equivalents) *per day* for Americans 9 years of age and older, and no less than 2 to 2.5 cups depending on age for children less than 9 years of age.[6]

[6] HHS and USDA, Dietary Guidelines for Americans (2015 – 2020), Chapter One at page 9.

The most recent Dietary Guidelines highlight the nutritional inferiority of plant-based beverages that are sold as "milks" which cannot function as nutritionally equivalent replacements for dairy foods, with the single exception of certain soy beverages, stating "[h]ealthy eating patterns include fat-free and low-fat (1%) dairy, including milk, yogurt, cheese, or fortified soy ***beverages*** [emphasis added]. . .. Soy beverages fortified with calcium, vitamin A, and vitamin D, are included as part of the dairy group [for purposes of the Dietary Guidelines] because they are similar to milk based on nutrient composition and in their use in meals. Other products sold as "milks" but made from plants (e.g., almond, rice, coconut, and hemp 'milks') may contain calcium and be consumed as a source of calcium, but they are not included as part of the dairy group because their overall nutritional content is not similar to dairy milk and fortified soy beverages . . .."[7]

The unlawful labeling practices used to position nutritionally inferior plant-based foods as forms of "milk" or other standardized dairy foods fail to disclose the highly significant material information that these products are merely imitations of milk or other dairy foods, as required by FDCA section 403(c), and are not, in fact, interchangeable with milk or any other dairy food for purposes of human nutrition, as reflected in the exclusion of these foods from the "dairy group" in the Dietary Guidelines.

The positioning strategy widely used to encourage consumers to consume nutritionally inferior plant-based imitations does not stop with functional equivalent but nutritionally inferior formulations and unlawful labeling practices. These imitation dairy foods are positioned for retail sale as refrigerated foods and offered for retail sale from display cases where standardized dairy foods also are displayed for retail sale. In addition, these imitation dairy foods are packaged in paperboard or plastic containers resembling the packaging typically used for the reference dairy food – further obscuring the fact that these plant-based imitations are not, in fact, interchangeable with dairy foods.

The proliferation of unlawfully labeled plant-based imitation dairy foods has far-reaching consequences for consumer nutrition and public health. As FDA food regulators learned the hard way as they continued to contend with the proliferation of cheap, debased imitation foods being successfully passed off even after the 1906 act was enacted, selling economically adulterated foods can readily become a profitable business with costly public-health consequences. The inadequacies of the 1906 act clearly demonstrated that it takes more than a ban on economic adulteration. The 1938 FDCA was informed by the failures of the 1906 act to stem the tide of economically adulterated and imitation foods, and FDA's longstanding policy to enforce these provisions – standards of identity, common or usual name requirements for nonstandardized substitutes, and imitation food disclosure requirement – has demonstrated that compliance with these requirements is essential to deter the marketing of economically

[7] Id.

adulterated foods, and to ensure that all foods are accurately identified in ways that both characterize nature of the food and its ingredients, and disclose factual information that is necessary to distinguish nutritionally inferior imitations from standardized foods.

VIII. First Amendment Compelled Commercial Speech Standards Support FDA Actions to Require Plant-Based Imitation Dairy Foods to Comply with FDCA Requirements for Identifying Nutritionally Inferior Dairy Food Substitutes By Common or Usual Name and Disclosing "Imitation" Dairy Food Status

First Amendment standards that protect commercial speech and limit the government's authority to regulate the content of commercial speech not only pose no obstacle, but fully support FDA enforcement and regulatory actions needed to require plant-based imitation dairy foods to comply with FDCA requirements for identifying nutritionally inferior dairy food substitutes by "common or usual name" under FDCA section 403(i) and the related misbranding provisions (e.g., sections 403(a) and 201(n)), and the imitation disclosure requirements established under FDCA section 403(c). As the NMPF Citizen Petition referenced above explains in the extensive analysis of pertinent First Amendment case law, regulations requiring the disclosure of factual information of the kind required under the misbranding provisions of the FDCA reference here falls well within the scope of FDA's authority to regulate commercial speech. These First Amendment standards fully support product labeling requirements that compel manufacturers to disclose factual information that accurately identifies a food and distinguishes the food from different foods, including the fact that a food qualifies as an "imitation milk," distinguishing the food from "milk," under FDCA section 403(c) and FDA implementing regulations defining "imitation" foods to be nutritionally inferior substitute foods.

