September 13, 2018

Ms. Felicia Billingslea
Director Food Labeling and Standards
US Food and Drug Administration
CPK 1 HFS-820
5001 Campus Drive
College Park, MD 20740

Re: Misbranded Plant-Based "Butter" Substitutes – Miyoko's "European Style Cultured Vegan Butter," Pure Blends' "Coconut Oil-" and "Avocado Oil-" "Plant-Based Butter Vegetable Oil Blend" Products, Fora Foods' "FabaButter Dairy-Free Butter," and WayFare Foods' Line of "Dairy Free" Butter Products, Including "Salted Whipped Butter," "Garlic Whipped Butter," and "Sweet Cinnamony Whipped Butter"

Dear Ms. Billingslea:

The American Butter Institute (ABI) is the Arlington, Virginia based trade association for manufacturers, processors, marketers, and distributors of butter and butter products. ABI's mission is to promote and protect the interests and welfare of the industry we represent and the consuming public we serve.

We write to call your attention to the above-referenced misbranded plant-based butter substitutes which contain no butter, milk, cream, or other dairy ingredients. These products are misrepresented to be "butter" products in direct conflict with the statutory standard of identity and FDA regulations and policies governing the naming of nonstandardized butter substitutes. All of these products are made from commonplace edible oils and other ingredients that are encompassed by the FDA standard of identity for margarine."[1] Some or all of these products may be subject to the margarine standard, including the requirement that such foods be identified as "margarine" or "oleomargarine."[2]

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[1] 21 C.F.R. § 166.110. Under section 166.110(a), "'margarine' . . . is the food in plastic form or liquid emulsion, containing not less than 80 percent fat," which contains "only safe and suitable ingredients." The standard of identity further defines "margarine" to be a food produced from one or more "optional ingredients" listed in section 166.110(a)(1) (*i.e.,* "edible fats and/or oils, or mixtures of these" which may be edible oils from plants), together with one or more "optional ingredients" listed in section 166.110(a)(2) (*e.g.,* water and vegetable proteins), and one or more "optional ingredients" in section 166.110(b) (*e.g.,* salt, color, acidulants, emulsifiers). To help ensure that margarine is not nutritionally inferior to standardized butter with respect to Vitamin A levels, section 166.110(a)(3) requires the addition of Vitamin A in amounts sufficient to yield a finished margarine containing no less than 15,000 international units of Vitamin A per pound. Section 166.110(c) further provides that "[t]he name of the food for which a definition and standard of identity are prescribed in this section is 'margarine' or 'oleomargarine.'" Accordingly, plant-based products that are subject to the margarine standard of identity must be identified as "margarine" or "oleomargarine" and may not be identified as "butter" or otherwise.

[2] All of the plant-based butter substitute products referenced above are made from ingredients that appear to be authorized for use in margarine under the standard of identity. 21 C.F.R. §§ 166.110(a)(1), (a)(2), (b). Publicly available information suggests that at least one of these products contains fat at levels exceeding the 80 percent threshold for margarine. *See* F. Fabricant, "I Can't Believe It's Chickpea Water," New York Times (July 23, 2018),

Irrespective of whether these products are subject to the standard of identity for "margarine," the products are misbranded under the Federal Food, Drug & Cosmetic Act ("FDCA") because they are represented to be "butter" products despite the fact that they contain no butter, milk, cream, or other dairy ingredients. We respectfully request that the agency take prompt enforcement action to redress the consumer harm and confusion resulting from these misbranded "butter" products.

I. Product Summary

Here is a summary of key information concerning the above-referenced plant-based butter substitutes.

- The "European Style Cultured Vegan Butter" product referenced above is manufactured by Miyoko's Kitchen of Sonoma, California ("Miyoko's"), and sold through the "Creamery Shop" pages of the company's website and through certain U.S. retail stores. According to the ingredient and nutrition labeling information that is posted on the company website, Miyoko's "vegan butter" product contains organic coconut oil, filtered water, organic sunflower oil, organic cashews, organic sunflower lecithin, sea salt, and cultures. (https://miyokos.com). The product contains no Vitamin A and is nutritionally inferior to butter as defined by 21 C.F.R. § 101.3(e)(4). See Attachment A for product labeling. In the case that Miyoko's butter substitute product is not subject to the "margarine" standard, the product qualifies as a nutritionally inferior butter substitute which must be labeled as "imitation butter" Under 21 C.F.R. § 101.3(e).

