BY ELECTRONIC SUBMISSION

July 31, 2017

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

RE: Citizen Petition from Soyfoods Association of America, FDA-1997-P-0016-0002

The Good Food Institute (GFI), a 501(c)(3) nonprofit organization, appreciates the opportunity to comment on the Soyfoods Association's petition seeking recognition of the term "soymilk." We write to urge you to respond to the Soyfoods petition by amending 21 C.F.R. § 102.5 to allow the use of qualifying words or phrases before the common or usual name of a food to characterize the main ingredient or component or to indicate the absence of a nutrient, allergen, or other substance typically found in the food, consistent with our pending petition FDA-2017-P-1298.

The Soyfoods petition has been before the agency since it was filed on February 28, 1997, and a reply is long overdue. While soy milk is a traditional food and has been consumed in the United States since at least the 1930s, its popularity has soared over the past twenty years. More and more consumers have sought out soy milk, almond milk, and other plant-based milks. In fact, when Danone purchased the plant-based milk company White Wave in 2016, the Financial Times reported that the company's strong sales had made it the fastest-growing company in the U.S. food and beverage industry.[1]

Moreover, interest in this topic seems to be escalating. Just last month, the U.S. District Court in the Eastern District of California stayed a case over the use of the term "almondmilk," referring the matter to your agency, which it found had primary jurisdiction.[2] And this month, the House Appropriations Committee used report language to ask your agency to prepare guidance to industry on how to implement the standard of identity for dairy products.[3] Furthermore, the recently proposed "DAIRY PRIDE Act" (S.130, H.R.778), if enacted, would explicitly prohibit

[1] Lindsay Whipp, *Big Business Identifies Appetite for Plant-Based Milk,* Financial Times, July 15, 2016, https://www.ft.com/content/7df72c04-491a-11e6-8d68-72e9211e86ab?mhq5j=e2.
[2] *Kelly v. Whitewave Operating Co.*, Civ. No. 17-117 (E.D. Cal. June 6, 2017).
[3] https://appropriations.house.gov/uploadedfiles/hrpt-115-hr_.pdf.

the use of any dairy terms like "milk" on labels of products like soy milk *and* require FDA to issue guidance on, and report to Congress about, enforcement.

We support the basic goal of the Soyfoods petition, which is the recognition of a common and usual name ("soymilk") used by consumers, industry, and even government agencies like FDA and USDA.[4]

But we believe that a broader approach is warranted. As we describe in our petition, attached here for the official record in support of our comment on Citizen Petition from Soyfoods Association of America, FDA-1997-P-0016-0002, soy milk is one of several food and beverage products that consumers are increasingly incorporating into their diets. When consumers do so, they typically refer to these foods and beverages by their familiar names preceded by qualifying terms.[5] Examples include rice noodles, gluten-free bread, and yes, soy milk. (A federal court pointed out that this approach is neither confusing nor limited to foods: e-books, of course, are books people read electronically, rather than on paper.[6])

Further, as detailed in GFI's petition, allowing food producers to use these common names, just as consumers and even USDA and FDA do, would be consistent with the First Amendment, and alternative legislative or regulatory approaches (such as the DAIRY PRIDE Act) would be unconstitutional.[7] In fact, after GFI filed its petition, the Eleventh Circuit held that a Florida standard of identity for "skim milk" violated the First Amendment, because the standard prohibited producers of low-fat milk without added Vitamin A from using the term on their labels, which the court deemed "clearly more extensive than necessary to serve its interest in preventing deception and ensuring adequate nutritional standards."[8]

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[4] FDA, *Health Claims; Soy Protein and Coronary Heart Disease* 63 Fed. Reg. 62977, 62978 (Nov. 10, 1998) (referring to "soy milk, soy yogurt, and soy cheese"); USDA, *Enhancing Retailer Standards in the Supplemental Nutrition Assistance Program (SNAP)* 81 Fed. Reg. 90675, 90693–94 (Dec. 15, 2016) (referring to "soy yogurt," "soy milk," "soy cheese," "almond milk," and "rice milk").

[5] *See, e.g.,* attached Google search data, showing approximately 25 times more U.S. Google searches for "soy milk" and "soymilk" versus "soy beverage" and "soy drink" and approximately 40 times more U.S. Google searches for "almond milk" and "almondmilk" versus "almond beverage" and "almond drink." (Also available online at http://bit.ly/2eQLzzn.)

[6] *Ang v. Whitewave Foods Co.*, Civ. No. 13-1953, 2013 WL 6492353 at *4 (N.D. Cal. Dec. 10, 2013) (finding the claim that a "reasonable consumer would view the terms 'soymilk' and 'almond milk,' disregard the first words in the names, and assume that the beverages came from cows...stretches the bounds of credulity.").

[7] First Amendment commercial speech doctrine has evolved significantly since the 1997 petition was filed. *See, e.g. Reed v. Town of Gilbert*, 135 S. Ct. 2218 (2015); *Sorrell v. IMS Health*, 131 S. Ct. 2653 (2011); *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012); *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999). Accordingly, as argued in detail in GFI's petition, it has become increasingly clear that any attempts to ban common and usual names like "soymilk" would be unconstitutional.

[8] *Ocheesee Creamery v. Putnam,* 851 F.3d 1228, 1240 (11th Cir. 2017), attached to this comment for your convenience.

Adopting the regulatory language proposed in GFI's petition would be a simple, commonsense resolution of the pending Soyfoods petition, and would further respond to requests from the judicial and legislative branches.

Consumers refer to soy milk as soy milk. The term clearly communicates that soy milk is a form of milk that is made of soy. Likewise, rice noodles are noodles that are made of rice, and gluten-free bread is a form of bread that does not contain gluten. FDA should provide clarity that such straightforward terms are acceptable.

Sincerely,

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ATTACHMENT 1

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Petition to Recognize the Use of Well-Established Common and Usual Compound Nomenclatures for Food	))))	Docket No. FDA-2017-P-1298

Submitted by the

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CITIZEN PETITION

The Good Food Institute[1] ("GFI") submits this petition under sections 403(i), 201(n), and 701(a) of the Federal Food, Drug, and Cosmetic Act ("FDCA" or "the Act")[2] to request that the Commissioner of Food and Drugs issue regulations clarifying how foods may be named by reference to the names of other foods. Many products named in this fashion are already on the market, with many more likely to be developed in the future. The requested clarification would be consistent with current FDA regulations and policies, would reflect consumer understanding and the current realities of products in the marketplace, and would serve to foster continued innovation. Further, promulgating a general regulation regarding the nomenclature of these products will avert perceived regulatory uncertainty surrounding such product names, and will promote honesty and fair dealing in the interest of consumers.[3]

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[1] The Good Food Institute is a 501(c)(3) nonprofit organization that is working toward a healthy, humane, and sustainable food supply, by publicly advocating for and encouraging research into alternatives to conventional animal foods.

[2] 21 U.S.C. §§ 343(i), 321(n), 371(a).

[3] 21 C.F.R. § 130.5(b). GFI further asserts that it is prepared to substantiate the information in this petition by evidence in a public hearing, if such a hearing becomes necessary. 21 C.F.R. § 130.5(c).

I. Action Requested

GFI requests that FDA issue a regulation clarifying that new foods may be named by reference to other "traditional" foods in a manner that makes clear to consumers their distinct origins or properties. As described herein, the practice of using such names is well-established in the marketplace, and consumers easily understand and accept such common or usual names for a wide variety of products. Specifically, GFI requests that FDA amend 21 C.F.R. § 102.5, to add the following language 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 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.

GFI further requests that FDA, in the interim while undertaking the proposed rulemaking, publish guidance for industry clarifying that such product names may generally be used, consistent with the proposed regulation and the contents of this petition.

II. Statement of Grounds

A. Statement of Factual Grounds

1. Consumers are increasingly seeking out new variations on familiar foods.

The American food supply today consists of a greater variety of foods than ever before. The diverse array of food products now on the market can cater to the needs and tastes of most any consumer, and the plethora of options available to consumers continues to grow year after year.[4]

The increasingly diverse varieties of food in the marketplace are available because consumers are demanding them, for several reasons. Changing consumer preferences may partly reflect changing demographics and greater awareness (and availability) of the variety of foods from different parts of the world. Additionally, a large and growing share of consumers are becoming more discerning of the food they buy, selecting certain foods over others for reasons of health, environmental and ethical concerns, or personal taste.[5]

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[4] US Department of Agriculture, Agricultural Research Service, Nutrient Data Laboratory, USDA National Nutrient Database for Standard Reference Dataset for What We Eat In America, NHANES (Survey-SR), October 2015, available at https://www.ars.usda.gov/Services/docs.htm?docid=25662 (noting the addition of 265 "new foods" to the latest NHANES survey database); US Department of Agriculture, Economic Research Service, New Products, October 12, 2016, available at https://www.ers.usda.gov/topics/food-markets-prices/processing-marketing/new-products/ (describing the upward trend of new food product introductions per year since the early 1990s).