As the NMPF Citizen Petition explains at length, while requirements compelling subjective and opinion-based statements, or ones requiring inflammatory images or words that are intended to shock or manipulate consumers (e.g., graphic images and related anti-smoking messages) have had difficulty surviving First Amendment scrutiny, the government has substantial latitude to compel factual and uncontroversial information to equip consumers with material information that can be used to inform consumer choice and can help advance consumer health and public health protection objectives. In this regard, the government has authority to require that factual information be disclosed through the use of terminology specified by statute and/or regulations, even when the regulated industry may prefer to use nomenclature of their own creation (e.g., "Nutrition Facts," "Reduced Fat," "Organic," "Imitation"). The term "Imitation Milk" may not be attractive to those who wish to promote nutritionally inferior substitutes for dairy foods, but the term presents no First Amendment obstacle to FDA's enforcement of this disclosure requirement. The terminology is mandated under FDCA section 403(c) and conveys the factually accurate information that the

labeled food is an "imitation" of the food for it is designed to substitute. FDA's enforcement of the imitation disclosure requirement, and "common or usual name" requirements for dairy food substitutes fall squarely within the boundaries of permissible compelled speech requirements under the First Amendment. These requirements provide material factual information to consumers and are appropriately tailored to help advance the consumer health and public health protection objectives intended.

IX. FDA's failure to take action to enforce longstanding, well-documented requirements for naming nutritionally inferior substitute food products under the FDCA endangers public health and violates the Administrative Procedure Act in multiple, independent ways.

As discussed above, despite repeated formal and informal requests by NMPF, FDA has refused to take appropriate action to stem the proliferation of nutritionally inferior, plant-based substitutes that are intentionally passed off as nutritionally equivalent substitutes to dairy products. FDA's refusal to enforce these requirements and justify this marked departure from historical requirements constitutes a violation of the Administrative Procedure Act (APA) in at least three independent ways.

First, FDA's refusal to enforce longstanding requirements violates the APA because it directly contravenes congressional direction to promulgate and enforce standards of identity, "imitation" labeling requirements, and the statutory standard of identity for "butter." The FDCA provides that the Secretary "*shall 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, a reasonable standard of quality, or reasonable standards of fill of container."[8] Further, the FDCA prohibits a food that "is an imitation of another food, unless its label bears. . . 'imitation' and, immediately thereafter, the name of the food imitated."[9] Finally, the FDCA expressly provides that "'butter' *shall be understood to mean* the food product usually known as butter, and which is made exclusively from milk or cream, or both, with or without common salt, and with or without additional coloring matter, and containing not less than 80 per centum by weight of milk fat, all tolerances having been allowed for."[10]

While certain agency decisions to decline to bring enforcement actions are unreviewable under the APA, this presumption does not apply either: (1) "where the substantive statute has provided guidelines for the agency to follow in exercising its enforcement powers,"[11] or (2) where "an agency's announcement of its interpretation of a statute

8 21 U.S.C. § 341.

9 21 U.S.C. § 343(c).

10 21 U.S.C. § 321a.

11 *Am. Acad. of Pediatrics v. FDA*, 379 F. Supp. 3d 461, 481 (D. Md. 2019) (citing *Heckler v. Chaney*, 470 U.S. 821, 832-33 (1985)).

even when that interpretation is advanced in the context of a decision not to take enforcement action."[12] Both of these circumstances apply here. Congress has directed FDA to promulgate and enforce standards of identity, which it has historically done to protect public health and prevent economic adulteration. FDA's unexplained abdication of its responsibility to do so in connection with nutritionally inferior, plant-based substitutes undermines its mission to protect the public health and the express direction by Congress to enforce standards of identity.

Second, FDA's failure to enforce requirements that have formed the basis for its historical approach to standards of identity and common or usual name requirements constitutes an unexplained and unjustified departure from precedent that is arbitrary and capricious under the APA. As the Supreme Court recently explained, "the reasoned explanation requirement of administrative law, after all, is meant to ensure that agencies offer genuine justifications for important decisions, reasons that can be scrutinized by courts and the interested public."[13] As with the Department of Commerce's decision in that case, FDA's failure to enforce longstanding standard of identity and common or usual name requirements is "arbitrary and capricious because, in multiple ways, it represented a dramatic departure from the standards and practices that have long governed" and the Agency has "failed to justify those departures."[14]

Notably, even if the Agency had acknowledged its change in course and attempted to justify it, rulemakings that contradict previous findings or overturn a prior policy that has engendered significant reliance interests, are subject to heightened scrutiny and the agency has an obligation to provide a more detailed and convincing justification to explain the departure than usual.[15] In explaining such a departure, the agency must also meaningfully to comments and information received.[16] Here, FDA has not only failed to adequately justify its radical departure from decades-old precedent by providing a detailed and convincing rationale, it has offered no justification while simultaneously acknowledging the departure by soliciting comments from stakeholders.

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12 *Am. Acad. of Pediatrics v. FDA*, 379 F. Supp. 3d 461, 481 (D. Md. 2019) (citing NAACP v. Trump, 298 F. Supp. 3d 209, 228 (D.D.C. 2018)).