- The Pure Blends' line of "Plant-Based Butter" products are produced by Upfield Foods (https://www.upfield.com), which was recently acquired by the KKR private equity firm. The Pure Blends' line includes "Coconut Oil Plant-Based Butter Vegetable Oil Blend" and "Avocado Oil Plant-Based Butter Vegetable Oil Blend" products. According to the "Store Locator" pages on the brand's website (https://pureblendbrands.com), these products are sold through various major U.S. retail grocery stores across the United States. The ingredient statements for these two "plant-based butter products" are identical, except that the second listed ingredient is coconut oil for the coconut oil product, and avocado oil for the avocado oil product. The ingredient statements list the following ingredients: Purified Water, [Coconut Oil or Avocado Oil], Soybean Oil, Palm Kernel and Palm Oil, Salt, Soy Lecithin, Monoglycerides, Vinegar, Natural Flavors, Vitamin A Palmitate, Beta Carotene (Color). Nutrition labeling shows that both of these products provide at least 10% DV of Vitamin A per tablespoon and thus are not nutritionally inferior to butter with respect to Vitamin A content. Nutrition labeling also shows that the fatty acid profiles for these two products are significantly different. (https://www.pureblendsbrand.com). See Attachment B for product labeling. In the case that Pure Blends' butter substitute products are not subject to the "margarine" standard, these products would qualify as nonstandardized butter substitutes that are not nutritionally inferior to butter. As such, under 21 C.F.R. § 101.3(e),these plant-based butter substitutes would not be required to be labeled as "imitation butter," but would be prohibited from employing the term "butter" or otherwise expressly or impliedly representing that these products are "butter," or contain "butter" or other dairy ingredients (*e.g.*, milk, cream, milk constituents), as represented in current labeling. The Fora Foods' "FabaButter Dairy-Free Butter" product was recently launched by the Brooklyn, New York based Fora Foods company. Reportedly, the product is being sold through Eataly markets (www.eataly.com)

available at: https://www.nytimes.com/2018/07/23/dining/faba-butter-substitute.html (reporting that Fora Foods' FabaButter is 84% fat). The percentage fat content of the Miyoko's, Pure Blend's, and WayFare Foods' products is not publicly available at this time.

in New York and nationwide.[3] We obtained sample labels by purchasing product samples at the Eataly market at 101 Liberty Street, Suite 3400, New York, NY 10007 on September 7, 2018. See Attachment C for product labeling. Reportedly, Fora Foods' FabaButter product is 84% fat – exceeding the 80% fat minimum threshold for standardized margarine.[4] The ingredient statement that appears on product labels reads as follows: "INGREDIENTS: COCONUT OIL, COCONUT CREAM, SUNFLOWER OIL, SEA SALT, CULTURED DEXTROSE, NUTRITIONAL YEAST, SUNFLOWER LECITHIN, AQUAFABA (CHICKPEAS), VEGAN LACTIC ACID (TO PRESERVE FRESHNESS), VITAMIN D2 (VEGAN).[5] Nutrition labeling shows that the FabaButter product contains no Vitamin A and is nutritionally inferior to butter as defined by 21 C.F.R. § 101.3(e)(4). In addition, while Vitamin D2 is listed as an ingredient, nutrition labeling indicates that FabaButter is [n]ot a significant source of . . . vitamin D." The addition of Vitamin D2 to FabaButter as an ingredient does not appear to comply with FDA requirements and the functional purpose of the added vitamin D2 is unclear. In the case that the Fora Food's plant-based butter substitute product is not subject to the "margarine" standard, the product qualifies as a nutritionally inferior butter substitute which must be labeled as "imitation butter" Under 21 C.F.R. § 101.3(e).