[5] The "new foods" added to the 2013–2014 NHANES database "include mainly commercially processed foods such as several gluten-free products, milk substitutes, sauces and condiments such as sriracha, pesto and wasabi, Greek yogurt, breakfast cereals, low-sodium meat products, whole grain pastas and baked products, and several beverages including bottled tea and coffee,

As part of this trend, consumers have become accustomed to seeing various qualifiers and claims in food labeling and advertising: organic, low-fat, reduced fat, fat-free, reduced calorie, low-carb, gluten-free, wheat-free, dairy-free, soy-free, no artificial colors, non-GMO, grown without pesticides, raised without antibiotics, no added sugars — the list goes on. Some of these qualifiers are subject to definitions under the law and regulations administered by FDA and USDA; others are constrained only by the general requirement that they not be false or misleading.

FDA and Congress have responded to these changes in the marketplace and in consumer demand by providing frameworks for new labeling claims (whether mandatory or voluntary), while also giving producers flexibility in formulating new products to suit these changes in consumer demand. One significant example of this trend is FDA's regulation relating to nutrient content claims, promulgated after the passage of the Nutrition Labeling and Education Act of 1990 (NLEA).[6] In that regulation, 21 C.F.R. § 130.10, FDA permitted modified versions of foods to be labeled with a "nutrient content claim and a standardized term," even if they did not comport with the standard of identity for the standardized term. This allowed new products with reduced levels of nutrients of concern to consumers (e.g. fat, sodium, calories) to be labeled in a clear manner that references standardized food terms (e.g. ice cream), leading to products with names like "low-fat ice cream" or "reduced calorie salad dressing."

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coconut water, malt beverages, hard cider, fruit-flavored drinks, fortified fruit juices and fruit and/or vegetable smoothies." USDA NHANES survey, note 4, above.

[6] Public Law 101-535.

Since the early 1990s, the list of nutrients or ingredients of interest to consumers has grown significantly. For example, the prevalence of common food allergies has apparently increased for unknown reasons,[7] and more consumers now seek foods free of specific allergens. Congress has responded by amending the FDCA to require labeling disclosures of common allergens,[8] and food producers have responded by making available varieties of (and alternatives to) traditional foods that do not contain common allergens such as wheat, milk, peanuts, egg, or soy. Similarly, the prevalence and identification of celiac disease appears to be increasing;[9] consumers with celiac disease are advised to avoid gluten, and many other consumers avoid gluten due to non-celiac gluten sensitivity or for other reasons. FDA has responded by defining the term "gluten-free,"[10] and food producers have responded by creating new varieties of traditional foods that do not contain gluten and are labeled "gluten-free."

Yet another significant (and growing) group of consumers has sought to reduce or eliminate certain animal products — especially dairy products — from their diet. Some of these consumers are avoiding allergens as described above (as milk is among the most

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[7] K.D. Jackson et al. *Trends in Allergic Conditions among Children: United States, 1997–2011*. National Center for Health Statistics Data Brief (CDC), May 2013, *available at* https://www.cdc.gov/nchs/data/databriefs/db121.pdf.

[8] *See* Food Allergen Labeling and Consumer Protection Act of 2004, Pub. Law 108-282; 21 U.S.C. §§ 343(w), 321(qq).

[9] *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.

[10] FDA, "Final Rule: Gluten-Free Labeling of Foods" 78 Fed. Reg. 47154 (Aug. 5, 2013).

common food allergies). Additionally, many consumers avoid dairy products due to lactose intolerance.[11] Still other consumers have reduced or eliminated their consumption of dairy for reasons of health, due to environmental or ethical concerns, or for mere personal taste. This trend has been most visible in recent years with a sharp increase in the consumption of alternatives to traditional fluid dairy milk. From 2011–2015, sales of almond milk grew 250%, surpassing the next most popular alternative (soy milk) and reaching nearly $900 million in annual sales in 2015.[12] Other plant-based alternatives to traditional dairy products (such as yogurt, cheese, and ice cream) are becoming more common as well, as just one part of a larger thriving plant-based food industry that has been growing so rapidly in response to consumer demand.

In sum, the growth in "new foods" described above, as well as many others has been ongoing since at least the 1990s and shows no signs of slowing.[13] Whether due to changes in demographics, or due to health, environmental, or ethical concerns of consumers, or merely due to changes in taste, the American food supply will continue to grow more diverse with a greater variety of products. GFI therefore submits this petition, requesting FDA to clarify that food producers may label and name their new products in

[11] Demographic shifts in the American population may contribute to an increasing incidence of lactose intolerance; FDA, citing NIH estimates, has noted that "up to 75% of all adult African Americans and Native Americans and 90% of Asian Americans are lactose intolerant." FDA, Problems Digesting Dairy Products?, October 2009, available at http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM143705.pdf.

[12] Nielsen Insights, *Americans Are Nuts for Almond Milk* (Mar. 31, 2016), available at http://www.nielsen.com/us/en/insights/news/2016/americans-are-nuts-for-almond-milk.html.

[13] See note 4 above.

a clear, commonsense manner consistent with consumer expectations, with the law applied fairly and equally to each.

2. **Many products on the market are already named in a manner consistent with the standard GFI proposes**.

The new food products described above — whether brought from other parts of the world or newly invented — often resemble familiar products that are considered traditional in the American diet. Consumers often name them by reference to such familiar and "traditional" products by adding a qualifying term in front of the name of the traditional product (as GFI proposes). Example of this practice are too many to list comprehensively, but in this section, GFI discusses numerous examples, some of which pre-date the FDCA itself. And more specifically, this section focuses on well-known food products that incorporate the most closely regulated food names — those with established standards of identity.

To start, consider bread, a food as old as civilization. Historically, bread has been made from the ground meal or flour of a variety of plant species, usually (but not always) leavened with yeast. Virtually every culture around the world has its own versions of this dietary staple — countless variations with different ingredients and methods of preparation that have been developing for centuries.

But in the United States, FDA has specifically defined "bread" as a product primarily consisting of (non-durum) wheat flour, and requires that it be leavened with

yeast and baked.[14] "Nonwheat flours, nonwheat meals, nonwheat grits, . . . and nonwheat starches" may be used, but only "if the total quantity is not more than 3 parts for each 100 parts by weight of [wheat] flour used."[15] Additionally, "bread" must weigh half a pound or more.[16] Does this regulation mean that other types of bread (e.g. unleavened or nonwheat varieties from around the world, cooked by different methods, in different shapes and sizes) cannot be called bread?

The answer, of course, is no. Almost any American consumer is aware of the existence of rye bread, cornbread, and potato bread — just a few examples of breads commonly eaten in the United States (especially in certain regions or communities). Consumers know that bread can take different forms, such as flatbreads like pita bread or matzo. Some consumers seek out "multigrain" breads precisely because they contain a variety of nonwheat grains.[17] Still other consumers with celiac disease or gluten sensitivity seek out gluten-free breads, a variety of which are now on the market, along with gluten-free rolls and buns.[18] No consumers purchasing these diverse offerings are deceived or confused by the fact that they are labeled "____ bread" even if the products do not conform to the standard of identity for "bread." The qualifying term immediately

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[14] 21 C.F.R. § 136.110(a), (c)(1), (c)(3); 21 C.F.R. § 137.105 (defining "flour" as a product made from "wheat, other than durum wheat and red durum wheat.").

[15] 21 C.F.R. § 136.110(c)(11).

[16] 21 C.F.R. § 136.3(a).

[17] A purchaser of "12-grain bread" might be unpleasantly surprised if the product *did* conform to the general standard of identity for "bread" (because in that case, the 11 nonwheat grains would, in total, constitute less than 3% of the total flour used).

[18] Rolls and buns must follow the same standard as "bread" except as to weight.

preceding "bread," denoting alternative grain sources or other origins or properties, provides enough clarity that the product is different from (unqualified) "bread."

Consider also another staple in many cultures — noodles. As with bread, FDA has defined noodles as "ribbon-shaped" products made exclusively from wheat flours (including durum, the variety of wheat typically used in pasta), and requires that they contain egg products.[19] (Per FDA's identity standards, ordinary pasta and similar products that do not contain eggs are "macaroni products.")[20] But many cultures, in East Asia and Southeast Asia for example, eat noodles made from rice, sometimes broad and flat rather than ribbon-shaped, and such noodles hardly ever contain egg. Other noodles of the world are made from different grains (e.g. Japanese *soba* noodles, made from buckwheat) or are made from wheat but without egg (e.g. ramen noodles). Are these products wrong to call themselves "noodles" in light of FDA's standard of identity? Of course not: they are rice noodles, ramen noodles, bean thread noodles, and so on. Again, the qualifying term — the "____" in "____ noodles" — notifies any reasonable consumer

[19] 21 C.F.R. § 139.150(a), (b).

