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Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, Maryland 20852

**Re: Docket No. FDA-2018-N-2381, “Horizontal Approaches to Food Standards of Identity Modernization”**

**Statement of Interest**

The Harvard Law School Animal Law & Policy Clinic respectfully urges the U.S. Food and Drug Administration (FDA) to adopt the regulatory approach proposed by The Good Food Institute (GFI) in its 2017 Rulemaking Petition to Recognize the Use of Well-Established Common and Usual Compound Nomenclatures for Food.<sup>1</sup> The Animal Law & Policy Clinic (ALPC) undertakes work in the field of animal law and policy, domestically and internationally, and focuses on high impact opportunities to improve the treatment of animals through advocacy, policy, and litigation. As part of this work, ALPC closely monitors technological and regulatory developments within the food sector that have the potential to affect animals. Plant-based and cell-based alternatives to animal food products are innovations with tremendous potential to positively impact animals, improve human health, and ensure environmental sustainability. Accordingly, ALPC proposes a labeling scheme clarifying that non-standardized food names can reference standardized terms. Such clarification from the FDA prioritizes public health, safety, and transparency, and also enables innovative food producers to truthfully label their products.

**Recommended Action**

ALPC recommends that FDA issue a regulation clarifying that foods may be named by reference to standardized foods so long as the nomenclature makes the foods’ origins or properties clear to consumers, as petitioned by GFI. Such nomenclature is commonplace in American food marketing, and consumers easily understand and accept its use for a broad range of products.

ALPC urges FDA to amend 21 C.F.R. § 102.5 by adding the following language, proposed by GFI, after part (d):

- (e) The common or usual name of a food may be —
  - (1) the common or usual name of another food preceded by a qualifying word or phrase that identifies (i) an alternative plant or animal source that replaces the main

<sup>1</sup> Bruce Friedrich et al., Petition to Recognize the Use of Well-Established Common and Unusual Compound Nomenclatures for Food, Docket No. FDA-2017-P-1298, Good Food Institute, (March 2, 2017).

characterizing ingredient(s) or component(s) of such other food, or (ii) the absence of a primary characterizing plant or animal source, or of a nutrient, allergen, or other well-known characterizing substance, that is ordinarily present in such other food; or

(2) any other word or phrase comprised of two or more terms, which may be separated by hyphens or spaces; but if such name includes the common or usual name of any other food, it must effectively notify consumers that the product is distinct from such other food.

The use of such a name does not violate section 403 of the Act or regulations of this chapter solely because it includes the common or usual name of another food (including a food for which a standard of identity is established) if the entire name serves to notify a reasonable consumer that the product differs from such other food.”<sup>2</sup> This approach would enable American food innovators to create healthier and more sustainable food products, while also ensuring that that products are labeled truthfully. Should FDA undertake the petitioned rulemaking, ALPC also recommends that FDA publish interim guidance for the industry affirming that such common and usual food names may be used with appropriate qualifying terms, consistent with the proposed regulation.<sup>3</sup>

#### **I. GFI’s proposed rule is consistent with FDA’s and Congress’s increasingly flexible approach towards standards of identity.**

The following federal regulatory and legislative history of standards of identity demonstrates how the proposed regulation is consistent with long-standing FDA and Congressional policy and practice, and how it aligns with the trajectory towards increased regulatory flexibility of the food standards. FDA originally established food standards of identity in 1938 to prevent fraud, promote honesty and fair dealing in the food industry, and enable consumers to make informed purchasing decisions.<sup>4</sup> Most of today’s existing food standards of identity were subsequently established through rulemaking between the 1950s and 1970s.<sup>5</sup>

FDA has repeatedly acknowledged the need for increased flexibility with standardized food terms to keep up with innovation. For example, FDA decided in the 1970s that it would sometimes be “necessary” to include one food name within another “to provide the consumer with accurate, descriptive, and fully informative labeling.”<sup>6</sup> Under this guidance, it would be accurate and fully informative to continue using a term such as “almond milk” because it accurately describes the product as coming from almonds while being functionally similar to conventional dairy milk. The rest of the label includes (as necessitated by law) the ingredients and nutritional information, and is thus fully informative. Later, in 1983, FDA decided that for “substitute” foods (i.e., “foods made in semblance” to the standardized foods, such as “milk”), it is “reasonable and appropriate” to utilize a standardized food name, if “the name of the food [is] modified such that the nature of the

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<sup>2</sup> *Id.* at 2.

