



December 13, 2019

Division of Dockets Management
Department of Health and Human Services
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

CITIZEN PETITION

The undersigned, Upfield US Inc. and its affiliates (“**Upfield**”), submit this petition under sections 401 and 701(e) of the Federal Food, Drug, and Cosmetic Act (“FD&C Act”), 21 U.S.C. §§ 341 and 371(e), to request the Food and Drug Administration (“**FDA**” or the “**agency**”) to amend the standard of identity for margarine, 21 C.F.R. § 166.110, to include new optional ingredients, new nutritional criteria, and modified nomenclature.

The goals of this petition are to:

- (1) modernize the margarine standard;
- (2) encourage manufacturers to produce more healthful foods;
- (3) meet consumer expectations; and
- (4) promote honesty and fair dealing in the marketplace.

These goals will make the standard clearer and less restrictive, advance industry innovation and encourage manufacturers to produce more healthful foods, while at the same time promoting honesty and fair dealing in the interest of consumers, as required by 21 C.F.R. § 130.5(b).

Upfield is a global leader in plant-based nutrition and the premier producer of plant-based spreads globally. Our mission is to make people healthier and happier with great tasting plant-based food. Our products include Country Crock, I Can't Believe It's Not Butter, Promise, Imperial, Brummel & Brown, and Pure Blends in the United States, and other brands around the world.

We are deeply committed to these products and the role of plant-based nutrition in promoting both healthy diets and sustainable agriculture. Our goal is to make it easier for consumers to make good dietary choices by giving them delicious and better-for-you plant-derived food options.

A. Action Requested

Upfield requests that FDA amend the standard of identity for margarine, 21 C.F.R. § 166.110, as described in Appendix A.

B. Statement of Grounds

(1) Granting the petition will modernize the margarine standard

The petition proposes a number of changes to make the standard clearer, more flexible and less restrictive when formulating new products. It is proposed that:

- (i) In 21 C.F.R. § 166.110(a), the phrase “food in **plastic form** or liquid emulsion” is changed to “food in **smooth, semisolid** or liquid emulsion.” The origin of “**plastic form**” was as a scientific descriptor, as an adjective. This now only serves to create consumer misunderstanding that “**plastic**” ingredients are used in the food, namely “**plastic**” as a noun. As such, the current wording of the standard positions margarine at a competitive disadvantage as compared to other emulsified foods that are not burdened by such a regulatory description that is prone to being misconstrued. Such an encumbrance stifles investment and innovation as well as causing consumer confusion.

The requested change to “**smooth, semisolid**” is consistent with FDA’s drafting conventions, such as the standard of identity for Fruit Butter, which is described as a “**smooth, semisolid**” food.¹

Implementing the requested change would eliminate consumer misunderstanding and the consequent competitive disadvantage currently experienced by margarine manufacturers whilst maintaining a description that is clear and consistent with FDA precedent.

- (ii) In 21 C.F.R. § 166.110(a) and (c), the nomenclature for margarine is revised to delete the alternative name “oleomargarine”. The term “oleomargarine” is obsolete, limited in use to describing the historical context of the food. The archaic nature of this term is reflected in recent dictionary entries; for example, the Collins Dictionary describes it as the “former term for margarine”² and the Webster’s College Dictionary describes it as an “older use.”³ As a practical matter, it has not to our knowledge been used for many years in the U.S. marketplace.
- (iii) In 21 C.F.R. § 166.110(b)(1), optional ingredients are revised to include any safe and suitable ingredient for purposes of nutrient addition. This change will ensure that margarine, like non-standardized spreads, may be fortified consistently with FDA’s rules governing nutrient content claims and the fortification policy.

¹ See 21 C.F.R. § 150.110 (“Fruit Butter. (a) The fruit butters for which definitions and standards of identity are prescribed by this section are the smooth, semisolid foods ...”).

² Collins Online English Dictionary, available at

<https://www.collinsdictionary.com/dictionary/english/oleomargarine> (American English definition for “oleomargarine”; last viewed Dec. 3, 2019).