[20] This antiquated term (established in 1944 under the heading "alimentary pastes", 9 Fed. Reg. 14881) demonstrates how far some standards of identity have fallen behind the evolution of the English language and consumer expectations: Americans today simply call it "pasta" and understand "macaroni" to refer exclusively to small tubular pasta varieties (meanings that reflect the Italian *pasta* and *maccheroni*). The standardized term is frankly confusing to the modern consumer, and the regulatory meaning cannot even be found in many modern dictionaries. Thus, some pasta producers have chosen to identify their products with the universally-understood term "pasta" rather than "macaroni products." This may technically violate FDA regulations, but justifiably so: pasta is simply the true common or usual name of these products, notwithstanding the outdated standard of identity.

that the product is distinct from what FDA may define as "noodles" (to the extent the reasonable consumer knows about FDA's definition of "noodles" from 1944).[21]

To give another example of similar compound names in action, "butter" has a standard of identity defined by statute — a product of more than 80% milkfat.[22] In spite of this, FDA defined standards for "peanut butter" and "fruit butters" (such as apple butter), products that do not contain butter.[23] And outside of FDA's identity standards, other "nut butters," such as almond butter or cashew butter, are now common in the market (for those allergic to peanuts, or who just prefer the taste), and consumers readily understand that these products are not (dairy) butter or other "____ butters."

It is in a similar vein that another global food — soy milk or soymilk — came to the United States in the mid-20th Century from areas of the world where cow's milk was often not traditionally consumed. And although the (unqualified) term "milk" has a standard of identity that refers exclusively to cow's milk,[24] consumers have long understood that various compound terms of the form "_____ milk" or "milk of _____" refer to distinct products unrelated to cow's milk. (Goat milk, buffalo milk, coconut milk, almond milk, or milk of magnesia, to name a few.) These compound constructions are so thoroughly lexicalized that they often appear in dictionaries as part of the first or

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[21] Similarly, many wheat-free pasta products are now on the market (e.g. "gluten-free pasta," "brown rice pasta"), and these products often incorporate the names of standardized "macaroni products" (e.g. "gluten-free spaghetti"). 21 C.F.R. § 139.110(b)–(d).

[22] 21 U.S.C. § 321a.

[23] 21 C.F.R. § 150.110; 21 C.F.R. § 164.150.

[24] 21 C.F.R. § 131.110.

second definition of the word "milk,"[25] and the overwhelming majority of consumers refer to these products by these names.[26] The government itself (including FDA) has played its role in this linguistic trend, using the common names of products like soy milk and other dairy alternatives in public statements and documents.[27]

These linguistic patterns are hardly limited to the English language or the U.S. market — various languages from around the world use the same semantic constructions to describe the same products.[28] And almond milk is similarly well-established —

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[25] *See, e.g.* Merriam-Webster Online, Definition of MILK, available at https://www.merriam-webster.com/dictionary/milk (accessed January 26, 2017): "1 b . . . (2): a food product produced from seeds or fruit that resembles and is used similarly to cow's milk <coconut *milk*> <soy *milk*>. 2: a liquid resembling milk in appearance[.]"

[26] Google statistics show that since 2004, consumer searches in the United States for the terms "soy milk" and "almond milk" have outnumbered searches for alternative names ("soy drink," "soy beverage," etc.) by more than 30-to-1. https://goo.gl/DLhGz0.

[27] *See, e.g.* FDA, *Health Claims; Soy Protein and Coronary Heart Disease* 63 Fed. Reg. 62977, 62978 (Nov. 10, 1998) (referring to "soy milk, soy yogurt, and soy cheese."); USDA, *Enhancing Retailer Standards in the Supplemental Nutrition Assistance Program (SNAP)* 81 Fed. Reg. 90675, 90693–94 (Dec. 15, 2016) (referring to "soy yogurt," "soy milk," "soy cheese," "almond milk," and "rice milk."); DHHS & USDA, *2015–2020 Dietary Guidelines for Americans* at p. 23 (describing dairy alternatives from soy and other plants, marketed as plant "milks").

[28] In China, the country of soy milk's origin, 豆奶 (Mandarin *dòu nǎi*, literally "bean milk") is used as one possible name of the product, although the name 豆浆 (*dòu jiāng*, loosely translated as "bean slurry") is more common in most places. The former name (literally "bean milk") is especially common in Taiwan. The Japanese 豆乳 (*tonyu*) has the same literal meaning of "bean milk," and the Korean 두유 (*duyu*) has a similar linguistic origin. This construction has extended to Western countries where the product appeared later in history — the French and Spanish *lait de soja* and *leche de soja* (literally "milk of soy") and the German *Sojamilch* ("soymilk") are a few examples. Often these alternative meanings of "milk" are thoroughly lexicalized and refer to other milky liquids, including other cow's milk alternatives. *See, e.g.* "leche" in DICCIONARIO DE LENGUA ESPAÑOLA, available at http://dle.rae.es/?id=N2tsDWF, accessed January 26, 2017 (definition 3, translating as "white juice obtained from some plants, fruits, or seeds. *Milk of coconut, of almonds.*") The European Union has generally disapproved of the use of such terms in food labeling since 2007 (later adding exceptions for almond and coconut milks), but Google

though it has had the recent astronomical rise in popularity described above, it was common (and named similarly) in Western and Middle Eastern kitchens *centuries* ago.[29] Clearly, names of this form have deep historical and linguistic roots.

Further, these age-old foods with names of the form "____ milk" are now as familiar and clear to consumers as rye bread, rice noodles, or cashew butter. Consumers choose these products precisely because they are not cow's milk, whether due to allergies, other ingredient sensitivities or health concerns, ethical concerns, environmental concerns, or simple taste preference. And although some have claimed that including the word "milk" may confuse consumers (leading them to think the product contains cow's milk), consumer research has demonstrated that practically all consumers who have heard of these products (including those who do not consume them) are aware of their basic nature as cow's milk alternatives that do not contain cow's milk.[30]

Non-wheat breads, non-wheat noodles, non-dairy butters, and non-dairy milks are merely a few of the instances in which established products on the market incorporate the

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statistics reveal that the EU has failed in its effort to regulate natural language: use of these names persists and predominates over alternative names. See https://goo.gl/9CLoKg.

[29] For example, the 14th-Century French recipe book *Le Viandier de Taillevent* contains numerous references to *lait d'almendes* (or in Modern French, *lait d'amande* — milk of almond). 23 LE VIANDIER DE TAILLEVENT (1892 transcription of the oldest surviving manuscript, circa 1326–1395), available at https://books.google.com/books?id=D_EYAAAAYAAJ&pg=PA23.

[30] Soyfoods Association of North America, *Summary of Research on Consumer Awareness of Soymilk and Dairy Milk*, appended to this petition as Attachment A. In this 814-consumer survey conducted in 2006, the share of consumers who answered that they believe "cow's milk" is an ingredient in "soymilk" was less than 0.5%, with approximately 3% reporting "milk" as an ingredient.

common or usual name of another food to clearly and directly describe what the product is, despite being a very different product.[31] This structure, the addition of one word to another to form an entirely different word with a new meaning, is not just a matter of how marketing works — it is simply a matter of how language works. GFI submits this petition asking that FDA acknowledge and accept this fact and practice, not only for the products described above, but for others that may become part of the American diet in the future. As described in detail below, doing so would be consistent with the FDCA and with FDA policy and past practice. It would also be consistent with FDA's responsibilities under the Constitution: to regulate the market neutrally and with due respect to the First Amendment rights of food producers to label their products in a clear manner that consumers understand and accept.

B. Statement of Legal Grounds

1. GFI's proposed regulation is consistent with the FDCA and with FDA policy and practices.

GFI is asking FDA to establish a framework that formally recognizes the reality of the marketplace regarding the compound naming of foods that incorporate the common names of other foods in a way consumers clearly understand. In a way, what GFI requests is a regulation that clarifies existing law and practice; not only has FDA allowed

[31] And for good measure, here are a few more: herbal teas (like peppermint, chamomile, or ginger teas) that contain no tea; coconut water, which is not water; turkey bacon, which is not bacon; coconut cream and non-dairy creamer, neither of which contain cream; root beer, which contains no beer; English muffins, which are not muffins; shellfish, which are not fish; jellyfish, which are neither jelly nor fish; and rice cakes, which seem particularly unworthy of being called "cake."

products with such names to remain on the market, but the standard proposed by GFI is also consistent with FDA's longstanding interpretation of the FDCA and its regulations.

Even though the proposed regulation would do nothing more than clarify existing law and practice, such clarification would be helpful to industry and the public. The full meaning of the law and regulations is not always apparent to those who simply read the general language found in the United States Code or the Code of Federal Regulations, because the meaning of these provisions develops over time through interpretation by FDA and the courts, as well as through the agency's practices and policies. To put it bluntly, this is an area of law that is sometimes misunderstood or misapplied by some. For example, the Act's standard-of-identity provision is sometimes misread to completely preclude the use of standardized terms in non-standardized food names, and the Act's prohibition on unlabeled "imitation" foods is misread to cover any similar-looking food that can be used in place of another. Such misapprehensions of the law are clearly incorrect, but the fact that they persist can still do real harm to competitive industry and the public.

Such harm is not merely speculative, but concrete and apparent. For example, misguided statements of the law are often put forth by some members of industry in an anticompetitive effort to increase regulatory burdens on other members of industry. The most visible example of this today is a campaign by dairy producers against plant-based dairy alternatives — particularly soy milk and almond milk, which (as described above)

have become particularly popular and mainstream in recent years.[32] These dairy industry campaigns against regulatory flexibility for new products have spanned decades,[33] and have only intensified as demand for soy milk, almond milk, and other dairy alternatives has grown.[34] Recently, members of Congress from dairy-producing states were enlisted to argue on behalf of the dairy industry's distortions of the law,[35] and one Senator has even proposed to amend the FDCA in service of the dairy industry's anticompetitive goals.[36] These efforts spawn confusion and uncertainty for producers — many of which are startups and small businesses particularly sensitive to perceived regulatory risk.