<sup>3</sup> *Id.*

<sup>4</sup> See, e.g., H. Thomas Austern, *The F-O-R-M-U-L-A-T-I-O-N of Mandatory Food Standards*, 2 FOOD, DRUG, COSM. L.Q. 532, 541-42 (1947); Richard A. Merrill and Earl M. Collier, Jr., *Like Mother Used to Make”: An Analysis of Standards of Identity*, 74 COLUM. L. REV. 561, 576 (1974).

<sup>5</sup> Andrea Kraus, Ph.D., *Standards of Identity History & Current Status*, Center for Food Safety and Applied Nutrition, U.S. Food & Drug Admin., Sept. 27, 2019, available at <https://www.fda.gov/food/workshops-meetings-webinars-food-and-dietary-supplements/public-meeting-horizontal-approaches-food-standards-identity-modernization-09272019-09272019#event-materials>.

<sup>6</sup> 44 Fed. Reg. 3964, 3965 (Jan. 19, 1979), quoting 38 Fed. Reg. 20702, 20703 (Aug. 2, 1973).

substitute food is clearly described and is clearly distinguished from the food which it resembles and for which it is intended to substitute.”<sup>7</sup> These decisions mark the beginning of FDA’s long-standing pattern and practice of permitting the use of qualifying terms in conjunction with standardized food names to describe alternative products that function similarly to standardized foods.

Congress also indicated its intention to better protect consumers while promoting food innovation when it passed the 1990 Nutrition Labeling Education Act (NLEA). The NLEA required nutrition and ingredient information on food packages to ensure that consumers are informed of food ingredients and are not misled into purchasing inferior products.<sup>8</sup> One of the primary goals of the NLEA was explicitly “to encourage product innovation through the development and marketing of nutritionally-improved foods.”<sup>9</sup> Today, nutrition fact panels and ingredient statements continue to provide information that allow consumers to select the foods that best fit their own preferences and needs.

FDA’s trajectory towards increased regulatory flexibility to enable increased innovation accelerated when the agency promulgated regulation 21 C.F.R. § 130.1 under the new NLEA.<sup>10</sup> This regulation permits modified versions of standardized foods to be labeled with a “nutrient content claim and a standardized term.”<sup>11</sup> This regulation allowed food manufacturers to create alternative versions of standardized foods that appealed to consumers seeking to reduce consumption of certain nutrients, such as fat and sodium. The regulation enabled food manufacturers to communicate to consumers that the modified product served the same function and had the same form as the standardized food, such as “ice cream” or “salad dressing,” but was modified to be, for example, “low-fat.”<sup>12</sup> The regulation also permitted deviation from the “non-ingredient provisions” of food standards of identity such as “moisture content, food solids content requirements, or processing conditions.”<sup>13</sup> It also permitted the addition of any “safe and suitable ingredients . . . used to improve texture, add flavor, prevent syneresis, extend shelf life, improve appearance, or add sweetness,” even if the addition of such ingredients to the standardized food would otherwise violate the standard of identity.<sup>14</sup> 21 C.F.R. § 130.1 represents an important step taken by FDA towards flexibility in utilizing standardized food terms to permit consumers to choose alternative versions of familiar products that better meet their nutritional needs, preferences, or values.

FDA continued to adopt a flexible approach towards standards of identity into the 1990s. In 1995, FDA requested public comment on the utility of food standards and how they might be modified, including how they “could be revised to grant the flexibility necessary for timely development and marketing of products that meet consumer needs, while at the same time providing consumer protection.”<sup>15</sup> Of the 95 submitted comments, many requested simplification of the standards, and more flexibility and clarity.<sup>16</sup>

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<sup>7</sup> 48 Fed. Reg. 37666, 37667 (Aug. 19, 1983).

<sup>8</sup> Public Law 101-535.

<sup>9</sup> 58 Fed. Reg. 2302 (Jan. 6, 1993).

<sup>10</sup> Public Law 101-535.

<sup>11</sup> *Id.*

<sup>12</sup> *Id.*

<sup>13</sup> 21 C.F.R. § 130.10(b)(A)(c).

