

June 25, 2025

Dr. Claudine Kavanaugh, Director Office of Nutrition and Food Labeling US Food and Drug Administration 5001 Campus Drive College Park, MD 20740 Sent via email to <u>Claudine.Kavanaugh@fda.hhs.gov</u>

Dear Dr. Kavanaugh,

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 Country Crock "Dairy Free" unsalted/salted butter product now available in the U.S. market (see labels in Appendix A further below). This product as labeled implies it is butter made without cow's milk – which is unlawful, according to Congress's definition of butter in 1906 as described subsequently in this letter. Because the Country Crock product's principal display panel prominently bears the term "Butter," includes an image of a traditional red barn associated with dairy farms and employs an image of butter, there can be no mistake about the marketer's intent to identify itself as butter, which is preferred by consumers, rather than what it really is, a plant-based spread similar to margarine.

The product offers the consumers two versions of what it is: first, it boldly calls itself "dairy free unsalted/salted butter." But it also offers in small writing on the package front that it is "79% plantbased oil spread." Butter, as written is law, can never be "dairy free" as it can only be made from cow's milk. Using the label of "dairy free" raises many concerns. Not only does it fool consumers in to believing that a "dairy free" version of butter could exist, but it also creates an idea that this product meets the standards that have been set for butter, when in fact it doesn't even meet the standard for margarine – itself an imitation of butter.

Regardless of the marketer's intended nomenclature for the product, it contains no butter, even as the labeling and accompanying vignette signify that it does. Consequently, the product's labeling not only is in direct conflict with FDA regulations and policies governing the labeling of foods, it also blatantly disregards the Congressionally-established standard of identity for butter. In reality, this product is nothing more than a vegetable spread, made from commonplace edible plant-based oils and other ingredients, that is attempting to leverage the premium perception of real dairy butter maintained by most consumers. The manufacturer is clearly trying to confuse the consumer about what this product is, an ultra-processed seed oil concoction.

## I. Product Summary

Country Crock "Dairy Free" unsalted/salted butter is marketed by Flora Food Company and manufactured in Johnson City, Kansas. According to the Country Crock website, this "butter" contains the follow ingredients: a blend of plant-based oils (palm fruit, palm kernel and canola oil), water, pea protein, glucose, sunflower lecithin, citric acid, natural flavors and beta carotene (color) (<u>https://www.countrycrock.com/en-us/our-products/homestyle-products/sticks-unsalted</u>). Appendix A includes photos of the products' labels. For the reasons discussed further below, we urge the agency to take prompt enforcement action against this misbranded product.

## II. FD&C Act Regulatory Framework for Naming Food Productsa. FD&C Act and FDA Common or Usual Name Requirements Generally

The federal standard of identity for "butter" is established by statute in 21 USC 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." FDA explained the purpose and implications of the "butter" standard in the preamble to proposed section 21 CFR 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, or 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.

The FD&C Act and FDA's 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 FD&C Act section 403(i)(1), a food product must be identified by "common or usual name . . ., if any there be." FD&C Act section 403(b) prohibits a food from being "offered for sale under the name of another food." FD&C Act 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." FD&C Act 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."

## b. FD&C Act Naming Requirements for Imitation and Substitute Foods

Under the FD&C Act and 21 CFR 101.3(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." The same regulation also speaks to this product's nutritional inferiority, by indicating that "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. According to the nutrition facts panel, the Country Crock "Dairy Free" Butter is "not a significant source of calcium" while a serving size of butter offers 3% of the reference daily intake, therefore making this ultra processed seed oil concoction a nutritionally inferior product, which should therefore be called an imitation.

## III. Conclusion

Based on the labeling violations cited above, the labeling of this product must either be corrected, or the product should be withdrawn from sale as a false and misleading product. The use of the term "dairy free" on an imitation product in addition to the use of "butter" without appropriate modification (e.g., "artificially flavored," "imitation," or "substitute") in the statement of identity confuses consumers and leads them to believe this product actually contains/is butter when in reality it is not. This plant-based spread fails to meet the standard of identity for butter while not containing a single ingredient specified in the Congressional Butter Act defining butter. In an egregious attempt to mislead consumers into believing this product is or contains butter, the marketer has violated several Federal food labeling regulations promulgated under the FD&C Act, and should be held accountable for their inappropriate actions.

For the foregoing reasons, we urge FDA to take prompt enforcement action against the misbranded ultra processed seed oil spread identified above.

Sincerely,

Christopher Galen Executive Director, American Butter Institute

CC: Nutrition Center of Excellence - Dr. Robin A McKinnon <u>Robin.McKinnon@fda.hhs.gov</u> Deputy Commissioner for Human Foods – Kyle Diamantas, JD <u>deputycommissionerforhumanfoods@fda.hhs.gov</u>

Appendix A.



