PLANT BASED FOODS ASSOCIATION

COMMENTS
RE LABELING OF PLANT- BASED ALTERNATIVES TO ANIMAL-DERIVED FOODS: DRAFT GUIDANCE FOR INDUSTRY

(DOCKET NO. FDA-2022-D-1102)

MAY 7, 2025

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VIA ELECTRONIC SUBMISSION (*www.regulations.gov*)

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Labeling of Plant- Based Alternatives to Animal-Derived Foods: Draft Guidance for Industry (Docket No. FDA-2022-D-1102)

Dear FDA:

The Plant Based Foods Association ("PBFA") submits these comments in response to the Draft Guidance issued by the U.S. Food and Drug Administration ("FDA") on "Labeling of Plant-Based Alternatives to Animal-Derived Foods" (the "Draft Guidance"), a matter that significantly impacts the plant-based foods industry.

PBFA is the first and only trade association in the U.S. representing the plant-based food industry, an industry that generates $8 billion in retail sales across more than 20 product categories. We currently represent nearly 200 of the nation's leading plant-based food companies. Ensuring a fair marketplace for the plant-based industry is core to our work.

The Draft Guidance creates an unfair and uneven playing field in the marketplace by singling out plant-based alternatives for unique regulatory treatment without any legitimate basis. Such targeted regulation places unnecessary burdens on the plant-based industry while offering no benefit to consumers or the market. The FDA has not provided any evidence suggesting that consumers are confused about the names of plant-based products.

We urge the FDA, under HHS Secretary Kennedy's leadership, to withdraw the Draft Guidance and instead continue supporting the use of simple, clear and consumer-friendly product names such as "veggie burger," which have been long understood by consumers and promote clarity in the marketplace.

We discuss our concerns with the Draft Guidance in more detail below.

I. THE DRAFT GUIDANCE IS UNPRECEDENTED AND UNFAIR

The Draft Guidance imposes new, unnecessary obligations for plant-based alternatives that diverge significantly from current FDA practices and lack regulatory precedent. These novel obligations would serve only to stifle innovation and undermine the principles of fairness and consistency that are critical to consumer protection and market competitiveness.

A. THE DRAFT GUIDANCE IS INCONSISTENT WITH EXISTING REGULATION

The stated aim of the Draft Guidance is to ensure that the labeling and names of "plant-based alternatives" are "truthful and not misleading and accurately describe the food." As discussed in Section IIA below, existing regulations already achieve these objectives. The Draft Guidance goes further, however, by imposing a unique obligation on plant-based foods to specify their specific plant source(s) in their product names. It offers examples such as "Chickpea & Lentil-Based Fish Sticks," "Chia & Flax Seed Eggless Scramble," and "Black Bean Mushroom Veggie Patties." This approach, along with these overly complex product names, deviates from the FDA's regulation of other foods.

FDA regulations require a product's statement of identity to be the standardized name established by any applicable law or regulation, or if there is none, the common or usual name of the food, or if there is none, an appropriately descriptive term.[1] The regulation on "common or usual names" provides that such name should be "in as simple and direct terms as possible" and should describe "the basic nature of the food ***or*** its characterizing properties ***or*** ingredients."[2] These are flexible regulations that do not require any specific information in the statement of identity of a non-standardized food; rather, they emphasize simplicity.

To wit, the FDA does not require specific information in the names of other types of food products. For example:

- **"Cereal" (and "Grain Free Cereal")**. The FDA permits breakfast foods of many types to be identified as "cereal" without the specific grain. It even permits the product name "grain free cereal," which seems like an oxymoron, without specifying substitute ingredient(s).

- **"Non-Dairy Creamer."** The FDA permits creamers and other products to use "non-dairy" product names without requiring the disclosure of the substitute ingredient(s). In fact, the FDA allows the term "non-dairy" even when products contain sodium caseinate, a dairy derivative – creating potential confusion for consumers, including those with dairy allergies. It is assumed that consumer confusion (and the related safety risk) is avoided because the milk allergen is listed in the ingredient and allergen statements on back of pack.[3]

[1] 21 CFR § 101.3 (b).
[2] 21 CFR 102.5 (a) (emphasis added).
[3] 21 CFR 101.4(d).

- **"Vegetable Oils."** The FDA allows oils, such as soybean oil or canola oil, to use the name "vegetable oil" without requiring the specific vegetable source(s) – even where made from just one – outside of the ingredient statement. In other words, soybean oil can use the statement of identity "vegetable oil" with the ingredient statement: "Ingredients: soybean oil."