<sup>14</sup> 21 C.F.R. § 130.10(d)(1). This regulation excluded foods “specifically prohibited by the standard,” which are not permitted in the modified foods. 21 C.F.R. § 130.10(d)(3).

<sup>15</sup> 70 Fed. Reg. 29217 (May 20, 2005).

<sup>16</sup> Kraus, *supra* note 5.

Since the beginning of the 21st century, the federal government has continued to demonstrate a preference for regulatory flexibility to allow innovation and development of food products that suit individualized health needs and preferences. In 2004, Congress amended the Federal Food, Drug and Cosmetic Act (FFDCA) to require disclosures of allergens on food labels.<sup>17</sup> Meanwhile, greater awareness of diseases related to consumption of certain foods (such as celiac disease), and food sensitivities and intolerances spurred a heightened demand for products that were free of allergens, such as gluten.<sup>18</sup> According to Food Allergy Research & Education (FARE), 32 million Americans have food allergies, 5.6 million of whom are children under age 18, and “childhood hospitalizations for food allergy tripled between the late 1990s and the mid-2000s.”<sup>19</sup> Interest in and demand for gluten-free foods has steadily risen and is expected to continue growing in the coming years.<sup>20</sup> A 2018 study found that 24 percent of Americans now “avoid gluten always or usually.”<sup>21</sup> Producers have responded by developing countless alternatives to traditional standardized foods to enable all consumers to have palatable options that suited their health needs, such as bread and noodles made without wheat.

FDA and the Food Safety Inspection Service (FSIS) within the U.S. Department of Agriculture (USDA) both recognized the continuing need to adopt a flexible approach to their standard of identity regulations to keep pace with accelerating food innovation driven by intensifying consumer demand. In 2005, the two agencies jointly solicited public comments on their proposed rule to modernize food standards through a set of general principles that would guide the creation, revision, or elimination of food standards.<sup>22</sup> The proposed rule included 13 principles, which included recognizing the need for flexibility so as not to “stifle innovations in food technology.”<sup>23</sup>

Fourteen years later, the ongoing discussion regarding the need for such modernization, and the length of time it has taken to make needed changes thus far, highlights the complexity of modernizing standards of identity in a way that prioritizes consumer health and safety, innovation, and consumer choice. The federal government now continues to emphasize the need for increased flexibility in food regulation. In June of 2019, the Administration affirmed these priorities in its 2019 Executive Order on Modernizing the Regulatory Framework for Agricultural Biotechnology Products when it articulated its ongoing intention to prioritize “timely, efficient” food regulation that avoids “undue regulatory burden” while protecting consumer health and safety.<sup>24</sup> Several months later, in the recent notice of its Public Meeting on Horizontal Approaches to Food Standards of Identity Modernization, FDA stated that one of its key goals is to “promote industry

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<sup>17</sup> See Food Allergen Labeling and Consumer Protection Act of 2004, Pub. Law 108-282; 21 U.S.C. §§ 343(w), 321(qq).

<sup>18</sup> See, e.g., J.F. Ludvigsson et al., *Increasing Incidence of Celiac Disease in a North American Population*, 108 AM. J. GASTROENTEROL. 818 (2013), available at <http://www.nature.com/ajg/journal/v108/n5/full/ajg201360a.html>.

<sup>19</sup> Food Allergy Research & Education, *Food Allergy Facts and Statistics for the U.S.*, available at <https://www.foodallergy.org/life-with-food-allergies/food-allergy-101/facts-and-statistics>

<sup>20</sup> Jeff Gelski, *Gluten-free: Evolving, Improving and Still Growing*, *Foods Business News* (Aug. 8, 2019), available at <https://www.foodbusinessnews.net/articles/14384-gluten-free-evolving-improving-and-still-growing>.

<sup>21</sup> *Id.*

<sup>22</sup> 70 Fed. Reg. 29214 (May 20, 2005).

<sup>23</sup> 70 Fed. Reg. 29221 (May 20, 2005).

<sup>24</sup> E.O. 13874, Executive Order on Modernizing the Regulatory Framework for Agricultural Biotechnology Products, Land & Agriculture (June 11, 2019).

innovation and provide flexibility to encourage manufacturers to produce healthier foods.”<sup>25</sup> While considering ways to modernize food standards of identity, FDA should prioritize this goal, which is entirely consistent with the rule proposed in this comment.

