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Dockets Management Staff (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Re: Labeling of Plant-Based Alternatives to Animal-Derived Foods: Draft Guidance for Industry; Docket No. FDA-2022-D-1102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 Sir or Madam:

Thank you for the opportunity to comment on the Food and Drug Administration's (FDA's) guidance entitled "Labeling of Plant-based Alternatives to Animal-Derived Foods: Draft Guidance for Industry." As the food industry association, FMI works with and on behalf of the entire industry to advance a safer, healthier, and more efficient consumer food supply chain. FMI brings together a wide range of members across the value chain — from retailers that sell to consumers, to producers that supply food and other products, as well as the wide variety of companies providing critical services — to amplify the collective work of the industry. More information about our organization is available at www.FMI.org.

FMI shares FDA's commitment, as stated in the draft guidance, to providing consumers with information to enhance their ability to make informed choices about the foods they buy and eat. Health and nutrition are of the utmost importance to the food industry and for years, FMI and its members have recognized the need to help consumers navigate the varying labeling attributes on today's products. We remain committed to transparency for consumers and continuously strive to label plant-based foods in a way that is clear and understandable to consumers.

General Comments

As noted above, FMI shares FDA's goals of supporting clear and transparent labeling that will help consumers make well-informed purchasing decisions to help meet their dietary needs and support healthy eating patterns. We also appreciate FDA's recognition of the developments in both availability and consumption of plant-based alternatives, and the important reasons, such as allergies, religious practices, taste preferences, environmental concerns, or dietary choices (e.g., vegan/vegetarian diets), that consumers select these products.

As an initial comment, FMI appreciates FDA's guidance-based approach, as opposed to rulemaking. As FDA notes in its draft guidance, research indicates that 70% of the U.S. population

is consuming plant-based foods and U.S. plant-based sales numbers have increased significantly in recent years. FDA appropriately recognizes that the predominant ingredients in these products vary widely, and may consist of legumes, tree-nuts, seeds, grains, starches, fungi, fruits, or vegetables alone or in combination with other ingredients. Given the diversity of products and plant-based ingredients, the rapid pace of innovation in the plant-based alternatives category, and the ongoing evolution of nutrition recommendations, rulemaking would present significant challenges, as it could be outdated before it is even finalized.

However, we question why guidance on the naming of plant-based foods is necessary, as we believe current labeling conventions are effective at this time. Plant-based alternatives to animal-derived foods are currently subject to a number of statutory and regulatory provisions that require these foods to be labeled and named in ways that are truthful and not misleading. 21 U.S.C. 343(a) and (i)(1); 21 CFR 101.3; 21 CFR 102.5(a). Any labeling of an alternative product, whether it be plant or animal based, is already required to use a name that distinguishes the food from the standardized food or from different food products. 21 CFR 102.5(a). The industry has many effective ways to disclose that a product is plant-based in ways that consumers understand. Demand for plant-based foods has rapidly increased in recent years and companies have an incentive to distinguish their product as an alternative to animal products: so consumers seeking those plant-based alternatives can quickly and easily identify them. Given the fast-paced innovation in alternative food products, we recommend that instead of issuing guidance on this topic, the agency maintain the flexible, case-by-case review of the specific context for individual products to ensure that all claims are truthful and not misleading remains more appropriate and consistent with First Amendment principles.

In the event FDA disagrees and moves forward with a final guidance on the labeling of plant-based alternatives, we believe it is particularly important for FDA to make clear that the Q&As in the guidance represent merely examples and are not intended to restrict the appropriate product names to only those examples listed in the guidance, and to ensure the guidance reflects the significant flexibility in FDA's binding naming regulations. We also request that FDA clarify that plant-based alternative foods include vegetarian foods that may contain animal-derived ingredients, such as eggs or milk.