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[32] Due to the attention these products have received, this petition will frequently use them as examples to illustrate how the proposed general language would apply.

[33] See, e.g. *Nat'l Milk Producers Fed. v. Harris*, 653 F.2d 339, 343 (8th Cir. 1981) (unsuccessful challenge to FDA's interpretation of the Act's "imitation" provisions); Letter from National Milk Producers Federation to CFSAN, February 14, 2000, available at http://www.fda.gov/ohrms/dockets/dailys/04/may04/050404/97p-0078-c00166-vol2.pdf; Comments of National Milk Producers Federation, July 28, 2010, available at https://www.regulations.gov/document?D=FDA-2010-N-0210-0092; Comments of National Milk Producers Federation, May 5, 2014, available at https://www.regulations.gov/document?D=FDA-2009-D-0430-0074.

[34] However, the dairy industry does not speak with one voice on this issue. For example, Dean Foods, the largest processor and distributor of fluid milk in the country, wrote to FDA in 2000 that "the term 'soymilk' has been widely recognized in our industry as the commonly used name for natural beverages made out of soybeans, water and other vegetable based ingredients for a number of years. We recognize this term to be accurately descriptive, meaningful and widely understood . . . . We have not found this term to be misleading to ourselves or our customers, [and w]e have not received any complaints from customers or consumers regarding this issue." Comment from Dean Foods Company, March 8, 2000, available at https://www.regulations.gov/document?D=FDA-1997-P-0016-0024. This comment, and many others like it, regards a 1997 citizen petition requesting that FDA establish a standard for "soymilk." GFI believes that this step is currently unnecessary because the name has already been clearly established by common usage, per 21 C.F.R. § 102.5(d).

[35] See Letter to Commissioner Califf from Congressman Peter Welch (D-Vt.) et al., Dec. 16, 2016, available at http://www.nmpf.org/files/Welch-Simpson%20Letter.pdf.

[36] DAIRY PRIDE Act, S. 130, 115th Cong. (2017), proposed by Senator Baldwin (D-Wisc.)

These misapprehensions of the law also manifest themselves in the courts. Some lawsuits have been filed alleging that soy milk and almond milk products are improperly named, and though such frivolous contentions have (so far) generally been dismissed at the pleading stage,[37] more such lawsuits have recently been filed.[38] Defending against these lawsuits creates costs for the producers of these products, and these costs may ultimately be passed on to the consumer. And these meritless lawsuits, just like perceived regulatory risk, can have a chilling effect that may dissuade businesses (especially small ones) from labeling their products in a clear, accurate manner that consumers understand. FDA's clarification of the law would pre-empt meritless lawsuits like these, to the benefit of producers and consumers alike.

To see how GFI's proposed language is consistent with the FDCA, and how it embodies FDA's policies and practices, this petition now reviews the (arguably) relevant provisions of the Act, and how they have been interpreted by FDA, and their applicability to names of the form GFI has proposed. This includes an analysis of (1) the Act's protection of standards of identity for certain foods; (2) the Act's requirement that products bear their common or usual name; and (3) the Act's provision regarding "imitation" foods.

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[37] See Order, *Gitson v. Trader Joe's Co.*, 13-cv-01333, Doc. 139 (N.D. Cal., Dec. 1, 2015); *Ang v. WhiteWave Foods Co.*, 2013 WL 6492353 (N.D. Cal., Dec. 10, 2013). These opinions are appended to this petition as Attachment B.

[38] *Kelley v. WWF Operating Co.*, 17-cv-117 (E.D. Cal., filed Jan. 24, 2017); *Painter v. Blue Diamond Growers*, BC 647816 (Los Angeles Super. Ct., filed Jan. 23, 2017).

Standards of Identity

When considering food names that incorporate the names of standardized food, section 403(g) of the Act[39] is sometimes seen to serve as the starting point of the analysis. That section states that a food is misbranded if it "purports to be or is represented as a food for which a definition and standard of identity has been prescribed . . . unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard[.]" For the various nonconforming articles described in detail above, the question, then, is whether a food name that merely includes the name of a standardized food necessarily "purports to be or is represented as" the standardized food.

The clear answer, as FDA and courts[40] have long recognized, is no. By their own terms, standards of identity only govern *unqualified* food names. Thus, this provision creates no barrier to qualified uses of standardized terms, because the use of a qualifier will generally indicate that the food does not purport to be the standardized food. So peanut butter does not purport to be "butter," rice noodles do not purport to be "noodles," and potato bread does not purport to be "bread," at least insofar as these terms are defined by regulation (as opposed to ordinary language).

Once again, take "milk" as an example. Despite the recent objections to qualified uses of the word "milk" described above, FDA has already recognized that its identity

[39] 21 U.S.C. § 343(g).

[40] See e.g. *62 Cases of Jam v. United States*, 340 U.S. 593, 600 (1951) ("Congress used the words 'purport' and 'represent'—terms suggesting the idea of counterfeit.")

standard applies only to the unqualified term — indeed, FDA has recognized this fact for as long as the term has been standardized. In the very same regulation establishing the standard of identity for "milk," FDA addressed its applicability to "flavored milk products" (e.g. chocolate milk).[41] On that topic, FDA stated, "[s]ince flavored milks, such as chocolate milk, *do not purport to be and are not represented as milk*, their distribution as nonstandardized foods could be continued after the establishment of an identity standard for milk."[42] Similarly, FDA formerly prescribed a standard for a food known as "ice milk"[43] (what is today called "low-fat ice cream") without any question that this product purported to be milk. And of course, buttermilk and milks from other animals (e.g. goat milk) have long existed on the market as nonstandardized foods, without any reasonable suggestion that they purport to be or are represented as "milk," as defined by regulation. By the same token, section 403(g) of the Act presents no problem for names like "soy milk" or "almond milk," as such products simply do not purport to be "milk."[44]

More generally, FDA noted long ago that the "existence of a standard of identity for a particular food does not necessarily preclude the use of the standardized name in

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[41] 38 Fed. Reg. 27924, 27925 (Oct. 10, 1973).

[42] *Id*. (emphasis added.) The Commissioner nonetheless found it "reasonable" to include provisions for such products in the standard of identity itself.

[43] 25 Fed. Reg. 7125 (Jul. 27, 1960).

[44] See *Gitson*, at 3–4 ("the standardization of milk simply means that a company cannot *pass off* a product as 'milk' if it does not meet the regulatory definition of milk. . . . Soymilk, in short, does not 'purport[] to be' from a cow within the meaning of section 343(g).")

connection with the name of a nonstandardized food, as 'in some cases it may be necessary to include a standardized name in the name of the substitute food in order to provide the consumer with accurate, descriptive, and fully informative labeling.'"[45] Regarding "substitute foods" specifically, FDA explained more fully in 1983:

> in some cases, it may be reasonable and appropriate to include the name of a standardize[d] food or other traditional food in the name of a substitute food in order to provide the consumer with an accurate description. When this is done, the name of the food must be modified such that the nature of the substitute food is clearly described and is clearly distinguished from the food which it resembles and for which it is intended to substitute. The modification of the traditional or standardized food's name must be descriptive of all differences that are not apparent to the consumer. Thus, the procedure for naming these foods will depend on the nature of the substitute food and the manner and extent to which it differs from the food it simulates.[46]

General principles like these were reflective of FDA's shift away from prescribing standards of identity for new foods, and towards regulating most foods under general principles governing common or usual names.[47] These principles chiefly govern the food naming patterns that are the subject of this petition, and we examine them next.

Common or Usual Names

Under section 403(i) of the Act, if a food does not represent itself as a standardized food, it must bear "the common or usual name of the food, if any there

[45] 44 Fed. Reg. 3964, 3965 (Jan. 19, 1979), quoting 38 Fed. Reg. 20702, 20703 (Aug. 2, 1973).

[46] 48 Fed. Reg. 37666, 37667 (Aug. 19, 1983).

[47] *See e.g. id.* (withdrawing a proposal to establish standards of identity for milk, cheese, and cream substitutes). The fact that FDA has not established a standard of identity for any new food since 2002 ("white chocolate," 67 Fed. Reg. 62177) is reflective of FDA's change in approach.

be[.]"[48] The most natural reading of this provision is that food producers must simply label their products in accordance with what consumers commonly or usually call them.[49]

In clarifying this requirement, FDA has issued a regulation establishing general principles governing common or usual names.[50] (It is this regulation, 21 C.F.R. § 102.5, that GFI proposes amending.) The regulation, consistent with the ordinary meaning of section 403(i) described above, notes that the "common or usual name of a food may be established by common usage[.]"[51] In the more general case (e.g. when there is no such established common usage), the regulation states that the common or usual name of a food "shall accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients."[52] The regulation also states that the common or usual name "may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name."[53]

For the purposes of naming variations on other foods, this last provision is unfortunately somewhat vague and open to subjective interpretation. What names are

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[48] 21 U.S.C. § 343(i).