³ Random House Kernerman Webster’s College Dictionary (2010), available at

<https://www.thefreedictionary.com/oleomargarine> (definition for “oleomargarine”; last viewed Dec. 3, 2019).

- (iv) In 21 C.F.R. § 166.110(a)(1), changes are made to clarify that “vegetable oils” include oils from algae and that physical and/or chemical modifications (and not necessarily both) are permitted.
- (v) In 21 C.F.R. § 166.110(b)(2), changes are made to clarify that a salt may include potassium chloride.
- (vi) In 21 C.F.R. § 166.110(a)(2)(iv), the word “oil” is added that appears to be missing from the current regulation.

(2) Granting the petition will encourage manufacturers to produce more healthful foods

As recognized by the U.S. Dietary Guidelines Advisory Committee, “a dietary pattern that is higher in plant-based foods and lower in animal-based foods is more health promoting....”.⁴ Recent studies support this conclusion, finding that plant-based diets are associated with lower risk of cardiovascular diseases and morbidity and improved cardiovascular risk profile.⁵ Plant-based diets have also been associated with weight loss⁶ and a lower prevalence of hypertension⁷ and Type 2 diabetes.⁸ For example, a recent systematic review and meta-analysis found that greater adherence to an “overall” predominantly plant-based diet reduced the risk of Type 2 diabetes by 23 percent.⁹

The movement toward plant-based diets includes replacing animal-derived fats with plant oils. The current *Dietary Guidelines for Americans* (2015-2020) encourage the consumption of oils as part of a healthy eating pattern. By “oils,” the *Dietary Guidelines* mean fats that contain a high percentage of monounsaturated and polyunsaturated fats, a low percentage of saturated fat, and are liquid at room temperature. The *Dietary Guidelines* specifically state that “[o]ils should replace solid fats.” In short, as part of a healthy eating pattern, “replacing butter, lard and ghee with oils rich in polyunsaturated fats, such as soybean, canola (rapeseed), corn, safflower and sunflower

⁴ Scientific Report of the 2015 Dietary Guidelines Advisory Committee, Advisory Report to the Secretary of Health and Human Services and the Secretary of Agriculture (Feb. 2015) at 9, available at: https://ods.od.nih.gov/pubs/2015_dgac/scientific_report.pdf.

⁵ Ambika Satija & Frank Hu, Plant-based diets and cardiovascular health, 28 Trends in Cardiovascular Med. 437 (2018) (“Satija 2018”); Hyunju Kim et al., Plant-Based Diets Are Associated With a Lower Risk of Incident Cardiovascular Disease, Cardiovascular Disease Mortality, and All-Cause Mortality in a General Population of Middle-Aged Adults, 8 J Am Heart Assoc. 16 (Aug. 7, 2019).

⁶ YM Lee, et al., Effect of a brown rice based vegan diet and conventional diabetic diet on glycemic control of patients with type 2 diabetes: A 12-week randomized clinical trial, PLoS One, 2016 Jun 2; 11(6); GM Turner-McGrievy, et al., Comparative effectiveness of plant-based diets for weight loss: A randomized controlled trial of five different diets, Nutrition 2015 Feb; 31(2).

⁷ PN Appleby, et al., Hypertension and blood pressure among meat eaters, fish eaters, vegetarians and vegans in EPIC-Oxford, Public Health Nutr 2002 Oct; 5(5):645-54; SE Berkow & ND Barnard, Blood pressure regulation and vegetarian diets, Nutr Rev 2005 Jan; 63(1):1-8.

⁸ S Tonstad, et al., Type of vegetarian diet, body weight, and prevalence of type 2 diabetes, Diabetes Care 2009 May; 32(5):791-6; LT Le & J Sabate, Beyond meatless, the health effects of vegan diet: Findings from the Adventist cohorts, Nutrients 2014 May 27;6(6): 2131-47.