FMI also appreciates that FDA has issued a separate draft guidance document to address plant-based foods other than plant-based milk alternatives, given that the considerations for plant-based milk alternatives may differ. In particular, we support that FDA has not recommended a labeling statement related to potential nutritional differences between plant-based alternatives and their animal-derived counterparts. A case-by-case review of the specific context for individual products to ensure that all claims are truthful and not misleading remains more appropriate and consistent with First Amendment principles. Additionally, such a statement regarding nutritional differences would not be necessary given the wide variety of reasons unrelated to nutritional consumers select these products, including allergies, intolerances, lifestyle choices, and other preferences.

Specific Comments and Request for Additional Clarification

1. **Imitation Food Labeling Regulation Does Not Apply**

FDA is on strong ground in not applying the imitation food labeling regulation to plant-based alternatives to animal-derived foods. Imitation foods are defined as those that "substitute for and resemble[] another food but [are] nutritionally inferior to that food." Section 403(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 343(c)) deems a food 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.

In its plant-based milk alternatives draft guidance, FDA states that when section 403(c) of the FD&C Act (21 U.S.C. 343(c)) was enacted in 1938, Congress was seeking to protect the consumer from uninformed purchase of an inferior substitute product which could be mistaken for a traditional food product.[1] The Agency further recognizes that consumers generally do not mistake plant-based milk alternatives as milk and often purchase plant-based milk alternatives because they are not milk (e.g., lactose intolerance, vegan diet). Based on the fact that not all plant-based alternatives meet the definition of imitation foods, and the Agency's conclusion that consumers generally do not mistake these products for milk even when they do, FDA indicated that it intends to exercise enforcement discretion for those products that might otherwise trigger the requirements of the imitation food labeling regulation.

FDA should apply this same logic here, as it has similarly recognized that consumers purchase plant-based alternatives to alternatives to eggs, seafood, poultry, meat, and dairy products (excluding plant-based milk alternatives) for a multitude of reasons, many having nothing to do with nutritional content (e.g., allergies, religious practices, taste preferences, environmental concerns, or dietary choices like vegan/vegetarian diets). We ask that FDA similarly communicate in any final guidance document that the imitation food labeling regulation does not apply to plant-based alternative foods covered by the draft guidance, or that in any case, FDA plans to exercise enforcement discretion with respect to such foods.

2. **Common or Usual Naming Principles**

The draft guidance also contains discussion of the common or usual naming principles that is helpful in a number of respects. As numerous examples illustrate, the mere use of an animal-derived or standardized food term on a food label does not necessarily represent the food as being animal-derived, nor does it necessarily subject a food to a standard of identity, provided the conventional or standardized term is sufficiently qualified to distinguish the product from the

[1] See *Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements: Guidance for Industry*, Food and Drug Administration Center for Food Safety and Applied Nutrition (February 2023).

standardized food.[2] The use of an animal-derived or standardized term on a label must be read in the context of the entire statement of identity, the label as a whole, and the nature of the food. This can include, but is not limited to, the use of voluntary descriptive terms and qualifiers, such as "plant-based", "vegetarian," "veggie," "vegan," and others. We encourage FDA to expressly discuss this principle about context in the background section of the guidance. FDA has not presented evidence that consumers are confused with these names.

As discussed further below, we also ask FDA to expressly recognize that the common or usual naming principles provide significant inherent flexibility, including to use a name that has been established by common usage, as well as to use an appropriately descriptive name or fanciful term where no common or usual name exists.

3. Guidance Suggesting Product Names Should Always Identify Plant-Based Sources Does Not Reflect the Flexibility in FDA's Naming Regulations.

FDA's draft guidance does not fully reflect the flexibility provided in the naming regulations. FDA should not suggest that specific ingredient callouts for plant-based sources are always recommended in a common or usual name. Rather, FDA should recognize the case-by-case nature of the assessment, which is largely guided by the specific product at issue, including which ingredients if any are characterizing, the number of plant-based sources, and other factors. For a guidance document, examples should be flagged as appropriate possibilities and not as the only means of compliance, consistent with Good Guidance Practices and First Amendment principles for commercial speech.