13 *Dept. of Commerce v. New York*, 139 S. Ct. 2551, 2575-76 (2019).

14 New York v. Dept. of Commerce, 351 F. Supp. 3d 502, 654-55 (S.D.N.Y. 2019) (citing *St. Lawrence Seaway Pilots Ass'n, Inc. v. U.S. Coast Guard*, 85 F. Supp. 3d 197, 207 (D.D.C. 2015); Tummino v. Torti, 603 F. Supp. 2d 519, 523 (E.D.N.Y. 2009); FCC v. Fox Television Stations, Inc., 556 U.S. 502, 515, 129 S. Ct. 1800, 173 L. Ed. 2d 738 (2009) ("T]he requirement that an agency provide reasoned explanation for its action . . . ordinarily demand[s] that it display awareness that it is changing position. An agency may not, for [**392] example, depart from a prior policy sub silentio or simply disregard rules that are still on the books."); SNR Wireless LicenseCo, LLC v. FCC, 868 F.3d 1021, 1029 (D.C. Cir. 2017) ("To provide a satisfactory explanation, an agency must acknowledge and explain any departure from its precedents."); Hooper v. Nat'l Transp. Safety Bd., 841 F.2d 1150, 1151, 268 U.S. App. D.C. 325 (D.C. Cir. 1988).

15 *FCC v. Fox TV Stations, Inc.*, 556 U.S. 502, 515, 129 S. Ct. 1800, 1811 (2009).

16 *PPL Wallingford Energy LLC v. FERC*, 419 F.3d 1194, 1198 (D.C. Cir. 2005) (citing *Canadian Ass'n of Petroleum Producers v. FERC*, 254 F.3d 289, 299 (D.C. Cir. 2001)).

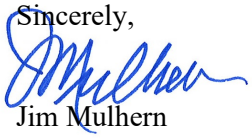
Third, by allowing the continued proliferation of products labeled in violation of the FDCA and FDA regulations, FDA's inaction is "tantamount to amending or revoking a rule."[17] It's even worse with respect to butter, as FDA's inaction is tantamount to amending or revoking a Congressional statute. As discussed above, the Agency carefully circumscribed the conditions under which the common or usual name of a standardized food can be used to identify a nonstandardized food in promulgating sections 101.67 and 130.10 of FDA regulations. NMPF's petition discusses in detail the Agency's rationale in determining that "general requirements as to how far a modified food may deviate from the standard of identity and still use the standardized name are necessary."[18] Allowing manufacturers of plant-based dairy substitutes to wantonly use standardized dairy terms to describe the products they are intentionally manufactured to resemble effectively repeals these requirements.

In addition to contravening sections 101.67 and 130.10, FDA's inaction further acts to effectively revoke sections 101.3(e), which more clearly defines the circumstances when "imitation" labeling is required for substitute foods under FDCA section 403(c). As discussed in Section I.C.2 of NMPF's petition and above, nutritionally inferior, plant-based substitutes fall clearly within the category of products required to bear "imitation" labeling and thus the Agency's decision to not apply these requirements amounts to an effective revocation of the rule.

Conclusion

Allowing unlawfully labeled "plant-based" imitation dairy foods to proliferate poses an immediate and growing risk to public health; it is a clear dereliction of the FDA's duty to enforce federal law and agency regulations. For these reasons, and others that are more fully explained in the NMPF Citizen Petition, the FDA's Office of the Ombudsman must intervene to break the bureaucratic logjam that is adversely affecting consumers. Doing so would fit squarely within the Office's own mission to ensure even-handed application of FDA policy and procedures.

Sincerely,



Jim Mulhern
President & CEO

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17 *Pub. Citizen Health Research Grp. v. Acosta*, 363 F. Supp. 3d 1, 18 (D.D.C. 2018) (citing *Clean Air Council v. Pruitt*, 862 F.3d 1, 6 (D.C. Cir. 2017) (per curiam); *Envtl. Def. Fund, Inc. v. EPA*, 716 F.2d 915, 920, 230 U.S. App. D.C. 264 (1983) (per curiam); *Envtl. Def. Fund, Inc. v. Gorsuch*, 713 F.2d 802, 816, 230 U.S. App. D.C. 8 (D.C. Cir. 1983); *Council of the S. Mountains, Inc. v. Donovan*, 653 F.2d 573, 580 n.28, 209 U.S. App. D.C. 318 (D.C. Cir. 1981)).

18 NMPF Petition Section I.B.3, Standardized Foods Modified by Nutrient Content Claim (citing Food Standards: Requirements for Foods Named by Use of a Nutrient Content Claim and a Standardized Term, 58 Fed. Reg. 2,431 (Jan. 6, 1993).