Nor does FDA require other alternatives to standardized products to identify their source in their product name. For example:

- **"Gluten Free Bread."** "Bread" is defined as containing wheat flour[4] and the FDA allows alternatives to simply be called "gluten free bread" and the specific ingredient(s) that are used instead of wheat flour must only be listed in the ingredient statement.

- **"Chinese Noodles."** "Noodles" is defined as prepared from specific flours and containing egg, along with other optional ingredients.[5] Yet, the FDA allows "oriental noodles" that do not meet this definition to simply be called "Chinese Noodles," "Chow Mein Noodles," or "Ramen Noodles," without any indication of how these products differ in composition from standardized "noodles."[6]

- **"Sugar Free Milk Chocolate."** "Milk chocolate" is defined as using only nutritive carbohydrate sweeteners. Yet, the FDA permits the product name "sugar free milk chocolate" with non-nutritive carbohydrate sweeteners, such as aspartame or stevia, only listed in the ingredient statement.

Even "imitation" foods are not required to specify their substitute ingredients in their product name. Instead, FDA regulations simply mandate that "imitation" foods – those that substitute for and resemble another food but are nutritionally inferior – include the word "imitation" before the name of the food they imitate.[7]

The FDA has long affirmed that plant-based foods are not "imitations." As early as 1973, the agency explained, "[T]he term 'imitation' suggests an inferior product….'in the sense that it is cheapened by the substitution of ingredients.' Vast strides in technology have taken place since…it is no longer the case that such food products are necessarily inferior to the traditional foods for which they may be substituted."[8] Modern courts agree. The Ninth Circuit has stated: "Almond milk is not an 'imitation' of dairy milk…. Notwithstanding any resemblance to dairy milk, almond milk is not a 'substitute' for dairy milk as contemplated by section 101.3(e)(1) because almond milk does not involve literally substituting inferior ingredients for those in dairy milk."

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[4] 21 CFR 136.110 (defining "bread" as produced by baking "dough" prepared from "flour"); 21 CFR 137.05 (defining "flour" as prepared from wheat).

[5] 21 CFR 139.150

[6] CPG Sec. 505.400 Chow Mein Noodles and other Oriental Noodles (Labeling).

[7] 21 CFR 101.3(e).

[8] 38 Fed. Reg. 2138, January 19, 1973.

If "imitation" products – those that "involve literally substituting inferior ingredients" – are not obligated to specify their substitute ingredients in their product names, it is irrational to impose such an obligation on non-inferior plant-based products.

For consistency with existing regulations favoring "simple and direct terms" in statements of identity[9]– and in line with the approach used for other products – the FDA should continue to allow names like "Veggie Burger," "Plant-Based Fish Sticks," and "Eggless Scramble."

B. UNIQUE OBLIGATIONS FOR "PLANT-BASED ALTERNATIVES" ARE ANTI-COMPETITIVE

The Draft Guidance's unique obligations for plant-based alternatives – requiring the specification of specific plant sources in product names – introduce a fundamentally unfair and anti-competitive framework. By singling out and imposing unique obligations on plant-based products, the FDA is creating an unequal playing field in the marketplace. This inconsistency in regulation undermines the principles of fair competition.

Moreover, these unique regulations risk disincentivizing innovation within the plant-based sector. The need to list specific plant ingredients in product names could limit the creativity and flexibility of manufacturers that are increasingly utilizing multiple plant-based ingredients to achieve new heights in flavor and nutritional composition. By placing these labeling restrictions on plant-based products, the FDA may discourage the development of new and diverse alternatives, ultimately stifling the growth and evolution of the plant-based food industry.

II. THE DRAFT GUIDANCE IS NOT REASONABLY RELATED TO ANY LEGITIMATE FDA CONCERN

The First Amendment "demands proof" that labeling obligations are, at the very least, reasonably related to a genuine FDA concern.[10] The Draft Guidance is not grounded in any legitimate concern. Instead, it appears to be a solution in search of a problem.

A. EXISTING REGULATIONS ARE SUFFICIENT TO PREVENT DECEPTION AND INFORM CONSUMERS

The stated aim of the Draft Guidance is to ensure that the labeling and names of "plant-based alternatives" are "truthful and not misleading." It supposedly addresses two areas of concern: (1) preventing consumers from being misled into thinking products contain animal ingredients, and (2) informing consumers of the specific plant source(s). However, existing laws and regulations already address both of these unfounded concerns.