More broadly, as FDA considers whether and how to finalize the guidance, we urge the agency to keep in mind the flexibility offered by FDA's naming regulations, which implement the statutory requirement that non-standardized foods be labeled by their "common or usual name." 21 U.S.C. 343(i)(1); 21 CFR 101.3; 21 CFR 102.5. The regulations provide, more specifically, that a non-standardized food must be labeled by its common or usual name, or if one does not exist, by an appropriately descriptive term, or when the nature of the food is obvious, a fanciful name. 21 CFR 101.3(a). Further, a common or usual name may be established either by FDA regulation or by common usage. 21 CFR 102.5(d). The common or usual name must identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients. The name must be uniform among all identical or similar products, and must distinguish the food from different foods. Aside from the product name, a product may bear

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[2] For example, FDA has recognized that "yogurt drink" is not subject to the yogurt standard of identity (FDA Memoranda to National Conference of Interstate Milk Shippers, Memoranda of Information M-I 10-6 June 17, 2010 (Q&A), at 4, http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM216462.pdf) and that a product can bear the term "mayo" so long as it bears the statement "spread and dressing" to distinguish it from standardized mayonnaise (*See* FDA close out letter to the August 12, 2015 Warning Letter issued to Hampton Creek Foods). Likewise, examples such as "bread" show that qualified standardized terms can be used as part of product names (e.g., without invoking the relevant standards).

truthful and non-misleading labeling claims or qualifiers to the product name, including terms such as vegan, plant-based, and others.

To give a few examples, "veggie burger" and "plant-based burger" are both long-established common or usual names that are simple, yet inform consumers of the basic nature of the food and distinguish it from traditional meat-based burgers. Other examples include "vegan nuggets" and "meat-free sausage." These names provide consumers with a clear understanding of the nature of the product without creating unnecessary complexity or confusion.

The draft guidance does not reflect this same flexibility in the naming regulations. In particular, the approach to call out plant-based sources may not be appropriate or required under FDA's naming regulations for all products.[3] The guidance should provide flexibility as to the appropriate naming for food products by recognizing that including the specific plant source(s) in the name is not always helpful and could mislead consumers if the taste or texture does not match ingredient expectations. For example, it could be misleading to identify the plant source for a food with multiple plant-based sources where none is particularly characterizing. Updating the name "vegan sausage patty" to say "vegetable oil, soy, wheat, potato starch sausage patty" when the patty would not taste like any of these ingredients, would not be helpful for consumers, nor would it be in line with the FDA regulations. In such situations, it would be appropriate to use generic terms such as "veggie" or "plant-based" without the need to specify the most predominant plant-based sources. The name could also identify the primary characterizing ingredient(s), when one exists, and allow more flexibility for ingredients that are less characterizing or present at a lower level "soy-based veggie burger." A detailed listing of plant-based components in the product name could also prove confusing to consumers for other reasons. For example, if multiple plant-based sources are identified in the name, the detailed nature of the name could convey that all components are identified and if dairy- or egg-based ingredients are not listed, a consumer might expect that they are not present.

As another example, taking the draft guidance to its reasonable conclusion, spreads from different companies could have identical or nearly similar appearances, flavors, and culinary uses, but because they are made from different oils would need to have different names. This could be confusing to consumers and suggest meaningful differences between products where none exist. Presumably, the similarities among products and the lack of a particular characterizing flavor factored into FDA's decision to close out its 2015 Warning Letter to Hampton Foods after the company clarified its use of "Mayo" and added a prominent "Dressing and Spread" identity with no specific ingredients called out as part of the product identity.[4] We urge FDA to similarly recognize that when plant-based sources need not always be identified in the product name and that there is flexibility to use a variety of naming practices.