Not only does the proposed rule align with the trajectory of increased flexibility to promote healthful food innovation, it also would codify FDA’s long-standing practice of tacitly permitting the use of qualifying terms such as “soy” or “rye” in conjunction with standardized terms such as “milk” and “bread” to accurately describe foods in a manner that reasonable consumers understand. This suggested approach would not require or provoke a change to existing standards of identity when common or usual food names are used in conjunction with qualifying terms. The approach also does not preclude otherwise modifying existing standards or creating new standards when deemed necessary for other reasons such as modernization of ingredients or production methods, or to prevent fraud. Accordingly, adoption of the proposed regulation satisfies the goal of modernizing food standards across product categories, while also obviating the risk of significant disruption in regulated industries that a systemic shift in standards of identity could provoke. Codification of existing FDA policy and practice would provide much-needed regulatory certainty for food innovators and their consumers.

## **II. Maintaining the current system without providing regulatory certainty would hinder FDA’s goal of promoting innovation.**

Currently, food innovators could be withholding the introduction of new products to the market because they are uncertain as to FDA’s policy regarding the use of common or usual standardized food names when paired with qualifying terms. Food producers seek to use the terms that most effectively indicate to consumers what a product contains and how a product is intended to be used. In the case of foods such as plant-based milks and noodles made without wheat, the use of qualifying terms in conjunction with standardized names such as “bread,” “milk, and “noodle” is often the clearest way to communicate how a consumer should use a product. The qualifying term indicates what the product contains while the standardized term indicates what the product can be used for. For instance, customers looking for alternatives to cows’ milk to pour on their cereal would likely understand that almond milk can be used on cereal than they might be with a product called “almond beverage” or “almond juice.” The term “almond” indicates that the product is made from almonds. Should the consumer seek further information, the product packaging already includes the ingredient statement and nutrition facts, pursuant to the NLEA.

Under the current climate of uncertainty regarding use of standardized terms, food companies may be hesitant to include on their labeling common nomenclature that includes a standardized term, even though it informs consumers of a food product’s form and function. Although companies can voluntarily consult with FDA regulators to discuss food labels prior to marketing a product, case-by-case discussions are ineffective and insufficient to address widespread uncertainty among food innovators. The current lack of regulatory clarity may thus be chilling innovation. Undertaking the petitioned-for rulemaking and publishing interim industry guidance would provide much-needed clarity to industry and substantially eliminate the possibility of such a chilling effect.

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<sup>25</sup> FDA Announces Public Meeting to Discuss Modernizing Food Standards of Identity, (Aug. 28, 2019), *available at* <https://www.fda.gov/food/cfsan-constituent-updates/fda-announces-public-meeting-discuss-modernizing-food-standards-identity>.

### **III. Banning the use of standardized food terms qualified by clear and accurate language would likely violate the First Amendment.**

Preventing the use of common and usual standardized names paired with qualifying terms, such as “almond milk,” “rye bread,” or “rice noodles,” would likely run afoul of the First Amendment. Under one of the leading cases on the issue, the Supreme Court held in *Sorrell v. IMS Health Inc.* that commercial speech is protected under the First Amendment as long as it is not inherently misleading.<sup>26</sup> Package labels are a form of commercial speech because they propose a commercial transaction.<sup>27</sup> Thus, product names on labels will be protected as commercial speech under the First Amendment unless they are inherently misleading. For restrictions of speech on product labels that are *potentially* misleading, but are not *inherently* misleading, courts apply the test set out in *Central Hudson Gas & Elec. Corp. v. Public Service Commission of New York*.<sup>28</sup> Under that test, to restrict truthful commercial speech, the government must assert a substantial interest, the government must not be mistaken in asserting that substantial interest, the limiting regulation must directly advance that substantial interest, and the limiting regulation must not be more extensive than necessary to meet the interest’s goal; otherwise the speech restriction is unconstitutional.<sup>29</sup> If FDA were to ban the use of standardized names paired with qualifying language on non-standardized foods, courts would likely hold the ban to be unconstitutional because such labeling clearly communicates a product’s form and function, and is thus not inherently misleading; there is no substantial interest in restricting this type of speech given that consumers choose these alternative products for their own individual health, taste and convenience preferences; and even if there were a substantial government interest in creating further distinction between standardized and non-standardized food names, there are less restrictive means available to serve that interest.<sup>30</sup>

