THE GOOD FOOD INSTITUTE

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

RE: Docket No. FDA-2018-N-2381
FDA's Comprehensive, Multi-Year Nutrition Innovation Strategy

The Good Food Institute (GFI) appreciates the opportunity to submit these comments regarding FDA's Nutrition Innovation Strategy. GFI commends FDA for its interest in improving nutritional choices and public health by reducing barriers to innovation. While FDA regulations often serve a vital role in protecting human health and welfare, some regulations may impede innovation or protect established players in the market from competition. GFI welcomes FDA's review of its regulatory approach to nutrition, including improvements to standards of identity, labeling claims, and ingredient information.

As FDA reviews its regulations, we hope FDA will also pay particular attention to how these regulations are interpreted and enforced. FDA should always seek to ensure that its regulations are enforced fairly and neutrally without favor to any party or industry, with protecting consumer health and safety as FDA's primary objective.

GFI is a nonprofit organization working toward a healthy, humane, and sustainable food supply by publicly advocating for and encouraging research into new ways of meeting global demand for meat and dairy, including with plant-based options such as plant-based burgers and plant-based milks. This mission aligns with public health, as significant scientific research has observed that diets lower in animal-based foods and higher in plant-based foods result in lower mortality from some causes, including America's top killer, heart disease.[1] One possible mechanism for decreased mortality is the positive effect of plant-based diets on blood lipid profiles.[2] As more Americans show an interest

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[1] Tao Huang et al., *Cardiovascular Disease Mortality and Cancer Incidence in Vegetarians: A Meta-Analysis and Systematic Review*, 60 ANNALS OF NUTRITION & METABOLISM 233 (2012).

[2] Fenglei Wang et al., *Effects of Vegetarian Diets on Blood Lipids: A Systematic Review and Meta-Analysis of Randomized Controlled Trials*, 4 J. AM. HEART ASS'N (2015) (4:e002408. doi: 10.1161/JAHA.115.002408).

in consuming plant-based foods, it is important that the channels of innovation remain clear for new plant-based products.

A varied diet is also a well-recognized ideal for optimal health.[3] And the American diet is expanding to include more variety by the year, with new foods and foods adopted from across the globe proliferating in the marketplace.[4] Yet FDA's existing standards of identity largely deal with "traditional" American foods, often made from a limited set of "traditional" dietary ingredients like wheat, dairy, and eggs. It would likely be undesirable — and is in any event impractical — for FDA to develop standard-of-identity-style recipes for the plethora of products now on the American market. A more worthy and attainable goal would be the clarification that existing standards of identity are not to be interpreted in a way that impedes the introduction or sale of innovative foods, even if the new foods are used as alternatives to existing standardized foods.

For these reasons, GFI focuses this comment on FDA's suggestion of "modernizing" standards of identity. GFI believes it especially important for FDA to clarify the role that standards of identity play in its overall regulatory regime — and the role they do *not* play. Historically, standards of identity have never been understood to prevent new products from referring to standardized terms in their marketing or labeling.[5] It is only when a new product is purported to be and represented as the *genuine* standardized product that the new product is misbranded under section 403(g) of the Act.[6] After all, identity standards were mainly intended to address fraud and economic adulteration, by preventing one product from falsely representing itself as another.[7] A new product with its own clear and distinct identity does not present such a risk.

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[3] *See generally* U.S. Dep't of Health & Human Serv. & U.S. Dep't of Agric., *2015–2020 Dietary Guidelines for Americans* 14 (2015).

[4] *See generally* U.S. Dep't of Agric., Econ. Research Serv., *New Products*, https://www.ers.usda.gov/topics/food-markets-prices/processing-marketing/new-products/ (last updated Apr. 5, 2017) (describing the upward trend of new food product introductions per year since the early 1990s).

[5] Indeed, "in some cases it may be *necessary* to include a standardized name in the name of a substitute food in order to provide the consumer with accurate, descriptive, and fully informative labeling." 44 Fed. Reg. 3,964, 3,965 (Jan. 19, 1979) (quoting 38 Fed. Reg. 20,702, 20,703 (Aug. 2, 1973)) (emphasis added).