If a plant-based product's name misled consumers into thinking the product contained animal ingredients, this would already constitute misbranding under federal law[11], rendering the Draft

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[9] 21 CFR 102.5 (a).

[10] *Miyoko's Kitchen v. Ross*, No. 20-CV-00893-RS, 2021 WL 4497867 (N.D. Cal. Aug. 10, 2021).

[11] 21 USC 343(a)(1) (prohibits false and misleading labels), 21 USC 343(g) (prohibits representing a product as a food that has a standard of identity, unless it conforms to that standard).

Guidance unnecessary. Furthermore, the supposed concern that consumers are misled by plant-based product names is baseless.

Courts have consistently rejected claims that the plant-product names mislead consumers into thinking the products contain animal ingredients, ruling that even the "least sophisticated" consumers would not be confused and that consumers choose plant-based products specifically because they lack animal ingredients.[12] In fact, in other draft guidance documents, the FDA itself has concluded that consumers are not misled into thinking that plant-based alternatives contain animal ingredients.[13]

Regarding the second alleged concern, the Draft Guidance is unnecessary because if consumers want to know the specific plant source(s), they can simply refer to the product's ingredient list. Existing regulations require all food products to list all their ingredients on their label in descending order of predominance by weight.[14]

B. FDA PROVIDES NO BASIS FOR IMPOSING UNIQUE AND UNFAIR OBLIGATIONS ON "PLANT BASED ALTERNATIVES"

The FDA provides no justification for imposing unique product naming obligations on "plant-based alternatives." The Draft Guidance simply asserts that statements of identity for "plant-based alternatives" should "inform consumers of the specific plant source" because "consumers should be able to readily observe this information when reading the label."

The FDA fails to explain why consumers of plant-based products need this additional information on the front of pack more than consumers of other food products. For instance, why would consumers of "gluten free" breads or noodles not be equally interested in knowing the source of ingredients?

The FDA does not even claim that consumers are confused about the ingredients of plant-based products. Rather, the agency suggests that consumers may want more information, but this alone does not justify imposing unique and burdensome labeling obligations on a category of products. The lack of evidence for consumer confusion or a legitimate need for this level of detail makes these proposed requirements both unfair and unnecessary.

C. THE RECOMMENDED STATEMENTS OF IDENTITY WOULD CONFUSE CONSUMERS

The Draft Guidance's recommended statements of identity, such as "Chickpea & Lentil-Based Fish Sticks" and "Chia & Flax Seed Eggless Scramble," are overly complex and more likely to confuse consumers than inform them. Consumers already understand widely accepted terms like

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[12] *Ang v. WhiteWave Foods Co.*, 2013 WL 6492353 (N.D. Cal. Dec. 10, 2013); *Gitson v. Trader Joe's Co.*, 2015 WL 9121232 (N.D. Cal. Dec. 1, 2015).

[13] Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements: Guidance for Industry (February 2023) ("The comments and information we reviewed indicate that consumers, generally, do not mistake plant-based milk alternatives for milk."

[14] 21 CFR 101.22

"Plant-Based Fish Sticks" or "Eggless Scramble" without requiring an exhaustive list of ingredients in the product name. Overloading product names with specific plant sources creates clutter, making labels harder to read and process at a glance. Rather than enhancing transparency, this approach could lead to greater uncertainty, making it more difficult for consumers to quickly identify and compare plant-based options. In contrast, simple and direct names align with existing labeling norms and better support informed decision-making.

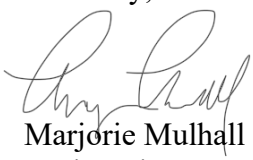
III. THE SCOPE OF THE DRAFT GUIDANCE IS UNCLEAR

Finally, the scope of the Draft Guidance is unclear, as it does not define what constitutes "plant-based alternatives." Without a clear definition, it is difficult to determine exactly which products the guidance applies to. The Draft Guidance does not specify whether it applies when a product includes the standard of identity of another product in its statement of identity, or when it uses the common or usual name of another product, or whether it extends beyond these situations. For example, the Draft Guidance appears to cover products like "veggie patties," which are not necessarily an alternative to any animal-derived food. This lack of clarity in scope would create confusion for manufacturers.

IV. CONCLUSION

In conclusion, the proposed Draft Guidance imposes unnecessary obligations on the plant-based food industry without justification – singling out plant-based alternatives and disrupting principles of fairness, competition, and innovation in the marketplace. Existing regulations already ensure that plant-based products are labeled truthfully and transparently. We urge the FDA to reconsider this Draft Guidance and withdraw it.

Sincerely,



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