THE GOOD FOOD INSTITUTE

March 20, 2020

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

RE: Supplemental Information:
Citizen Petition from The Good Food Institute, Docket FDA-2017-P-1298

Dear Sir/Madam:

Under 21 C.F.R. § 10.30(g), The Good Food Institute ("GFI") submits the following supplemental information in support of its Petition to Recognize the Use of Well-Established Common and Usual Compound Nomenclatures for Food, Docket No. FDA-2017-P-1298 ("Petition").

In the three years since GFI filed this citizen petition, the development of innovative new foods (especially plant-based meat and dairy alternatives) has progressed rapidly. While the plant-based sector's growth may be the most visible development, we have also seen innovations such as "blended" products, which combine plant-based ingredients with traditional meat and dairy ingredients. And many other new products have come to the market for consumers seeking to improve their diets, for example by reducing intake of calories, simple carbohydrates, saturated fat, sodium, or sugar. In response to these trends, FDA has solicited comments on how to account for existing standards of identity, through its Nutrition Innovation Strategy. As described in GFI's petition, a restatement of principles governing common or usual names would provide a flexible approach for new foods without requiring continuous agency action in a quickly developing marketplace.[1]

[1] *See* Comment from The Good Food Institute, in Horizontal Approaches to Food Standards of Identity Modernization, Docket No. FDA-2018-N-2381, available at https://www.regulations.gov/document?D=FDA-2018-N-2381-1285.

With the growth of innovative foods, there has also been an unfortunate increase in anticompetitive calls for government intervention to stop innovative producers from communicating clearly with consumers. (See Petition at 14–15.) In addition to proposed bills in the federal Congress that seek to censor common food nomenclature, state legislators have proposed several bills with various (often conflicting) approaches, and a few of these bills have become law.

Against this backdrop of a conflicting patchwork of state laws, a clear statement of policy from FDA would be more valuable now than ever. Congress gave FDA the authority and duty to maintain uniform national labeling standards, and a clear statement from FDA on common nomenclature would help protect national label uniformity and the flow of interstate commerce.

This submission addresses the above matters and provides additional factual and legal grounds for granting GFI's petition.

I. Market Developments

From 2017 through the end of 2019, total sales in the U.S. plant-based food market surged 29%.[2] The greatest rates of growth were experienced in plant-based egg products and plant-based non-fluid dairy (including yogurt, creamer, cheese, and frozen desserts), with plant-based meat and plant-based meals also growing substantially. As described in GFI's petition (at 19, 21–23), these products are almost uniformly named by reference to the food for which they substitute, in accordance with longstanding FDA policy.[3] Most commonly, these foods use qualifying language such as "alternative," "vegan," "substitute," or "plant-based," or they denote the specific plant source from which they are derived (e.g. soy or oat). These common qualifiers clearly describe "the manner and extent to which [the food] differs" from its conventional counterpart.

More recently, consumer demand for plant-based foods has also led to the development and sale of "blended" products that combine plant and animal ingredients. For instance, Dairy Farmers of America (the largest dairy cooperative in the country) recently

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[2] Good Food Institute, *Plant-Based Market Overview* (summarizing SPINS retail sales data for the Natural, Speciality Gourmet, and MULO channels), *available at* https://www.gfi.org/marketresearch.

[3] *See, e.g.,* FDA, *Substitutes for Milk, Cream, and Cheese; Withdrawal of Proposed Standards of Identity* 48 Fed. Reg. 37666, 37667 (Aug. 19, 1983).

introduced products labeled "Dairy + Almond Milk Blend" and "Dairy + Oat Milk Blend" which contain 50/50 mixtures of cow's milk and almond or oat milk.[4] Some of the largest meat companies have introduced blended products as well, with both Tyson and Perdue introducing blended beef and chicken products labeled as, for example, "nuggets made with plants," or "chicken breast & vegetable tenders."[5] Products marketed this way were entirely unknown just three years ago, and in a rapidly developing market, flexible nomenclature is necessary for producers to describe novel products like these in terms consumers understand.

Lower-calorie foods have also seen increased innovation and consumer demand. Some alternatives to common staple foods like rice and noodles are increasingly being made with alternative ingredients. In form, rice alternatives look like rice and cook like rice for easy substitution. Similarly, new varieties of noodles resemble and cook like wheat noodles but do not conform to FDA's standard of identity for noodles.[6] Rice alternatives from cauliflower or konjac ("shirataki") have seen particular popularity, and are commonly labeled as "cauliflower rice," "riced cauliflower," or with fanciful names that refer to rice together with identity statements disclosing the main ingredient.[7] Such product labels clearly convey their nature as rice alternatives for consumers seeking to lower their caloric intake. Similarly, noodle alternatives are marketed to calorie-conscious consumers and to consumers avoiding gluten or wheat.

Although these labels are perfectly clear to any reasonable consumer, the conventional rice industry is now leveling complaints against these rice alternatives. A major trade association filed comments with FDA objecting to any use of the word "rice" on the labels of any rice alternative, arguing that the word's use should be limited to grains from *Oryza sativa*.[8] (Such comments do not appear to account for other species that are commonly known as "wild rice.") The trade association's comments vaguely allude to consumer "confusion" and nutritional differences, but it is obvious that consumers pay premium prices for rice alternatives *because* they are aware that they are distinct products with different nutritional profiles, including fewer carbohydrates and calories.