[6] *See 62 Cases of Jam v. United States*, 340 U.S. 593, 600 (1951); 38 Fed. Reg. 27,924, 27,925 (Oct. 10, 1973) (noting that "flavored fluid milk products" like "chocolate milk" "do not purport to be and are not represented as milk" within the meaning of section 403(g)).

[7] U.S. Cong. Research Serv., *Standards of Identity for Foods and Plant-Based Food Products* 2 (Jan. 18, 2018); *see also* Richard A. Merrill & Earl M. Collier, Jr., *"Like Mother Used to Make": An Analysis of FDA Food Standards of Identity*, 74 COLUM. L. REV. 561, 561 (1974).

Yet some voices in industry have advocated for FDA to weaponize identity standards against innovative products, contrary to this historical understanding. Doing so would work against public health, would be out-of-step with the trends and realities of the marketplace, would raise grave First Amendment concerns, and would contravene FDA's mission to regulate the marketplace fairly and neutrally in the interest of consumers.

Modernizing Standards of Identity

GFI generally supports FDA's goals in proposing "modernization" of standards of identity. Producers should always have the freedom to innovate, adapt, and create new products to offer consumers more and better choices. But standardized foods are far from the only game in town – they are a dwindling minority of foods available in today's diverse marketplace. While specific standards could be updated on a case-by-case basis, it is more important to clarify whether and when existing standards cast a regulatory shadow over other, nonstandardized foods. GFI urges FDA to clarify that any such shadow is much narrower than some appear to believe.

An example may illustrate the issue. Multiple commenters have noted the strict definition of "canned tuna," which does not permit flavoring ingredients other than lemon oil. As a result, some have suggested updating the standard to allow the addition of any "safe and suitable" flavoring ingredient, or to allow the addition of vegetables like peppers or celery. It seems patently absurd that in today's market tuna processors feel the need to seek a regulatory amendment so that consumers may buy canned tuna with vegetables or spices.

There is a better way. GFI has submitted a rulemaking petition (FDA-2017-P-1298, attached) to codify common nomenclature patterns for nonstandardized foods. In the petition, GFI asks FDA to clarify that a new food's name may refer to a standardized term so long as a reasonable consumer would understand that the new food's name connotes a distinct product. A consumer purchasing "seasoned tuna and red peppers" would hardly be surprised to find red peppers mixed in with her tuna, nor would she be surprised to discover that "spicy Sriracha tuna" has flavoring other than lemon oil. Whatever the definition of "canned tuna" may be, products *not* conforming to that definition should be permitted in commerce, and no regulatory cloud should hang over their very existence merely because they contain tuna and come in cans. Such products should only need an appropriate name that notifies consumers of the product's distinct nature. GFI's proposed approach goes beyond canned tuna, creating space for numerous nonstandardized alternatives to standardized foods, such as cheddar-style buffalo milk cheese or cheddar-style soy cheese, goat milk yogurt or cashew milk yogurt, brown rice noodles or zucchini noodles, and more.

FDA has made significant steps towards allowing flexibility and innovation like this before. As noted above, FDA has repeatedly and explicitly noted that "substitute" food names may sometimes *necessarily* include the names of the standardized foods they replace.[8] Another significant advancement came in 1993 with FDA's treatment of foods named with nutrient content claims.[9] In a food named with a nutrient content claim and a standardized term, FDA permits the addition of new ingredients not permitted in the standardized food, including "safe and suitable ingredients" "used to improve texture, add flavor, prevent syneresis, extend shelf life, improve appearance, or add sweetness."[10]

Rather than going case-by-case through existing standards or developing new standards, FDA should simply continue this historical trend toward greater flexibility. For over 25 years now, FDA has allowed modified versions of standardized foods to deviate from identity standards when the foods' names are qualified by a narrow set of claims like "reduced fat" or "low calorie." But there is a whole universe of other potential qualifying terms that would adequately inform consumers that a new product is fundamentally distinct, allowing endless possibilities for innovation in nonstandardized foods. The regulation proposed in GFI's petition would codify some of these possibilities, many of which are already commonly used without confusion.