[49] Additionally, the language "if any there be" implies that some foods may *not* have a common or usual name, and that in such a case, there is no such obligation to identify the food under any particular name.

[50] Broadly speaking, this regulation is entitled to judicial deference under the *Chevron* doctrine, but only to the extent that it is a reasonable interpretation of the legal requirement of the Act. If, for example, FDA's regulation could be interpreted to prohibit the use of a name that consumers commonly use to identify a product, such an interpretation may not be entitled to judicial deference, particularly in light of the First Amendment concerns described later in this petition.

[51] 21 C.F.R. § 102.5(d).

[52] 21 C.F.R. § 102.5(a).

[53] *Id.*

"confusingly similar"? What names are "not reasonably encompassed within" another name? Without clarification of FDA's practices and policies, the vagueness of this provision leads to reasonable concerns about the risk of arbitrary (or even discriminatory) enforcement against some food products but not others.

Fortunately, FDA's stated policies and actual practices have added some clarity to these provisions. As we saw above, since the 1970s FDA has taken the position that it is sometimes "necessary" to include one name within another "in order to provide the consumer with accurate, descriptive, and fully informative labeling."[54] In the case of "substitute" foods, it is "reasonable and appropriate" to do so, as long as "the name of the food [is] modified such that the nature of the substitute food is clearly described and is clearly distinguished from the food which it resembles and for which it is intended to substitute."[55]

This policy faced opposition from some in industry — most notably the dairy industry, which was opposed to any use of dairy terms in the names of modified dairy products (most commonly, products with decreased milkfat content). But to the extent there was debate over naming such products,[56] it was largely settled with the passage of the NLEA in 1990 and FDA's subsequent promulgation of regulations under that law.[57] As a result of this change, food producers have been allowed to label food products with

[54] 44 Fed. Reg. 3964, 3965 (Jan. 19, 1979), quoting 38 Fed. Reg. 20702, 20703 (Aug. 2, 1973).

[55] 48 Fed. Reg. 37666, 37667 (Aug. 19, 1983).

[56] FDA established standards for some such products, but was not always consistent in its positions on other unstandardized products.

[57] 21 C.F.R. § 130.10.

nutrient-content qualifiers modifying the names of traditional foods. These names can be surprising at first, like "fat-free cheddar" (cheese without milkfat) or "fat-free ice cream" (ice cream without cream), often outright contradicting what consumers would ordinarily expect from these products. And the contradictions are not limited to the qualifying terms: FDA also allowed such food products to deviate from the standards of identity for the standardized foods in ways besides the clearly-identified changes in nutrient content. FDA permitted deviations from "non-ingredient provisions" such as "moisture content, food solids content requirements, or processing conditions."[58] Additionally, FDA 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 ordinarily violate the standard of identity.[59]

As FDA explained at the time of this change, the qualifying nutrient-content language, together with "accompanying label statements[ ] and nutrition labeling, will enable consumers to distinguish traditional foods from modified versions of these foods . . . ."[60] This language demonstrates FDA's position that if qualifying language in

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[58] 21 C.F.R. § 130.10(c).

[59] 21 C.F.R. § 130.10(d)(1). However, ingredients "specifically prohibited by the standard" are not permitted in the modified foods. 21 C.F.R. § 130.10(d)(3).

[60] 58 Fed. Reg. 2431, 2439 (Jan. 6, 1993). The introduction of nutrition labeling by the NLEA was especially important — if a consumer is confused by what exactly "fat-free ice cream" is (because the ingredients of this product can vary drastically from brand to brand), the consumer has access not just to a list of all the ingredients, but also to detailed nutritional information about the product. The "Nutrition Facts" panel has become familiar to consumers over the past two decades, and consumer consciousness of this information has significantly decreased consumer reliance on expectations that food products conform to recipes specified in identity standards.

the product name, together with other information on the label, effectively enables consumers to distinguish the modified food from the traditional food, consumers will not be confused or otherwise deceived by the product, notwithstanding the inclusion of the name of a traditional food that it resembles. The language that GFI proposes in this petition follows this standard.

This general principle applies just as well to cashew butter, rice noodles, and soymilk, as it does to "fat-free [cream-free] ice cream." Indeed, the first three terms are (if anything) *clearer* than the last, as they provide much more information as to what *is* in the product, as opposed to what is not. More analogous still would be products like gluten-free bread — as above, if a consumer is confused by what exactly "bread" is without gluten (or wheat), the ingredients list and Nutrition Facts are no more than a panel away.

Imitation

Finally, it is necessary to discuss how GFI's proposed regulation is consistent with the law and FDA policies governing "imitation" labeling, as some food products (like soymilk) are sometimes argued to be "imitations."[61] Section 403(c) of the Act deems any product misbranded if it is "an imitation of another food, unless its label bears . . . the word 'imitation' and, immediately thereafter, the name of the food imitated."[62] By

[61] See, e.g. Comments of National Milk Producers Federation, May 5, 2014, available at https://www.regulations.gov/document?D=FDA-2009-D-0430-0074.

[62] 21 U.S.C § 343(c).

regulation, FDA has clarified that a food "shall be deemed to be an imitation . . . if it is a substitute for and resembles another food but is nutritionally inferior to that food."[63]

FDA described this regulation as "fully consistent" with early court cases interpreting section 403(c), which "discussed factors of resemblance, substitution, and inferiority in concluding that the products involved were imitations."[64] These early cases discussed "substitution and resemblance" in terms of taste, smell, appearance, color, texture and body, as well as its intended uses and method of manufacture, packaging, sale.[65] (Elsewhere in its regulations, FDA uses the catchall term "organoleptically" — pertaining to all senses, including sight, taste, touch, and smell — to determine whether a food is a "substitute for" another food in deeming it an "imitation.")[66] Further, in establishing its regulation regarding imitation foods, FDA made clear that new food products (clearly identified as such) would not be deemed imitations, favorably citing cases "holding that a vegetable oil substitute for cream, which looks like, tastes like, and is intended to replace cream, is not an 'imitation cream' but rather a separate and distinct product that should bear its own common or usual name."[67]

In light of these narrow criteria for what makes a food an "imitation" of another food, specified in FDA's regulatory decisions and early court cases, only convincing

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[63] 21 C.F.R. § 101.3(e)(1).

[64] 38 Fed. Reg. 20702, 20702 (Aug. 2, 1973).

[65] *United States v. 651 Cases . . . Chil-Zert*, 114 F. Supp. 430, 432 (N.D.N.Y. 1953).

[66] 21 C.F.R. § 101.13(d).

[67] 38 Fed. Reg. at 20702, citing *Coffee-Rich, Inc. v. Kan. State Bd. of Health*, 388 P.2d 582 (Kan. 1964), *Coffee Rich, Inc. v. Mich. Dept. of Agriculture*, 135 N.W.2d 594 (Mich. 1965).

counterfeit products (which are also nutritionally inferior) fall into the category of "imitation" foods. Partly due to this exacting standard, and partly due to the more recent trends in "common or usual" nomenclature described in this petition, the "imitation" label is practically never seen on any products today.

Arguments that products like soymilk or almond milk are "imitations" of cow's milk rely too much on FDA's language "substitute[s] for and resembles another food," without evaluating this language in terms of the court decisions this language codifies (or even FDA's own use of the term "organoleptically"). A basic flaw in such arguments is that they appear to construe "resembles" too narrowly in a visual sense — essentially, they argue that because soymilk *looks* like cow's milk and is used in similar ways, it is an imitation. For one thing, this completely ignores other "organoleptic" factors (like taste, smell, and texture) that are manifestly different to anyone who has compared such products. Another obvious flaw in this argument is that, if taken at face value, it would prove too much: rye bread would be "imitation bread" and gluten-free spaghetti would be "imitation spaghetti," because both products look very much like their wheat counterparts and are used in the same way. Even goat milk would not escape this fate — it has significantly less Vitamin B_{12} than milk from cows — and would therefore need to bear the name "imitation milk." This would be nonsense. The Act's "imitation" provision has, since at least the 1960s, been understood to target nutritionally-inferior, cheap

counterfeit products — and not distinct food products that clearly identify themselves as such.[68]

For the reasons stated above, the standard described by GFI is consistent with FDA's recent policy and practices regarding the naming of new food products.[69] The language GFI proposes would allow labels to state clearly, as qualifiers to other common names, "alternative plant or animal source[s] that replace[ ] the main characterizing ingredient(s) or component(s) of" these other foods — be it goat milk or almond milk, rye bread or cornbread, rice noodles or buckwheat noodles. In the modern marketplace, consumers are very familiar with products like these that advertise alternative plant and animal sources. Products may also state, as clear qualifiers to other common names, the "absence of a primary characterizing plant or animal source, or of a nutrient, allergen, or other well-known characterizing substance" — like gluten-free bread, dairy-free ice

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[68] On this point, some are apparently attempting to relitigate bygone unsuccessful challenges to FDA's narrow definition of "imitation." *Nat'l Milk Producers Fed. v. Harris*, 653 F.2d 339, 343 (8th Cir. 1981) (citing *Fed. of Homemakers v. Schmidt*, 539 F.2d 740 (D.C. Cir. 1976)).