#### **A. The use of qualified terms paired with common and usual food names is lawful and not inherently misleading to consumers.**

Commercial speech only falls outside protection of the First Amendment if it is *inherently* misleading, not if it is simply *potentially* misleading.<sup>31</sup> If it is only potentially misleading, the rest of *Central Hudson* test is applied in full, and the government carries the burden of demonstrating that it has a substantial interest in restricting the speech (for instance, to prevent deception) and that the restriction is narrowly tailored to directly serve that interest.<sup>32</sup> The “inherently misleading” standard is a very high bar for the government to meet.<sup>33</sup> Product names that use qualifying terms to differentiate their content from standardized foods, such as rye bread, rice noodles, soymilk and almond milk, all of which use common and usual but standardized terms such as “noodles,” “milk,” and “bread,” would not meet this very high bar.

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<sup>26</sup> 564 U.S. 552, 557 (2011).

<sup>27</sup> *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 557 (2011) (defining commercial speech); *Zauderer v. Off. of Disc. Counsel of S. Ct. of Ohio*, 471 U.S. 626, 637 (1985) (quoting *Ohralik v. Ohio State Bar Assn.*, 436 U.S. 447, 455–56 (1978)) (“Our commercial speech doctrine rests heavily on ‘the “common-sense” distinction between speech proposing a commercial transaction ... and other varieties of speech””).

<sup>28</sup> 447 U.S. 557, 564 (1980).

<sup>29</sup> *See, e.g., id.* at 564 (1980); *Pearson v. Shalala*, 164 F.3d 650, 655 (D.C. Cir. 1999) (citing, *inter alia*, *In re R.M.J.*, 455 U.S. 191, 203 (1982)).

<sup>30</sup> *Central Hudson*, 447 U.S. at 564.

<sup>31</sup> *See Pearson v. Shalala*, 164 F.3d 650, 655 (D.C. Cir. 1999) (citing, *inter alia*, *In re R.M.J.*, 455 S. 191, 203 (1982)).

<sup>32</sup> *Id.* at 655–56.

<sup>33</sup> *See id.* at 655 (describing “inherently misleading” standard in terms of “awesome impact” leaving consumers “bound to be misled.”)

FDA uses a “reasonable consumer” standard when evaluating whether a consumer is likely to be misled.<sup>34</sup> Many studies show that reasonable consumers are not confused by product labels that use qualified terms in conjunction with a standardized term. For example, a study funded by the dairy industry found that more than 90 percent of consumers surveyed understood that plant-based milks such as soy, coconut, and almond milk do not contain cows’ milk.<sup>35</sup> Studies such as this show that the reasonable consumer is not confused about the contents of plant-based milk. Dairy industry-funded studies have found that approximately 38 percent of consumers now purchase both plant-based and dairy-based milk.<sup>36</sup> These reasonable consumers are not continuing to purchase both products because they mistakenly believe the two products to be identical. Rather, they are purposefully buying both types of milk to suit their own needs and preferences, with a full understanding that the products are distinct from one another.

Indeed, courts have already adjudicated the question of consumer confusion around terms such as “almond milk” and “soymilk” and have concluded that reasonable consumers would not be misled by such product names.<sup>37</sup> For instance, the 9th Circuit Court of Appeals found that by using the qualifying term “almond” in front of “milk,” almond milk manufacturers were clearly communicating that almond milk is indeed distinct from cows’ milk, and that reasonable consumers would therefore also expect the nutritional profile of almond milk to be distinct.<sup>38</sup> In another case involving plant-based milks, a court noted that if a consumer were to be confused by this kind of nomenclature for dairy alternatives, that the “consumer might also believe that veggie bacon contains pork, that flourless chocolate cake contains flour, or that e-books are made out of paper.”<sup>39</sup> Qualified terms can be highly effective in conveying the nature of a product so that consumers can understand what it is and how it is to be used, especially as applied under the current labeling regime, which requires ingredient statements and nutrition facts, and prohibits false or misleading labeling.