Changes in the market and consumer understanding since 1993 also counsel in favor of a more flexible approach. Twenty-five years ago, comprehensive nutritional labeling was a new addition to food labels, and before that time, standards of identity played a critical role in not just preventing consumer deception or fraud but also ensuring nutritional adequacy in products that did not provide consumers with any nutritional information. Today, consumers are very familiar with alternatives to "traditional" foods, including those using nutrient content claims, as well as the variety of entirely new products on the market. Further, consumers can now easily inform themselves about nutritional differences between different products, empowered by the now-familiar Nutrition Facts panel. Indeed, FDA noted in 1993 that the addition of nutritional information, together with nutrient content claims and other information on the label, would "enable consumers to distinguish traditional foods from modified versions of these foods."[11]

Historical practice also establishes the viability of GFI's proposed approach. As noted in GFI's petition, many foods already have names that reference or qualify standardized terms, and such foods have existed on the market for decades without any reasonable question about possible "violations" of standards of identity. It is patently obvious to any consumer that goat milk is milk from a goat, notwithstanding FDA's prescription that

[8] 44 Fed. Reg. 3,964, 3,965 (Jan. 19, 1979).
[9] 21 C.F.R. § 130.10(c)–(d).
[10] 21 C.F.R. § 130.10(d)(1).
[11] 58 Fed. Reg. 2,431, 2,439 (Jan. 6, 1993).

standardized "milk" comes from cows alone.[12] It is equally obvious that soymilk is a milky-white liquid made from soybeans.[13] Just as obviously, rice noodles are noodles made from rice rather than wheat, though the standard of identity for "noodles" requires wheat. And gluten-free spaghetti and rye bread are pasta and bread products made from non-wheat grains, despite the standards of identity dictating that "bread" and "macaroni products" be made from wheat. Similarly, any reasonable consumer knows that coconut cream or non-dairy creamer are entirely distinct products from cow's cream, and the list goes on.[14]

Thus, rather than proceeding piecemeal through existing identity standards to create specific updated product recipes, FDA should simply explain how foods not meeting existing standards may be named by reference to the standardized foods, so long as the full name ensures that consumers are not confused or deceived. To this end, FDA should grant GFI's rulemaking petition. This approach would allow greater flexibility for continued innovation and consumer choice while minimizing the risk of consumer confusion. Such an approach would also minimize FDA's future need to repeatedly evaluate proposed changes to standards of identity to account for new consumer preferences or for changes in food technology and nutrition science.

Labeling Claims

FDA has invited comments on the possibilities for "new or enhanced labeling statements or claims." GFI recognizes that a large number of labeling statements and claims have proliferated in the marketplace, and few are defined or regulated by FDA. Some are regulated by third-party certification. e.g. kosher and halal certifications, vegan certifications, or non-GMO certifications. Many more are only constrained by the Act's general requirement that label statements not be "false or misleading in any particular."

GFI views the variety of labeling claims on the market as a necessary and often desirable consequence of commercial free speech. However, FDA should take action against

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[12] 21 C.F.R. § 131.110.

[13] Certain interest groups have long targeted common names of plant-based dairy alternatives by promoting a different interpretation of the law, and many comments at the public hearing focused on this issue. As noted in GFI's petition, these repeated demands for bovine-dairy favoritism illustrate the First Amendment perils of an inflexible approach to food standards. But FDA has opened a Request for Information on the matter of plant-based dairy alternatives, and GFI will reserve its full comments on that specific issue for the corresponding docket, FDA-2018-N-3522.

[14] Beyond the FDA-standardized-name context, other examples abound: reasonable consumers know that veggie burgers or turkey burgers do not contain beef, veggie bacon or turkey bacon do not contain pork, peppermint tea contains no tea, and so on.

labeling claims in circumstances presenting a particular risk of consumer deception and injury.