⁹ Frank Qian et al., Association Between Plant-Based Dietary Patterns and Risk of Type 2 Diabetes, JAMA Intern Med. Published online July 22, 2019. doi:10.1001/jamainternmed.2019.2195.

oils”¹⁰ is advised by the World Health Organization. These are the type of oils contained in margarine.

As then FDA Commissioner Scott Gottlieb, M.D., stated in July 2018:

The food industry is innovating to give people more of what they want, and we need to encourage this trend. I believe that FDA can help advance the public health by both empowering consumers with information and facilitating industry innovation toward healthier foods that consumers want.¹¹

Modernizing the margarine standard of identity will incentivize manufacturers to invest in development of innovative margarines. Innovation in this category would be consistent with FDA’s Nutrition Innovation Strategy, fostering market forces in the development of healthier opportunities at an affordable cost.

(3) Granting the petition will meet consumer expectation

In recent years, consumers have shifted their diets to be increasingly plant-based.¹² As many as 39% of Americans are actively trying to eat more plant-based foods.¹³ Globally, consumers demonstrate positive attitudes towards plant-based products for reasons as varied as the promotion of long-term and day-to-day health, disease prevention, increased energy, sustainability and animal welfare.¹⁴ On top of this, various consumers choose plant foods over their dairy counterparts for religious reasons or as a result of allergies and intolerances (like lactose or casein intolerance). As a recent study concluded, “[t]he consistent beneficial associations observed with a wide variation of plant-based diets . . . allows for personalized and culturally relevant applications of dietary recommendations.”¹⁵

¹⁰ World Health Organization (WHO) Healthy Eating Factsheet 2019, available at <https://www.who.int/news-room/fact-sheets/detail/healthy-diet> (last viewed Dec. 3, 2019).

¹¹ Remarks by Scott Gottlieb, M.D., Commissioner of Food and Drugs, FDA’s Comprehensive Multi-Year Nutrition Innovation Strategy, Rockville, MD (July 26, 2018).

¹² A recent consumer survey conducted by the International Food Information Council (IFIC) showed that nearly 75% of consumers surveyed had heard of plant-based diets and nearly 50% of consumers surveyed stated they wanted to learn more about plant-based diets. IFIC, 2019 Food & Health Survey (May 2019), available at: <https://foodinsight.org/wp-content/uploads/2019/05/IFIC-Foundation-2019-Food-and-Health-Report-FINAL.pdf>. FDA has also recognized the “rising demand for plant-based products,” which “has created a growing number of new food choices in supermarket aisles.” See Statement from FDA Commissioner Scott Gottlieb, M.D., on modernizing standards of identity and the use of dairy names for plant-based substitutes (Sept. 27, 2018), available at: <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm621824.htm>.

¹³ See Plant-Based Food Options are Sprouting Growth for Retailers, Nielsen FMCG and Retail (June 13, 2018), available at: <https://www.nielsen.com/us/en/insights/news/2018/plant-based-food-options-are-sprouting-growth-for-retailers.html> (“Nielsen FMCG and Retail Data”).

¹⁴ HealthFocus: Navigating the World of Plant: Understanding Shopper Attitudes Towards Plant-Based Foods & Beverages (June 2019), available at https://www.healthfocus.com/wp-content/uploads/2019/06/2019-HealthFocus-Global-Report_-Navigating-the-World-of-Plant_-FREE-EXCERPT.pdf (“HealthFocus data”).

¹⁵ Satija 2018.

Environmental sustainability has become a major driver in consumers' shift to plant-based diets. 48% of U.S. consumers are likely to make choices for environmental reasons, with the market for sustainable products estimated at \$150 billion by 2021.¹⁶

Regardless of why consumers are choosing plant foods, plant-based eating is "gaining particular prominence" among Americans, and in particular with young and diverse consumer groups.¹⁷ According to data commissioned by the Plant Based Foods Association (PBFA), from April 2018 to April 2019, U.S. plant-based food dollar sales grew by 11% with sales topping \$4.5 billion (as compared to the total U.S. retail food market growing by 2% in dollar sales during the same period).¹⁸ Since April 2017, total U.S. plant-based food sales have increased by 31%.¹⁹

Modernizing the margarine standard, at a time when consumers are actively seeking plant alternatives to dairy foods, will make it easier for consumers to identify and choose foods that are right for them.