Enforcing rigid standards of identity for dairy products or other products such as breads and noodles would only increase confusion among consumers who are already familiar with, accept, and understand the use of qualified standardized terms. Indeed, the U.S. Department of Health and Human Services (HHS) and USDA recognize that qualified standardized terms for

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<sup>34</sup> U.S. Food & Drug Admin., GUIDANCE: QUALIFIED HEALTH CLAIMS IN THE LABELING OF CONVENTIONAL FOODS AND DIETARY SUPPLEMENTS, 2002 WL 32811482, at \*5 (2002) (superseded on other grounds by U.S. Food & Drug Admin., GUIDANCE: INTERIM PROCEDURES FOR QUALIFIED HEALTH CLAIMS IN THE LABELING OF CONVENTIONAL HUMAN FOOD AND HUMAN DIETARY SUPPLEMENTS, 2003 WL 24014304 (2003) (“In assessing whether food labeling is misleading, FDA will use a ‘reasonable consumer’ standard.”).

<sup>35</sup> Beth Newhart, *75% of US adults aren’t confused by dairy alternative labels, new study finds*, Dairy Reporter, Oct. 12, 2018 (survey of 1,000 individuals), available at <https://www.dairyreporter.com/Article/2018/10/12/75-of-US-adults-aren-t-confused-by-dairy-alternative-labels-new-study-finds>.

<sup>36</sup> *Id.* (finding that 38 percent of consumers purchase both); Dairy Management Inc. (DMI) published a similar study, (Oct. 2018) (survey of 3,823 individuals finding that nearly available at [https://www.usdairy.com/~/\\_media/usd/public/dairy-and-plant-based-beverages-research.pdf](https://www.usdairy.com/~/_media/usd/public/dairy-and-plant-based-beverages-research.pdf).

<sup>37</sup> See, e.g., *Painter v. Blue Diamond Growers*, No. 17-55901, 2018 WL 6720560 (9th Cir. Dec. 20, 2018) (mem.); *Ang v. WhiteWave Foods Co.*, 2013 WL 6492353 (N.D. Cal., Dec. 10, 2013) (order granting motion to dismiss) (“The first words in these products’ names should be obvious to even the least discerning of consumers. . . . [Claiming that] a reasonable consumer might confuse plant-based beverages such as soymilk or almond milk for dairy milk . . . stretches the bounds of credulity. Under Plaintiff’s logic, a reasonable consumer might also believe that veggie bacon contains pork, that flourless chocolate cake contains flour, or that e-books are made out of paper.”); *Gitson v. Trader Joe’s Co.*, 13-cv-01333, Doc. 139 (N.D. Cal., Dec. 1, 2015) (order granting in part and denying in part partial motion to dismiss; granting in part and denying in part motion to strike).

<sup>38</sup> *Painter v. Blue Diamond Growers*, No. 17-55901, 2018 WL 6720560 (9th Cir. Dec. 20, 2018) (mem.).

<sup>39</sup> *Ang v. WhiteWave Foods Co.*, 2013 WL 6492353 (N.D. Cal., Dec. 10, 2013) (order granting motion to dismiss).

plant-based dairy alternatives are commonly understood because the two agencies repeatedly use the terms “soymilk” and “almond milk” in the current 2015–2020 Dietary Guidelines for Americans.<sup>40</sup> In the Guidelines, HHS and USDA also refer to “soy beverages (soymilk),”<sup>41</sup> and refer to “products sold as ‘milks’ but made from plants (e.g., almond, rice, coconut, and hemp ‘milks’).”<sup>42</sup>

The rule petitioned for by GFI would continue to allow common and usual food names to be used, together with qualifying terms, on non-standardized foods precisely because consumers understand them and rely on them to easily identify foods that they are choosing for health, sustainability, taste, or other reasons. Should consumers seek more detailed information about any particular food, they can find such information in the ingredient statements and nutrition facts panels required by NLEA. Because use of a common or usual name with a qualifying term is not inherently misleading commercial speech, it is commercial speech protected under the First Amendment.