GFI echoes the concerns expressed by Food Allergy Research & Education (FARE) during FDA's public meeting, specifically regarding "non-dairy" labeling claims. To a reasonable consumer, "non-dairy" means no dairy ingredients, yet several products on the market are prominently labeled "non-dairy" but *do* contain dairy ingredients. Such labeling creates serious health risks for some individuals with dairy allergies, and in any event is misleading to consumers who may not wish to purchase dairy products.

More broadly, FDA should examine the use of "non-" or "-free" claims, particularly when common allergens are disclaimed, to ensure the use of such modifiers is truthful and not misleading. Consumers should have confidence that foods claiming to be "non-" or "-free" are free of any ingredients derived from the disclaimed source.

Improvements to Ingredient Information

GFI supports FDA's goal of improving the usefulness of ingredient information and generally supports improvements to readability of ingredient lists.

The content of ingredient lists presents important issues as well. FDA's regulation of the common or usual names of food ingredients has caused some confusion and inconsistent practices in industry, to the detriment of consumers. FDA has occasionally interpreted its regulation regarding "intervening material"[15] to forbid producers from including additional information about food ingredients, even where that information is likely to be of interest to consumers. For example, FDA has occasionally objected in warning letters to ingredients like "fresh ginger root" or "fresh basil," stating that "fresh" is not part of the common or usual name of these ingredients and therefore is "intervening material." But it is apparent here that using the modifier "fresh" helps consumers distinguish these ingredients from the common, dried forms of these herbs and spices.

FDA has also occasionally stated that its "intervening material" regulation does not permit the use of modifiers to ingredient names generally, including for example "filtered" (e.g. filtered water) or "non-GMO." But a restrictive approach such as this could have negative impacts on potential innovation and labeling that is fully informative to consumers.

For example, chymosin is an enzyme (commonly called rennet) used in making most hard cheeses. This enzyme was traditionally derived from the stomachs of young ruminant animals. Today, due to advances in biotechnology, most of the rennet used in cheeses produced in the United States is produced through microbial fermentation. Some

[15] 21 C.F.R. § 101.2(e).

consumers prefer to consume only this newer form of rennet, and therefore some cheese producers may describe the microbial-produced enzyme as "non-animal rennet" or "vegetarian rennet." But a strict interpretation of FDA's "intervening material" or common-or-usual name regulations may preclude the use of such modifiers, however clear they may be to consumers.

In a similar vein, gelatin is a generic name for collagen proteins derived from any number of animals. But some individuals with religious dietary restrictions are forbidden to consume gelatin derived from pigs or horses. To better serve these consumers, many products are labeled with ingredient names like "kosher gelatin" or "fish gelatin," although such modifiers could perhaps be considered intervening material.

With ever more ingredients being produced using biotechnology, the possibility for ambiguity in the origins of certain ingredients will only grow. Companies are now working on producing at industrial scale microbially-derived whey protein, gelatin, casein, and much more. Because these new ingredients will be functionally and chemically indistinguishable from their animal-originating counterparts, it may be considered "intervening material" to alert consumers to the origin of such ingredients. Yet consumers may be interested in those origins, and producers should not be prevented[16] from giving consumers that information in the most natural place possible: the ingredients list.

FDA should not object to "intervening material" in ingredients lists when it serves the important interest of informing consumers about ingredient origins or forms. FDA should also consider whether a generic descriptive modifier such as "non-animal" is permissible and clear enough to describe ingredients like rennet, gelatin, whey protein, or vitamin D that may have either animal or non-animal origins. In general, producers should not be prevented from communicating to consumers features about their products and ingredients about which consumers may be interested.

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[16] However, any such disclosures should be strictly optional, not mandatory, unless FDA determines that the ingredient is fundamentally different in its relevant characteristics.

Again, GFI appreciates the opportunity to comment on the issues raised by FDA and interested parties at the public meeting and thanks the agency for its careful review of these comments. We look forward to working with the agency to ensure that the path to innovation remains clear for the sake of public health, better nutrition, and consumer choice.

Sincerely,

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