- The WayFare Foods' line of "Dairy Free . . . Whipped Butter" products are sold under the WayFare private label brand through the WayFare Online Store, which currently ships products primarily to states that are east of the Mississippi River (htttps://wayfarefoods.com/shop). In addition, according to the Store Locator posted on their online store site, the dairy free whipped butter products are sold through various grocery retail stores across the United States, including in states that are west of the Mississippi River. WayFare is headquartered in Bozeman, Montana. The WayFare line of "Dairy Free . . . Whipped Butter" products includes "Dairy Free Salted Whipped Butter," "Dairy Free Garlic Whipped Butter," and "Dairy Free Sweet Cinnamony Whipped Butter." The ingredient statement for the "Dairy Free Salted Whipped Butter" product lists the following ingredients: "WayFare Dairy Free Base (Water, Organic Butter Beans), Vegetable Oil Blend (Coconut Oil and Safflower Oil), Sea Salt, Cultured Dextrose, Calcium Citrate, WayFare Natural Flavors, Sunflower Lecithin, Konjac Root Powder, Natural Colors, Vitamin E."[6] The ingredient statements for the remaining two dairy free

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[3] *See* F. Fabricant *supra* note 2.

[4] *Id.*

[5] The ingredient statement for the FabaButter does not comply with FDA requirements in several respects, including but not limited to the listing of "AQUAFABA (CHICKPEAS)" as an ingredient. The term, "aquafaba" appears to be a term that was recently introduced in the United States to refer to the cooking liquid of beans and other legumes like chickpeas. See "The Official Aquafaba Website," "What is aquafaba?" (Feb. 1, 2016) (http://aquafaba.com/). According to the Fora Foods' website, FabaButter contains "aquafaba," which is described as "the leftover water after cooking chickpeas." The page elaborates that "[d]uring the boiling process, the proteins, starches, and other soluble solids migrate from the seed to the water." (See Attachment C) (https://forafoods.com/faq). Notably, while this description suggests that aquafaba consists primarily of water, the ingredient statement of FabaButter lists no water and suggests that "aquafaba" and "chickpeas" are the same ingredient, which clearly is not the case.

[6] The ingredient statements for the three WayFare "Dairy Free . . . Whipped Butter" products fail to comply with FDA ingredient labeling requirements in a number of respects. Section 101.4 of FDA regulations requires ingredients to be listed by common or usual name in descending order of predominance by weight, and to be named

whipped "butter" products in the line are largely identical, except that the "Dairy Free Garlic Whipped Butter" contains garlic, and the "Dairy Free Sweet Cinnamony Whipped Butter" contains organic cane sugar and "natural flavors" that presumably include cinnamon flavors. The additional garlic, sugar, and cinnamon flavoring ingredients appear to result in modest adjustments in the order of predominance of ingredients by weight as compared to the "Dairy Free Salted Whipped Butter" product which are immaterial here. The three WayFare "Dairy Free . . . Whipped Butter" products contain no Vitamin A and are nutritionally inferior to butter as defined by 21 C.F.R. § 101.3(e)(4). See Attachment D for product labeling. In the case that the WayFare butter substitute products are not subject to the "margarine" standard, these products qualify as nutritionally inferior butter substitutes which must be labeled as "imitation butter" Under 21 C.F.R. § 101.3(e).

For the reasons discussed further below, we urge the agency to take prompt enforcement action against these misbranded butter substitutes.

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using a "specific name" and not a "collective (generic) name," except when FDA has authorized the use of a collective term for this purpose under section 101.4(b). FDA regulations do not authorize the use of the collective terms "WayFare Dairy Free Base," "WayFare Natural Flavors," or "Natural Colors." "WayFare" is a company brand name and is not part of a lawful common or usual name for any ingredient. "Dairy Free Base" is a novel, collective, descriptive term which does not qualify as an "established common or usual name" or otherwise satisfy the requirements of section 102.5 with respect to common or usual names for nonstandardized foods. As a result, "Dairy Free Base" does not qualify for the parenthetical listing of its component ingredients under 21 C.F.R. §101.4(b)(2)(i). Section 101.4(b)(2) provides that "the name of an ingredient shall be a specific name and not a collective (generic) name, except that: . . . An ingredient which itself contains two or more ingredients *and which has an established common or name*, conforms to a standard established . . . by the U.S. Department of Agriculture, or conforms to a definition and standard of identity established pursuant to section 401 of the [FDCA], shall be designated in the statement of ingredients on the label of such food by either of the following alternatives: (i) By declaring the established common or usual name of the ingredient followed by a parenthetical listing of all ingredients contained there in . . . , or (ii) By incorporating into the statement of ingredients in descending order of predominance in the finished food, the common or usual name of every component of the ingredient without listing the ingredient itself."