**B. Banning the use of common and usual names of food that involve a standardized term combined with a qualifying term on non-standardized foods would not advance a substantial governmental interest.**

Because consumers are not confused by the use of such names when appropriately qualified, restricting their usage would not directly advance a substantial government interest. In contrast, restricting these terms might negatively affect public health and would restrict consumer choice by creating more confusion around products that may be healthier for humans or the planet. As the Consumer Federation of America (CFA) highlighted in its response to FDA’s call for comments on the “Use of the Names of Dairy Foods in the Labeling of Plant-Based Products,” if FDA restricts the use of the term “milk” to dairy products despite qualifying descriptors to differentiate plant-based products, doing so would “entail arbitrary line drawing and likely lead some consumers to make poorer choices.”<sup>43</sup> CFA highlighted the example of sugary chocolate milk qualifying for the term “milk,” while unflavored, unsweetened, almond milk would no longer qualify despite being a preferred choice for many Americans.<sup>44</sup>

Meanwhile, many individuals are now selecting among a wide variety of alternative food products, which allow consumers to choose options that meet their own health needs and preferences, such as reduced calories in almond milk, or fortification of soy milk, while avoiding allergens, such as gluten, soy, nuts, or lactose. For example, for the millions of Americans who must avoid wheat gluten for health reasons, rice noodles are likely a healthier and convenient alternative. For the 30 to 50 million Americans who are lactose intolerant—with rates of intolerance that are far higher for populations of color such as Asians (95 percent), African Americans (60-80 percent), Hispanics (50-80 percent), and American Indians (100 percent)—

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<sup>40</sup> U.S. Dep’t Health & Human Serv. and U.S. Dep’t Agric., Dietary Guidelines 2015–2020, at 23, 49, 82, 109, 113, available at [https://health.gov/dietaryguidelines/2015/resources/2015-2020\\_Dietary\\_Guidelines.pdf](https://health.gov/dietaryguidelines/2015/resources/2015-2020_Dietary_Guidelines.pdf).

<sup>41</sup> *Id.* at 23, 49, 60, 86.

<sup>42</sup> *Id.* at 23.

<sup>43</sup> Thomas Gremillion, *Letter to Scott Gottlieb Re: Use of the Names of Dairy Foods in the Labeling of Plant-Based Products*, Consumer Federation of America, (Jan. 28, 2019), available at <https://consumerfed.org/wp-content/uploads/2019/01/dairy-standards-of-identity-comments.pdf>.

<sup>44</sup> *Id.*

plant-based milks may be a healthier choice.<sup>45</sup> Making alternative products harder to find, understand, and consume by restricting commonly known labeling terms such as “soy milk,” and instead requiring terms such as “soy beverage,” would not only be unduly restrictive, but it could also be discriminatory to Americans of color who rely on these products more than white Americans for health reasons.

Modernizing standards of identity should promote healthful innovation, not unduly burden food producers with labeling restrictions that would make it difficult to convey the nature of food products to consumers. Likewise, regulations should not create confusion by restricting familiar and truthful labeling terms about a product’s contents and function. There are many compelling reasons for FDA to adopt the proposed regulation, including conserving agency resources, facilitating innovation, increasing consumer choice, and enabling healthier and more sustainable consumption. As a result, the government arguably has an interest in *not* restricting the use of common and usual names when qualified terms for non-standardized food products.

**C. Even if FDA could show that restricting the use of standardized food names directly advanced a substantial interest, there are less restrictive means of advancing that interest and would thus not be constitutional.**

Under *Central Hudson*, if the government seeks to restrict truthful and not inherently misleading commercial speech, it must use the least restrictive means necessary to achieve the substantial interest it advances.<sup>46</sup> A labeling restriction that bans use of certain terms on non-standardized foods would not be upheld because there is a less restrictive way to differentiate non-standardized foods from the standardized foods that their labels refer to.<sup>47</sup> Requiring additional disclosures or appropriate qualifying language, just as the proposed regulation suggests, is such an example of less restrictive means. Many plant-based milk companies already disclose that their products are not a suitable substitute for baby formula (just as cows’ milk is not suitable for this purpose). If FDA finds that voluntary disclosures are insufficient to inform parents and that the health of infants are at risk, the agency could mandate such disclosures. Any such disclosures would have to be reasonably related to the agency’s interest in protecting consumer health, and would have to be no more restrictive than necessary to serve this interest to be constitutional.<sup>48</sup>