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4 *See* Live Real Farms "Dairy Plus Milk Blends" available at https://liverealfarms.com/dairy-plus-milk-blends/ (Appendix A).

5 *See* Examples in Appendix B.

6 Other non-wheat noodle varieties have been common for decades or centuries, see Petition at 9–10.

7 *See* Examples in Appendix C.

8 *See* Comment from USA Rice, Docket No. FDA-2018-N-2381, available at https://www.regulations.gov/document?D=FDA-2018-N-2381-1129.

In a similar way, the United Egg Producers recently objected to the existence of nonstandardized noodles (like rice noodles) that do not contain egg products as a minor ingredient (Petition at 9–10) without providing any evidence of consumer confusion around the vast variety of eggless noodles.[9] And the National Turkey Federation filed a comment[10] objecting to plant-based products mimicking turkey burgers, seeming to forget that turkey "burgers" themselves are mimicries of beef burgers — and that the Turkey Federation *itself* fought a hard battle to use common nomenclature like "turkey bacon" and "turkey ham" for non-pork products.[11]

Comments like these illustrate that once the door is opened to pedantic arguments about common names, there will be no shortage of industry interests seeking government protection from their competitors.[12]

II. Importance of National Uniformity

Some special interest groups have lobbied state legislatures for bills to restrict common food names at the state level, and a few of these bills have become law. For example, Arkansas Code § 2-1-305 now prohibits representing any "agricultural product under the name of another food," with more specific provisions about meat, beef, pork, and rice. (As a result of a lawsuit brought by GFI and others, this law has been enjoined on free-speech grounds.)[13] A law in Missouri[14] prohibiting "misrepresenting a product as meat" is also being challenged in court. Additionally, a few states have passed laws defining "milk" as the product of "hooved mammals," in contrast with FDA's regulation providing that the unqualified term "milk" must refer specifically to the lacteal secretions

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9 Comment from United Egg Producers, https://www.regulations.gov/document?D=FDA-2018-N-2381-1395.

10 Comment from the National Turkey Federation, https://www.regulations.gov/document?D=FDA-2018-N-2381-1413.

11 *Amer. Meat Inst. v. U.S. Dep't of Ag.* 646 F.2d 125 (4th Cir. 1981) (National Turkey Foundation's successful appeal defending the common name "turkey ham").

12 More reasonably, although the Tea Association of the USA maintains that the word "tea" should be "preserved" for teas from the *Camellia sinensis* plant, and argues that herbal teas are not "true teas," the Tea Association acknowledges that herbal teas are properly labeled as "herbal tea" — another common-sense use of a qualifier to give a word a different meaning. *See* Comment from Tea Association of the USA, available at https://www.regulations.gov/document?D=FDA-2018-N-2381-1376.

13 *Turtle Island Foods v. Soman*, __ F.Supp.3d __, 2019 WL 7546141 (E.D. Ark. Dec. 11, 2019), attached as Appendix D.

14 Missouri Senate Bill 627 (2018 session).

of cows.[15] In redefining "milk" in this way together with state enforcement provisions, these bills effectively require that "milks" be specifically enumerated in state law, with plant milks (and hooveless animal milks) forbidden to use the word. Bills and laws like these threaten to create a patchwork of state food labeling requirements that conflict both with federal law and with each other.

In passing the Nutrition Labeling and Education Act of 1990, Congress enacted a clear national policy in favor of uniform food labeling with an express preemption provision in section 403A of the Act. Many of the proposed state laws violate section 403A(a)(3), because they would establish requirements "of the type required by section 403(i)(1)" — the Act's common or usual name requirement, over which FDA has sole regulatory authority. Under section 403A(a)(3), state labeling requirements are expressly preempted where they ban the use of common or usual names that are permitted under federal law.[16]

A clear statement from FDA regarding common compound nomenclatures would establish the acceptability of these names under federal law, and it would more conclusively preempt state laws to the contrary. GFI again respectfully requests that FDA issue guidance for industry on this topic in accordance with GFI's proposed regulation. (Petition at 2.) By preserving national uniformity with a clear restatement of existing policy, FDA can avoid the confusion that these state laws foster among industry and consumers.[17]

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[15] *See, e.g.* North Carolina Senate Bill 711 (2017 session). Existing laws of this type only become effective after a total of 12 states enact similar laws. As of this filing, North Carolina and Maryland have passed laws of this type, and a similar bill is awaiting signature or veto by the Governor of Virginia.

[16] *See, e.g. Regan v. Sioux Honey Ass'n Co-op.*, 921 F.Supp.2d 938, 942–43 (E.D. Wisc. 2013) (preemption of state law preventing honey without pollen from being called "honey," which is the product's common or usual name); *Brod v. Sioux Honey Ass'n Co-op.*, 895 F.Supp.2d 972, 981 (N.D. Cal. 2012) (same).

[17] To be sure, these state laws are also unconstitutional speech restrictions, and are destined to be struck down for this reason too. See Petition at 28–37; *Turtle Island Foods*, supra note 11. But even a constitutionally invalid law can chill protected speech and foster confusion until a court rules on its constitutionality. Before that point, FDA has an opportunity to preempt needless and wasteful legislation and litigation, and to provide clarity to industry and consumers.

GFI respectfully submits the above information and attached materials for FDA's consideration in connection with GFI's petition.

Sincerely,

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