Notably, the improper use of "WayFare Dairy Free Base" as a collective name followed by a parenthetical listing of the ingredients, "water," and "Butter Beans," seems calculated to mislead consumers by obscuring the fact that water is the most predominant ingredient in these butter substitutes, and that water is more predominant even than the "Butter Beans," "Coconut Oil," and "Safflower Oil" ingredients which make up the bulk of these product formulations. In addition, the use of the U.S. regional term, "Butter Beans," rather than the term, "Lima Beans," which is the nationally established common or usual name for the flat bean that is used in these dairy free "butter" substitutes, does not square with FDA ingredient labeling requirements, and functions to employ the term "butter" in the ingredient statements of products that contain no butter, milk, cream or other dairy ingredient. *Compare* Merriam Webster's Online Dictionary, Definition of "Lima Bean" ("a bushy or vining tropical American bean (*Phaseolus lunatus* synonym *Phaseolus limensis*) that is widely cultivated for its flat edible starchy seed which is usually pale green when immature and whitish or beige when mature") *with* Merriam Webster's Online Dictionary, Definition of "Butter Bean" (noting use "chiefly in Southern US and Midland US" and defining as "Lima Bean").

The term, "natural colors," also violates FDA ingredient labeling requirements. Section 101.4(b)(1) provides that "colorings" must be declared "according to the provisions of section 101.22." Section 101.22(a)(1) defines "artificial color" and "artificial coloring" to mean "any 'color additive' as defined in [section] 70.3(f)," which is defined to include "a food substance such as beet juice [that] is deliberately used as a color, as in pink lemonade." Because all colors regardless of source result in an artificially colored food, FDA has consistently objected to the declaration of any added color as "natural." *See* FDA CPG Sec. 587.100 Label Declaration of Certification-Exempt Color Additives.

II. FDCA Regulatory Framework for Naming Food Products

A. FDCA and FDA Common or Usual Name Requirements Generally

The FDCA and FDA implementing regulations have established a well-defined regulatory framework that requires food products to be identified using names that are truthful and not misleading, and prohibiting the use of names that would pass off one food under the name of another or otherwise mischaracterize the basic nature and characterizing properties of the food. Specifically, 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." FDCA 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) prohibits a food for which labeling is "false or misleading in any particular."

FDA regulations governing the "statement of identity" that is required on the food label implement and expand upon these statutory requirements. 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 "butter" and "margarine," the name that is assigned by the applicable law or regulation must be used as the statement of identity on the label. Section 101.3(b)(2) further 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 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."

In accordance with FDCA section 403(c), FDA regulations governing the required statement of identity, also require "imitation" foods to be named as such on the label. Section 101.3(e)(1) provides that a food "shall be deemed to be an imitation and thus subject to the requirements of [FDCA] section 403(c) . . . if it is a substitute for and resembles another food but is nutritionally inferior to that food." Section 101.3(e)(2) further provides that a food "shall not be deemed to be an imitation" provided the food (1) is not "nutritionally inferior to the food for which it substitutes and which it resembles" and (2) the food label identifies the food using a "common or usual name that complies with the provisions of 21 C.F.R. § 102.5 . . . that is not false or misleading." The regulation defines "nutritional inferiority" as any reduction in an essential nutrient[7] 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) (*i.e.,* 1 tablespoon for butter and margarine).

B. FDCA and FDA Naming Requirements for Butter Substitutes

Plant-based butter substitutes that contain no standardized "butter," milk, cream or other major ingredients that are milk or milk components do not qualify as "butter" under the statutory standard of identity or nonstandardized "butter" products, and are prohibited from being represented as "butter" products.

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[7] Under 21 C.F.R. § 101.3(e)(4), the determination of whether a substitute food is nutritionally inferior to the food it resembles does not consider calories, fat, selenium, molybdenum, chromium, or chloride.