(4) The petition would promote honesty and fair dealing in the marketplace.

Granting this petition will make the margarine standard clearer and less restrictive and eliminate consumer confusion. These changes will promote industry innovation and provide flexibility to encourage manufacturers to produce more healthful foods, while at the same time protecting consumers against economic adulteration and maintaining the basic nature, essential characteristics and nutritional integrity of the food. For these reasons, granting the petition would promote honesty and fair dealing in the interest of consumers.

On November 12, 2019, Upfield submitted a comment in response to FDA's request for comments on horizontal approaches to food standards of identity modernization.²⁰ In our comment, we recommended that FDA adopt a horizontal standard of identity that establishes criteria to be met for naming plant-derived food products with appropriately qualified, standardized names of animal-derived foods. Such appropriate descriptors may include "plant," "vegan," "dairy-free," and so forth. Our comment noted the importance of ensuring that foods labeled with descriptors such as "plant" be made of 100% plant ingredients (other than those ingredients that are neither plant-derived nor animal-derived, such as water and salt). The adoption of this approach would

¹⁶ See Nielsen, Was 2018 The Year of the Influential Sustainable Consumer? (Dec. 17, 2018), available at: <https://www.nielsen.com/us/en/insights/article/2018/was-2018-the-year-of-the-influential-sustainable-consumer/>.

¹⁷ See Nielsen FMCG and Retail Data.

¹⁸ In 2019, PBFA commissioned SPINS, a wellness-focused data technology company and retail analytics provider, to collect retail sales data to provide a snapshot of the annual growth and revenue from plant-based alternatives. See PBFA Press Release, U.S. Plant-Based Retail Market Worth \$4.5 Billion, Growing at 5X Total Food Sales (July 12, 2019), available at: <https://plantbasedfoods.org/2019-data-plant-based-market/> ("SPINS PBFA Data"). PBFA is a trade association that represents the interests of companies producing meat and dairy alternatives. The SPINS PBFA Data specifically looked at retail sales of plant-based foods that directly replace animal products, including meat, seafood, eggs, and dairy, as well as meals that contain plant-based alternatives.

¹⁹ Id.

²⁰ Horizontal Approaches to Food Standards of Identity Modernization; Public Meeting; Request for Comments, 84 Fed. Reg. 45,497 (Aug. 29, 2019), Docket No. FDA-2018-N-2381-1371. Upfield's comment may be found at the following link: <https://www.regulations.gov/document?D=FDA-2018-N-2381-1400>.

“boost” transparency and increase consumer confidence in plant foods. Thus, manufacturers would be encouraged to further invest in research and development for new plant foods and ingredients. Our comment noted that such a horizontal standard would be useful for purposes of establishing uniform criteria for terms that are already common in the marketplace, such as “soy milk,” “vegan yogurt” and “plant butter.”

The amendment to the margarine standard proposed by this petition is consistent with our November 12, 2019 comment on qualified descriptive names for standardized foods. As our comment pointed out, such an approach would help consumers select the plant-based products they want and would thereby promote honesty and fair dealing in the interest of consumers within the meaning of 21 U.S.C. § 341.

C. Environmental Impact

Preparation of an environmental assessment is not required for a petition to establish or amend a food standard. 21 C.F.R. § 25.32(a).

D. Economic Impact

Economic impact information will be submitted upon request of the Commissioner.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition. Pursuant to 21 C.F.R. § 130.5(c), petitioner commits to substantiate the information in the petition by evidence in a public hearing, if such a hearing becomes necessary.

Respectfully submitted,


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