[69] GFI recognizes that, in 2008 and 2012, FDA issued warning letters expressing an opinion that "soy milk" is not an appropriate name simply because "milk" is a standardized term. *See* Warning Letter to Fong Kee Tofu Co., March 7, 2012, available at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm295239.htm; Warning Letter to Lifesoy, Inc., August 8, 2008, available at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048184.htm. But FDA has maintained (and courts have agreed) that such letters are "informal and advisory." *Holistic Candlers and Consumers Assn. v. FDA*, 664 F.3d 940, 944 (D.C. Cir. 2012). As such, courts have not deferred to interpretations in such letters. *See, e.g. Ang v. WhiteWave Foods Co.*, 2013 WL 6492353 (N.D. Cal., Dec. 10, 2013) (declining to recognize these warning letters as FDA's considered, reasoned policy); *cf. Nat'l Mining Assn v. McCarthy*, 758 F.3d 243, 251 (D.C. Cir. 2014) (noting lack of deference to interpretive rules and statements of policy) (citing *United States v. Mead Corp.*, 533 U.S. 218 (2001)). For the reasons stated in this petition, GFI does not believe that FDA would, after careful consideration, formally adopt the line of reasoning stated briefly and informally in these warning letters.

cream, or wheat-free soy sauce.[70] As FDA has stated for qualifiers like "fat-free," these qualifiers effectively serve to notify consumers that these products differ from their traditional counterparts, and other information on the label enables consumers to inform themselves exactly how such products differ, including nutritionally. For the same reasons, the regulation also generally allows for any other compound name, provided it clearly notifies consumers that the product differs from the standardized or traditional food.

Finally, although the principles described in this petition are firmly rooted in established FDA policy and the practice of the agency, GFI is motivated to file this petition because others vocally disagree and, as noted earlier, have recently urged FDA to take a different course, specifically regarding plant-based dairy alternatives. As described below, this is constitutionally perilous territory: if FDA (or Congress) were to heed such calls and target new (and old) non-dairy alternative products for selective enforcement, it would violate the First Amendment rights of the producers of these

[70] GFI is also aware of 21 C.F.R. § 105.62, governing "food [that] purports to be or is represented for special dietary use by reason of the decrease or absence of any allergenic property or by reason of being offered as food suitable as a substitute for another food having an allergenic property[.]" At first blush, this regulation seems to provide some support for GFI's more general language, as it requires (and deems sufficient) "qualification of the name of the food . . . to reveal clearly the specific plant or animal [sources]." But it also contains onerous provisions, like requiring such products to label the "*proportion* of each ingredient" and the "specific plant or animal" source of *each* ingredient. A broad reading would imply that all foods that bear claims like "soy-free," "wheat-free," or "dairy-free," as well as many substitute foods, would be subject to these burdensome and heightened labeling requirements. Because it is unclear what (if any) relevance this provision has today in view of developments since its initial promulgation in 1941 (6 Fed. Reg. 5921) — such as mandatory allergen labeling and the NLEA — GFI has chosen not to discuss this provision extensively in this petition. GFI instead simply notes that this language, similar to GFI's proposal, has previously been used by FDA.

products to label and describe their products in a truthful and clear manner consistent with consumer expectations.[71]

2. Restrictions on commercial speech are subject to judicial scrutiny under *Central Hudson*, and proposed restrictions against dairy alternatives do not withstand such scrutiny.

Forbidding producers and sellers of products like soymilk or almond milk[72] from using such names would be a restriction on protected commercial speech, and would be subject to judicial scrutiny under the First Amendment. The constitutionality of such restrictions is determined under the Supreme Court's four-prong *Central Hudson* test:[73] if commercial speech (1) concerns lawful activity and is not misleading; and (2) the government asserts a substantial interest in restricting such speech; then (3) the government regulation must directly advance that interest and (4) not be more extensive than necessary to serve that interest. As described below, attempts to restrict food producers from using names of traditional products to describe new products would fail to satisfy this standard and would therefore violate the First Amendment.

Those who propose banning names like "soymilk" and "almond milk" frequently refer to such names as "misleading," simply because the products do not contain cow's

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[71] Further, in light of the First Amendment concerns described in this petition, courts would likely construe the Act and FDA's regulations as narrowly as possible to avoid these serious constitutional questions. See, e.g. *Solid Waste Agency of N. Cook Cnty. v. U.S. Army Corps of Eng'rs*, 531 U.S. 159, 172–73 (2001). This consideration would strongly favor the interpretation of the Act and regulations described above.

[72] GFI uses these products throughout this section for illustrative purposes because these products have been most visibly targeted by the dairy industry. However, the analysis is much the same for any other product conforming to the standard proposed by GFI.

[73] *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 (1980).

milk. Under the first prong of *Central Hudson*, regulations of false or misleading speech do not require extensive constitutional analysis, but the meaning of "misleading" in this context is narrowly delineated. Only when speech is *inherently* misleading will it fall outside of the protection of the First Amendment.[74] Otherwise, if speech is only *potentially* misleading, *Central Hudson* scrutiny applies in full, and the government may restrict such speech only in a manner that directly and narrowly serves its interest in preventing deception (or any other demonstrated substantial interest).[75] Further, the *government* carries the burden of demonstrating that such an interest in preventing deception is "substantial" and directly and narrowly served by the speech restriction.[76]

The government would not meet the very high bar of demonstrating that common names such as soymilk or almond milk are inherently misleading.[77] These products have long carried these names, and as described extensively in this petition, names such as these (constructed by adding a qualifying term in front of the name of another food) are used extensively in the marketplace for many products (as well as in natural language) without any apparent confusion. And courts that have considered the issue have concluded, as a matter of law, that no reasonable consumer would be misled by these

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[74] See *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)).

[75] *Id.* at 655–56.

[76] *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1217 (D.C. Cir. 2012) (citing *Edenfield v. Fane*, 507 U.S. 761, 770–71 (1993)).

[77] See *Pearson*, 164 F.3d at 655 (describing "inherently misleading" standard in terms of "awesome impact" leaving consumers "bound to be misled.")

product names.[78] Furthermore, consumer research on the understanding of the name "soymilk" has demonstrated that the proportion of consumers confused by the name is nearly zero.[79] It is unclear whether the government would be able to demonstrate that the term even has substantial *potential* to mislead, given the results of such research and how courts have addressed the issue. However, because this petition concerns the prospective nomenclature of a variety of products, we may assume for the sake of argument that the naming of at least *some* such products may have the conceivable potential to be misleading.

But even if the government could demonstrate that such names have substantial potential to mislead consumers, an outright ban on such names would still need to satisfy the final two prongs of *Central Hudson*. To do so, the restriction of such names must "directly advance" the interest in preventing consumer deception or confusion to a "material degree,"[80] and must be no more extensive than necessary to serve that interest. In the case of soymilk and almond milk, forbidding such names, which an overwhelming majority consumers already understand and use to refer to such products, could not

[78] See Order, *Gitson v. Trader Joe's Co.*, 13-cv-01333, Doc. 139 (N.D. Cal., Dec. 1, 2015); *Ang v. WhiteWave Foods Co.*, 2013 WL 6492353 (N.D. Cal., Dec. 10, 2013) ("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.") These opinions are appended to this petition as Attachment B.

[79] Soyfoods Association of North America, *Summary of Research on Consumer Awareness of Soymilk and Dairy Milk*, appended to this petition as Attachment A.

[80] *R.J. Reynolds*, 696 F.3d at 1218 (citations omitted).

possibly "directly and materially" serve an interest in preventing deception or confusion. (Labeling with an alternative name, like "soy beverage," might *itself* be confusing to consumers who are used to calling it "soymilk.") Although in general, banning a potentially confusing name outright may directly avoid potential confusion, banning the use of an already well-established name would result in *more* consumer confusion, and so would hardly serve the government's interest in *preventing* confusion.

Yet even in cases where the government could show that banning a potentially confusing name would "directly and materially" avoid deception, the government would still need to satisfy the last part of the *Central Hudson* test. It is here that restrictions on GFI's proposed naming pattern would *always* fail to withstand scrutiny: such restrictions are emphatically *not* necessary to serve any interest in preventing confusion or deception, and are not narrowly tailored to that end. The government has many alternative tools at its disposal for combating whatever potential deception it might claim; in fact, many of these tools are already in place. The FDCA requires food labels to bear a full list of ingredients that can instantly dispel most any question a confused consumer may have, such as whether there is any wheat in gluten-free bread, or whether there is any egg in rice noodles, or whether there is any cow's milk in soymilk. Similarly, nutritional labeling is already required, which allows consumers to compare these foods to their traditional counterparts in yet another way.[81]

[81] This was the very same logic FDA used in addressing objections to nutrient-content qualified names like "fat-free ice cream." 58 Fed. Reg. 2431, 2439 (Jan. 6, 1993).