FDA already mandates multiple sources of consumer information on packaging, including ingredients, nutrition facts, and warnings that certain products are not suitable for children under a certain age.<sup>49</sup> Courts have recognized that such labeling requirements are sufficient to highlight nutritional differences between dairy and dairy alternatives.<sup>50</sup> As a result, restriction of familiar food names would likely be unconstitutional. Indeed, with an ever-increasing availability of food

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<sup>45</sup> U.S. Dep’t Health & Human Serv., *Lactose Intolerance: Information for Health Care Providers*, January 2006, available at

[https://www.nichd.nih.gov/sites/default/files/publications/pubs/documents/NICHD\\_MM\\_Lactose\\_FS\\_rev.pdf](https://www.nichd.nih.gov/sites/default/files/publications/pubs/documents/NICHD_MM_Lactose_FS_rev.pdf).

<sup>46</sup> *Central Hudson Gas & Elec. Corp. v. Public Service Commission of New York*, 447 U.S. 557, 564 (1980).

<sup>47</sup> See *Zauderer v. Off. of Disc. Counsel of S. Ct. of Ohio*, 471 U.S. 626, 651 (1985) (stating that “disclosure requirements trench much more narrowly on an advertiser’s interests than do flat prohibitions on speech”).

<sup>48</sup> *Zauderer v. Off. of Disc. Counsel of S. Ct. of Ohio*, 471 U.S. 626, 651 (1985).

<sup>49</sup> A Food Labeling Guide: Guidance for Industry, FDA Center for Food Safety and Applied Nutrition, (Jan. 2013), available at <https://www.fda.gov/files/food/published/Food-Labeling-Guide-%28PDF%29.pdf>.

<sup>50</sup> See, e.g., *Gitson* at 3 (“[A] reasonable consumer (indeed, even an unsophisticated consumer) would not assume that two distinct products have the same nutritional content; if the consumer cared about the nutritional content, she would consult the label.”).

options in the marketplace, consumers will benefit from food companies having *more* speech—not less—in order to navigate food choices through easily recognizable descriptive language.

**D. Restricting the use of language for specific foods or food categories will likely be subject to heightened judicial scrutiny.**

Restrictions on speech that target specific foods or food categories would be content-based and would likely face a higher level of judicial scrutiny.<sup>51</sup> For example, a ban that applied to the use of standardized terms such as “milk” on plant-based milk, but did not apply to other categories of standardized foods would be content-based because it could not be justified without reference to the content of the speech, which in that case would be the dairy-specific speech. Courts consider this type of restriction to be “presumptively invalid,” and thus apply heightened scrutiny when evaluating First Amendment claims.<sup>52</sup> Permitting the use of standardized food terms with qualifying language across product categories, as the proposed rule suggests, would allow FDA to avoid any such First Amendment pitfalls.

**Conclusion**

The Harvard Law School Animal Law & Policy Clinic thanks FDA for this opportunity to provide comment related to horizontal approaches to food standards of identity modernization. As outlined above, ALPC supports the amendment to 21 C.F.R. § 102.5 proposed in the petition for rulemaking submitted to FDA in 2017 by GFI, which would permit the use of common and usual names of foods on non-standardized foods when paired with appropriate qualifying terms. ALPC also supports GFI’s recommendation that FDA publish an interim guidance document affirming that standardized names may be used with qualifying language. Adoption of this rule would facilitate continued food innovation and obviate the need for resource-intensive and time-consuming vertical changes to food standards of identity. Further, the rule would enable FDA to “protect consumers against economic adulteration,” “maintain the basic nature, essential characteristics and nutritional integrity of food,” and “promote industry innovation and provide flexibility to encourage manufacturers to produce healthier foods”<sup>53</sup> while respecting the commercial speech protections guaranteed by the First Amendment.

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<sup>51</sup> *Sorrell v. IMS Health*, 31 S. Ct. 2653, 2664–65 (2011).

<sup>52</sup> *Id.* at 2667 (quoting *R.A.V. v. St. Paul*, 505 U.S. 377, 382 (1992)).

<sup>53</sup> FDA Announces Public Meeting, FDA (Aug. 28, 2019), *available at* <https://www.fda.gov/food/cfsan-constituent-updates/fda-announces-public-meeting-discuss-modernizing-food-standards-identity>