The federal standard of identity for "butter" is established by statute in FDCA section 201a 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." FDA explained the purpose and implications of the "butter" standard in the preamble to proposed section 101.67, which is discussed further below:

> Congress provided the definition for "butter" in section 201a of the act to protect consumers from butter-like products that were inferior to the butter that they expected to purchase. Consistent with this, one of the main purposes of the act is to protect consumers from economic deception. A product using the term "butter" must comply with the statutory definition of butter, it its labeling would be false, and it would be misbranded under section 403(a)(1) of the act . . . . A food sold under the name "butter" that does not comply with the statutory standard for butter also is in violation of section 403(b) of the act . . . in that is sold under the name of another food.[8]

Section 102.5 of FDA regulations governs common or usual names for nonstandardized foods and allows the standardized term, "butter," to be used to name nonstandardized foods for which the reference to standardized "butter," accurately conveys the basic nature of the food and its characterizing properties and dairy ingredients (*e.g.,* "Garlic Butter," "Parsley Butter," "Spreadable Butter with Canola Oil"). Section 102.5 in no way permits the standardized term, "butter," to be used to name a nonstandardized plant-based butter substitute that is characterized by its plant-based ingredients and the complete absence of milk, cream and other milk constituents that comprise standardized butter unless such products constitute and are labeled as "imitation butter."

FDA recognized the need for nonstandardized butter products to be characterized by their dairy ingredients when it issued section 101.67 authorizing the use of FDA-approved nutrient content claims for nutritionally modified versions of standardized butter as part of the agency's regulatory initiative to implement the Nutrition Labeling and Education Act of 1990 ("NLEA"). The terms of section 101.67(a)(3) are narrowly tailored to require the statement of identity of a butter product that has been nutritionally modified to meet the requirements of an FDA-approved nutrient content claim to include the respective nutrient content claim with the term, "butter" (*e.g.,* "Light Butter"). More specifically, section 101.67(a)(3) provides that, if a nutritionally modified butter product would violate the standard of identity "but for the nutrient content claim that characterizes the level of nutrients, that claim shall be an explicit claim that is included as part of the common or usual name of the product."

In issuing section 101.67, FDA recognized that the types of modifications to standardized butter that would be necessary for butter products to qualify for such claims as "reduced fat" or "light" butter would require the use of nondairy ingredients that are not authorized by the butter standard. For example, FDA recognized that nondairy ingredients would be needed to help ensure that such nutritionally modified butter products would not be nutritionally inferior to standardized butter, and would have taste, appearance, and performance characteristics that are comparable to butter. At the same time, FDA recognized that, for nutritionally modified butter products to be fairly represented to consumers as "butter" products, these foods must be comprised principally of milk, cream and other milk constituents that are found in standardized "butter." In the preamble to the final rule, FDA explained that while, in contrast to standardized butter, no minimum milkfat level would apply to nutritionally modified butter substitutes under section 101.67, the

[8] 56 Fed. Reg. 60523, 60524 (November 27, 1991).

"major ingredients used in manufacturing" the products covered by section 101.67 "are cream, milk, or constituents of milk and cream."[9]

To ensure that such dairy ingredients are, in fact, "major ingredients" of the butter substitutes that are covered by section 101.67, the regulation both specifies the dairy ingredients that must be used to formulate these products, and sets firm limits on the use of nondairy ingredients in these foods.[10] Specifically, section 101.67(a)(2) requires that these butter substitutes contain "cream or milk, including milk constituents." In addition, section 101.67(b) provides that "[d]eviations from the ingredient provisions of the [butter standard of identity] . . . must be the minimum necessary to achieve similar performance characteristics" as standardized butter. Section 101.67(b) further provides that a butter substitute that deviates from the butter standard to an extent that is more than the "minimum necessary" to achieve such performance characteristics will result in the food being "deemed to be adulterated" under the economic adulteration provisions of section 402(b) of the Act. Under FDCA section 402(b), a food is adulterated if:

> (1) if any valuable constituent has been in whole or in part omitted or abstracted therefrom; or
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> (2) if any substance has been substituted wholly or in part therefor; or
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> (3) if damage or inferiority has been concealed in any manner; or
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> (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.

In addition, under section 101.67(c)(2), FDA required the use of such ingredients to be highlighted in the ingredient statement with an asterisk (*) linked to a disclosure immediately following the ingredient statement: "*Ingredients not in regular butter." Section 101.67(a)(3) prohibits covered butter products from being nutritionally inferior to standardized butter as defined by section 101.3(e)(4) of FDA regulations.