In the case of soymilk and almond milk, these measures are more than sufficient to fully inform consumers, as courts have recognized.[82] And even if they were not, the government has no shortage of other, more narrowly-tailored options available. For example, the government could potentially require products to label themselves with additional statements that describe significant differences that are alleged to be a source of potential confusion (e.g. requiring soymilk and almond milk products to bear "dairy-free" declarations — as most already do.)[83] In sum, there are many alternative narrowly-drawn ways to dispel potential deception, and "[i]f the First Amendment means anything, it means that regulating speech must be a last — not first — resort."[84] The government would bear a heavy burden in demonstrating that these alternative approaches (especially those already in effect) are insufficient to advance its interests before courts would permit an outright speech ban[85] — and this, GFI submits, the government would be unable to do for any of the names under GFI's proposed standard.

Proponents of a ban on the names "soymilk" and "almond milk" also argue alternatively that consumers may suffer some sort of nutritional injury if they purchase

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[82] See *Gitson* and *Ang* (Attachment B).

[83] However, GFI notes that even less-restrictive measures like this would be difficult to justify constitutionally, in light of the negligible risk of consumer confusion and the mandatory ingredient and nutritional labeling already required by the FDCA.

[84] *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 373 (2002).

[85] See *Pearson*, 164 F.3d at 659–60 (describing First Amendment preference for disclaimers and disclosures over suppression.)

and consume these products believing them to be nutritionally equivalent to cow's milk.[86] But no reasonable consumer would assume that two distinct products have identical nutritional content,[87] so this speculative risk cannot possibly justify a ban on such names.[88] Under *Central Hudson*, the government would first face the (likely impossible) task of showing that a significant number of consumers hold a belief that these distinct products are totally nutritionally equivalent. And even assuming the government could demonstrate that this presents a real, substantial, and material risk, the government has available other tools for addressing it, all of which are more narrowly drawn than an outright speech ban. In fact, mandatory nutritional labeling already suffices to inform consumers not just *that* the products are distinct, but exactly *how* they are distinct nutritionally — and this comprehensive disclosure is more than enough to protect against any supposed risk of deception.[89] Just as above, this argument in favor of an outright ban on such names would fail to stand up to *Central Hudson* scrutiny.[90]

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[86] See Comment from National Milk Producers Federation, July 28, 2010, available at https://www.regulations.gov/document?D=FDA-2010-N-0210-0092.

[87] "[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." *Gitson*, at 3.

[88] Further, a logical extension of this argument would require a ban on labeling goat or sheep or buffalo milk with the word "milk," as all of these products have different nutritional profiles from cow's milk. And the same is true for rye bread vis-à-vis wheat bread, rice noodles vis-à-vis wheat noodles, and so on.

[89] See *Gitson*, at 3 (quoted above, note 87). And as above, in addition to already-mandatory comprehensive nutritional labeling, courts would also consider whether any other possible measures for disclosure would be more narrowly-drawn and therefore preferable to an outright speech ban. See *Pearson*, 164 F.3d at 659–60.

[90] Note also that, before the passage of NLEA and FDA's subsequent regulations, federal courts used similar reasoning in analyzing state bans on the use of dairy names by other products,

For these reasons, proposals to ban common names for dairy alternatives would run afoul of the First Amendment, failing to withstand scrutiny under *Central Hudson*. Additionally, such proposals infringe the First Amendment for other reasons, discussed next.

3. Attempts to restrict or ban common names for dairy alternatives would be subject to heightened scrutiny.

Although restrictions on commercial speech are generally subject to *Central Hudson* "intermediate" scrutiny, recent developments in the law indicate that, in some cases, such restrictions will require an even greater level of judicial scrutiny. Proposals that particularly target dairy alternatives with a ban on their commonly-used names would fall into this category, and would not withstand heightened judicial scrutiny.

The Supreme Court has recently made clear that "content-based" burdens or restrictions are subject to "heightened" judicial scrutiny, even in the commercial context.[91] The Court has not clarified exactly what form this "heightened" scrutiny takes, though it has noted that ordinarily, it is "all but dispositive to conclude that a law is content-based."[92] Further, even some restrictions that *appear* on their face to be content-neutral "will be considered content-based regulations of speech: laws that cannot be

striking down such restrictions under the First Amendment. See, e.g. *Lever Bros. Co. v. Maurer*, 712 F. Supp. 645, 651–52 (S.D. Ohio 1989); *Anderson, Clayton & Co. v. Washington St. Dept. of Agriculture*, 402 F. Supp. 1253, 1257–58 (W.D. Wash 1975).

[91] *Sorrell v. IMS Health*, 31 S. Ct. 2653, 2664–65 (2011).

[92] *United States v. Caronia*, 703 F.3d 149, 164 (2d Cir. 2012), quoting *Sorrell*, 31 S. Ct. at 2667.

'justified without reference to the content of the regulated speech' or that were adopted by the government 'because of disagreement with the message [the speech] conveys.'"[93]

Restricting the common names of dairy alternatives, such as soymilk, would be a content-based restriction on speech, because such restrictions cannot be justified without reference to the content of such speech — to wit, the fact that such names reference dairy products specifically. Such content-based restrictions are "presumptively invalid,"[94] and the government would need to put forth compelling evidence-based justifications to overcome this heavy presumption.

To avoid this heightened level of scrutiny, the government would need to develop and apply any proposed restriction in a content-neutral manner.[95] In order for a restriction of this sort to be truly content-neutral, it would need to apply with equal force to *any* product name that encompasses another, and not merely non-dairy alternatives to dairy products. The government, for example, could potentially ban *any* product from bearing the name of another unless it satisfies the definition of such other product. But the government could not do so without contradicting established FDA policies regarding the naming of foods with nutrient-content claims (e.g. "fat-free cheddar cheese"), or established commonsense practice regarding other product names that incorporate standardized terms (such as rye bread or rice noodles).

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[93] *Reed v. Town of Gilbert*, 135 S. Ct. 2218, 2227 (2015) (citation omitted).

[94] *Sorrell*, 131 S. Ct. at 2667 (quoting *R.A.V. v. St. Paul*, 505 U.S. 377, 382 (1992)).

[95] The current legislative proposal for such restrictions is not content-neutral; it exclusively singles out dairy terms for protection. DAIRY PRIDE Act, S.130, 115th Cong. § 3 (2017).

Nor could the government, in this context, rely on the content-neutral justification that it is merely targeting "potentially misleading" names of any sort, because many other products with similar names have *greater* potential to mislead or confuse consumers than products like soymilk or almond milk (which declare their basic nature — "soy" and "almond" — clearly and up-front). Take multigrain bread, for instance. There is no standard for such product, and a "5-grain bread" could conceivably be 98% white flour, with the other four grains constituting the remaining 2% — not the significant share consumers might expect.[96] Or rice noodles, the name of which does not declare up-front whether it contains egg or wheat, as required of "noodles" under FDA's standard of identity.[97] And so on. The government could offer no content-neutral justification for banning outright the names of "soymilk" or "almond milk," while allowing other products named in similar fashion to keep their names.

This highlights yet another reason a ban on such non-dairy names would be subject to heightened judicial scrutiny: courts would likely determine that such a restriction is a content-based *and* speaker-based restriction, targeting producers of plant-based alternative products specifically. For one thing, it would be a speaker-based restriction because it would forbid only producers of such products (though not consumers, academics, or even the government itself) from using such names to describe

[96] Ironically, as noted earlier, such a product would satisfy the standard of identity for "bread" — and would be all the more misleading for it!

[97] Also, unenriched rice flour contains lesser amounts of some nutrients (like protein and iron) than wheat flour does. This mirrors the situation of unfortified soymilk *vis-à-vis* cow's milk.

these products.[98] But it would also not escape judicial notice that these restrictions have been publicly and loudly demanded by the dairy industry for many years in an effort to protect its market share. This historical fact would infect any subsequent government action with the stench of favoritism — using the power of the state to benefit one politically powerful group at the expense of its competitors — and could lead a reviewing court to conclude that such government action is an attempt to burden "disfavored speech by disfavored speakers."[99] As the cases cited herein demonstrate, courts are particularly likely to strike down speech restrictions in such circumstances.

Simply put, proposed restrictions on the names of dairy alternatives cannot be justified in a content-neutral way, and even if they could be, such restrictions would fail to withstand *Central Hudson* scrutiny. FDA should resist the dairy industry's calls for anticompetitive regulation, and instead adopt GFI's neutral regulation that allows not just dairy alternatives, but *any* alternative products, to use clear and concise compound names noting alternative sources, properties, or origins, which consumers readily understand. This framework is not merely a good idea — under our Constitution, the freedom to use such names must generally be maintained.

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[98] See *Caronia*, 703 F.3d at 165; *Sorrell*, 131 S. Ct. at 2663.

[99] *Sorrell*, 131 S. Ct. at 2663.

III. Conclusion and request for action

For the reasons described above, and consistent with FDA policy and practice as well as the First Amendment, GFI respectfully asks that FDA adopt the proposed regulation to clarify that FDA will generally allow the use of compound food names whenever a reasonable consumer would understand that such a modified food name denotes a distinct product.

IV. Environmental Impact

Preparation of an environmental assessment (EA) or an environmental impact statement (EIS) is not ordinarily required for the "issuance, amendment, or repeal of a food standard," 21 C.F.R. § 25.32(a).

V. Economic Impact

Pursuant to 21 C.F.R. § 10.30, information on economic impact will be submitted only if requested by the Commissioner following review of this petition.