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[3] This approach is also not a standard in other foods without standards of identity, such as crackers.

[4] Warning Letter to Hampton Creek Foods, Inc. (Aug. 12, 2015); Letter from Joshua Schiller, Bois, Schiller and Flexner LLP, to Anam Drumheller, Food and Drug Administration (Sept. 16, 2015); *see also* Beth Kowitt, *The Mayo Wars Just Ended*, Fortune, Dec. 17, 2015, http://fortune.com/2015/12/17/hampton-creek-just-mayo-fda/.

In summary, we believe that for many plant-based products, simple identity statements that may not call out particular plant-based sources are appropriate. While identity statements that name specific plant-based ingredients are appropriate and may be required where the food already has an established common or usual name or is uniquely characterized by one or two ingredients, this is not the case for all products. Many plant-based foods (including some plant-based dairy products, as well as most spreads, veggie burgers, links, and other foods) have multiple synergistic ingredients and no single one or even a combination of two or three is uniquely characterizing. For some products, calling out some ingredients could actually create confusion because the product does not taste like the ingredient – for example, coconut, peas, or cabbage. The use of innovative ingredients in creative ways is likely to increase in the future. For such products, simple names like "Veggie Burger" or "Plant-based Spread" are often appropriate and adequately convey to consumers the basic nature of the food. As another example, a name like "Vegetarian Bacon" would better describe the food than a name such as "Soy, corn, egg, and wheat veggie bacon." We ask FDA to take an approach in the final guidance that sufficiently accounts for this flexibility under the naming regulations, either by withdrawing the draft guidance, or issuing a final guidance that reflects these principles.

However, if FDA instead chooses to move forward with the approach in the draft guidance, we believe it is critical to provide clarification on what is meant by "primary" or "predominant" characterizing ingredients.[5] Does it apply only to ingredients above a certain percentage? For meat, poultry, or egg alternatives, does it apply exclusively to protein ingredients present at a particular percentage of the recipe, rather than also covering plant-based oils and starches? How should products created mainly of plant-based oils and starches with no "predominant" ingredient be named?

Without this type of clarity as to what is considered a primary or predominant ingredient, industry would not have sufficient information to implement the guidance.

4. **FMI Strongly Supports the Continued/Existing Use of Qualifying Terms Such as Plant-Based, Vegan, Meat-Free, Egg-less, Animal-Free, Vegetarian**.

We appreciate FDA's approach regarding use of terms such as vegan, meat-free, animal-free, and others, in the sense that FDA has recognized these terms can be appropriate to help inform consumers that the products are derived from plants rather than animals. This recognition is helpful in relation to the state laws enacted in the past seven years that restrict the use of certain conventional food terms, such as meat and poultry in the naming of novel alternative foods, such as cell-cultured and plant-based meat and poultry products. In some states, these laws include express recognition that foods are not considered mislabeled if they bear a prominent qualifier that the food is "plant-based," "veggie," or other similar terms, but in other cases, this recognition is not provided in the law. Additionally, we believe the term "vegetarian" can be similarly truthful

[5] Members have also indicated that clarity is needed regarding how the weight should be calculated when multiple predominant ingredients come from the same source.

and not misleading, and appropriate to help inform consumers. FDA recognizes that the term "vegetarian" is commonly used on food labels to communicate the food does not contain ingredients from meat, fish, or poultry but may contain dairy or eggs. We ask that FDA clarify that such terms can be sufficient when used as a qualifier on their own and are not inherently false or misleading.

As a final comment, we ask FDA to make clear that there is flexibility in terms of the timing for companies to make any labeling changes to implement the guidance, particularly given the non-binding nature of the guidance.

We greatly appreciate the opportunity to comment on the draft guidance on labeling of plant-based alternatives to animal-derived foods. FMI is happy to answer any questions regarding our comments and look forward to continuing to work with FDA on this important product sector.

Sincerely,

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