Section 101.67 in no way supports the notion that the term "butter" can be used to name a plant-based butter substitute for which milk, cream and/or other dairy ingredients fail to qualify as "major" characterizing ingredients, but are entirely absent from such foods.

The policies that apply to nutritionally modified butter substitutes under section 101.67 that are named using an FDA-approved nutrient content claim and the term, "butter," (*e.g.*, "Light Butter") are consistent with longstanding FDA policies concerning "common or usual names" for foods, and the highly limited conditions under which a standardized name may be used to name a 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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[9] 58 Fed. Reg. 2448, 2450 (January 6, 1993); *see also* 21 C.F.R. § 101.67(a)(2) (providing that the product "contains cream or milk, including milk constituents (including but not limited to, whey, casein, modified whey, and salts of casein), or both . . .").

[10] *See also*, 21 C.F.R. § 130.10 (establishing similar requirements for substitutes for foods subject to standards of identity established by FDA under FDCA section 401 which are named by an FDA approved nutrient content claim and standardized term (*e.g.*, "Light Ice Cream").

> 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 to the food simulated and is labeled with the term 'imitation.' However, 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.*[11]

"Light Butter" products complying with section 101.67 plainly illustrate the core elements of FDA's more general policy. First, "imitation butter" labeling is required for any butter substitute that does not consist of butter as defined under the standard of identity and is nutritionally inferior to butter. "Light Butter" products meeting the requirements of section 101.67 are not nutritionally inferior to standardized butter and thus are not required to be labeled as "Imitation Butter." Second, the "Light Butter" substitute uses the term, "butter," in a manner that is an "accurate description" of the butter substitute because the Light Butter substitute is made from milk, cream and milk constituents of the kinds that comprise standardized butter and deviations from the standard ingredients are kept to the minimum necessary to avoid nutritional inferiority to butter and achieve performance characteristics that are comparable to butter. Third, the term "butter" is modified by the FDA approved nutrient content claim, "Light," which in the context of the requirements of section 101.67, clearly describes the "nature of the substitute food" and "all the differences" from standardized butter "that are not apparent to the consumer."

FDA's well-established labeling policies with respect to butter substitutes are plain and unambiguous, and provide no grounds for the use of the term, "butter," to name a butter substitute that contains no butter, milk, cream or other milk constituents that comprise butter. Under these policies, plant-based dairy free butter substitutes that do not qualify as "margarine," must be labeled as "imitation butter" products if they are nutritionally inferior to standardized butter. Such products that are not nutritionally inferior may avoid "imitation butter" labeling, but must be named in a manner complies with section 102.5, including by avoiding any express or implied representation of the food as "butter."

III. Conclusion

None of the seven plant-based butter substitutes identified above comply with the applicable FDA labeling requirements. Some or all of these products may be subject to margarine labeling requirements for under the margarine standard of identity. All of these products are named in a manner that employs the term, "butter," in a manner that is false and misleading, and serves to offer the products for sale under the name of another food. As such, all of these products are misbranded under FDCA sections 403(a)(1) and 403(b). In addition, in the case that these butter substitutes are not subject to the margarine standard, no less than five of these products under FDCA section 403(c) for failing to comply with "imitation butter" labeling requirements.

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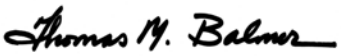
11 48 Fed. Reg. 37666, 37667 (August 19, 1983)(emphases added).

For the foregoing reasons, we urge FDA to take prompt enforcement action against the misbranded plant-based butter substitutes identified above.

Respectfully submitted,



Thomas M. Balmer
Executive Director

Cc: Dr. Susan Mayne, Director, FDA, Center for Food Safety and Applied Nutrition (CFSAN)
William Jones, Acting Director, Office of Food Safety, FDA-CFSAN
John F. Sheehan, JD, Director, Division of Dairy, Egg & Meat Products, FDA-CFSAN
Dr. Douglas Balentine, Director, Office of Nutrition & Food Labeling, FDA-CFSAN

2107 Wilson Blvd., Suite #600; Arlington, VA 22201 Phone: 703-243-5630; Fax: 703-841-9328