* * *

VI. Certification

The undersigned certifies that, to the best of his knowledge and belief, this petition includes (1) all information and views on which the petition relies and (2) any representative data and information known to the petitioner that are unfavorable to the petition.

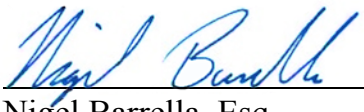
Sincerely,

Bruce Friedrich
Executive Director
The Good Food Institute

Nicole Negowetti
Policy Director
The Good Food Institute

Nigel Barrella
Law Office of Nigel A. Barrella

By:



Nigel Barrella, Esq.

Attachments:

A. Soyfoods Association of North America, Summary of Consumer Research
B. Orders from Federal Court Cases: *Gitson* and *Ang*

ATTACHMENT A

Soyfoods Association of North America

1050 17th Street, NW • Suite 600 • Washington, DC 20036 • USA

Summary of Research on Consumer Awareness of Soymilk and Dairy Milk

Market Tools conducted this research in 2006

Study Design

- Overview of Study Design
  - Method: Awareness and Usage
  - Sample Description:
    - Gen pop, adults ages 18-64
    - Primary grocery shopper
    - Industry security screen
  - Sample Size: 814 (135 Soymilk category users)
  - Field Dates: September 21 – 26, 2006

Summary of Findings

- **There is no confusion between soymilk and cow's milk.**
  - Very few have mistakenly purchased soymilk when looking to purchase cow's milk.
  - People are clear that there is no cow's milk in soymilk.
    - Nearly all listed soy first as an ingredient followed by water, vitamins, and minerals.
- Most soy using households also purchase cow's milk.
- Many believe that there are heart healthy ingredients in soy that are not in cow's milk.
- Future growth for the soy category is likely as many indicate an interest in buying soymilk.

Question: Cow's milk is not associated with soymilk

MAIN INGREDIENTS OE: What do you think are the main ingredients of soymilk ?

		AGE		USAGE			POTENTIAL
	TOTAL	UNDER 45	45+	SOY USER	DAIRY USER	DAIRY ONLY	POTENTIAL
		B	C	D	E	F	G
Base: Total Respondents	**814**	**510**	**304**	**135**	**804**	**673**	**258**
	%	%	%	%	%	%	%
INGREDIENTS (NET)	**84**	**84**	**83**	**92** F	**84** F	**82**	**86**
SOY (SUBNET)	**80**	**80**	**81**	**89** EF	**80** F	**79**	**81**
Soy	**53**	**55** c	**49**	**51**	**53**	**54**	**52**
Soy bean	**23**	**21**	**26**	**32** EF	**23** F	**21**	**23**
Water	**22**	**22**	**24**	**38** EF	**22** F	**19**	**23**
Sugar	**6**	**6**	**6**	**17** EF	**6** F	**4**	**5**
FLAVORING (SUBNET)	**6**	**6**	**6**	**18** EF	**6** F	**3**	**5**
Milk	**3**	**4**	**2**	**2**	**3**	**4**	**4**
Dry/Powder Milk	**0**	**0**	**1**	**0**	**0**	**1**	**1**
Cow's milk	**0**	**0**	**1** b	**0**	**0**	**0**	**0**
NA	**5**	**5**	**5**	**5**	**5**	**5**	**4**
Nothing/none	**4**	**4**	**3**	**0**	**4**	**8** DE	**2**

Capital letters indicate significant difference at the 90% confidence level.

ATTACHMENT B

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

AMY GITSON, et al.,

Plaintiffs,

v.

TRADER JOE'S COMPANY,

Defendant.

Case No. 13-cv-01333-VC

ORDER GRANTING IN PART AND DENYING IN PART PARTIAL MOTION TO DISMISS; GRANTING IN PART AND DENYING IN PART MOTION TO STRIKE

Re: Dkt. No. 131

The plaintiffs allege that Trader Joe's has mislabeled a number of products in violation of California law. Two motions to dismiss have been decided by the district judge previously assigned to the case. The pleadings have been settled for the most part.

In its current (and presumably final) motion to dismiss, Trader Joe's primarily seeks dismissal of the claims relating to "soymilk" products. The Third Amended Complaint alleges that the use of the word "soymilk" by Trader Joe's to describe products that don't contain cow's milk violates the federal Food, Drug and Cosmetic Act, which in turn would constitute a violation of the California Sherman Act, which in turn would potentially be the basis for a claim under the "unlawful" prong of California's Unfair Competition Law. Although the previously-assigned district judge has ruled on certain aspects of this question, the case law has developed since that time, warranting full reconsideration of whether the plaintiffs have stated a claim with respect to the soymilk products.

Often in food labeling cases, courts jump straight to the question whether a plaintiff may state a claim under California's Unfair Competition Law. But there is a threshold question. Although a plaintiff may not sue directly under the federal Food, Drug and Cosmetic Act (because it does not create a private right of action), the plaintiff must nonetheless allege facts that, if

proven true, would amount to a violation of that federal statute. If the alleged conduct would indeed amount to a violation of the federal statute, a plaintiff might be able to pursue a claim under state law based on that conduct (assuming the plaintiff satisfies any additional requirements for bringing a claim under the applicable state law). But if the alleged conduct would not violate the federal statute, it doesn't matter whether the plaintiff could pursue a state law claim based on that conduct. If a food label does not violate the federal statute, any state law claim arising from that label is automatically preempted, because when it comes to food labels, state law may only impose liability for what the federal statute proscribes. *Perez v. Nidek Co.*, 711 F.3d 1109, 1119–20 (9th Cir. 2013); *Garrison v. Whole Foods Mkt. Grp., Inc.*, 2014 WL 2451290, at *1–2 (N.D. Cal. June 2, 2014). The threshold question in this case, then, is whether the use of the word "soymilk" in the Trader Joe's products could conceivably violate the federal Food, Drug and Cosmetic Act. The answer to that question is no.

There are two potential theories for how the products could violate the federal statute. The first is that the use of the word "soymilk" is, generally speaking, "false or misleading" within the meaning of 21 U.S.C. § 343(a). Whether a food label is "misleading" is typically analyzed from the perspective of a reasonable consumer. *See* 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.").[1] The plaintiffs cannot state a claim because they have not articulated a plausible

[1] Some courts, in decisions rendered before the FDA issued this guidance, have suggested that a label violates section 343(a) if it is misleading to the least sophisticated of consumers (even if it is not misleading to the reasonable consumer). *See United States v. Strauss*, 999 F.2d 692, 696–97 (2d Cir. 1993); *cf. United States v. El-O Pathic Pharmacy*, 192 F.2d 62, 75 (9th Cir. 1951) (stating in a different context that the purpose of the federal Food, Drug and Cosmetic Act is to protect people who are "ignorant" and "unthinking"). Other courts have, like the subsequent FDA guidance, suggested that a label violates section 343(a) only if it is misleading to an ordinary consumer. *See United States v. Kocmond*, 200 F.2d 370, 373 (7th Cir. 1952); *United States v. 46 Cases, More or Less, Welch's Nut Caramels*, 204 F. Supp. 321, 322 (D.R.I. 1962). More recent decisions tend to assume without discussion that a "reasonable consumer" standard applies to the

explanation for how "soymilk" is misleading. At one point the plaintiffs seem to suggest the term is misleading because people might mistake soymilk for actual milk from a cow, but that is not plausible. The reasonable consumer (indeed, even the least sophisticated consumer) does not think soymilk comes from a cow. To the contrary, people drink soymilk in lieu of cow's milk. *See, e.g.*, *Ang v. Whitewave Foods Co.*, 2013 WL 6492353, at *4 (N.D. Cal. Dec. 10, 2013) ("Moreover, it is simply implausible that a reasonable consumer would mistake a product like soymilk or almond milk with dairy milk from a cow. The first words in the products' names should be obvious enough to even the least discerning of consumers."). The plaintiffs also suggest that the word "soymilk" is misleading under section 343(a) because it implies that the product has a similar nutritional content to cow's milk. But 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.[2]

The second and more specific theory for how a "soymilk" product could violate the federal statute is that it "purports to be or is represented as" a food that has been given a "standard of identity" by FDA regulations. *See* 21 U.S.C. § 343(g). Milk is indeed a food that that the FDA has standardized. *See* 21 C.F.R. § 131.110 (describing "milk" as from a cow and explaining the way it should be labeled). But the fact that the FDA has standardized milk does not categorically preclude a company from giving any food product a name that includes the word "milk." Rather, as the language of section 343(g) indicates, the standardization of milk simply means that a company cannot *pass off* a product as "milk" if it does not meet the regulatory definition of milk. Trader Joe's has not, by calling its products "soymilk," attempted to pass off those products as the food that the FDA has standardized (that is, milk). To the contrary, as already discussed, it is

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federal statute. *See, e.g.*, *Alamilla v. Hain Celestial Grp., Inc.*, 30 F. Supp. 3d 943, 944 (N.D. Cal. 2014), *Ang v. Whitewave Foods Co.*, 2013 WL 6492353, at *4 (N.D. Cal. Dec. 10, 2013). This makes sense. However, as discussed herein, the plaintiffs do not state a plausible claim under either standard of liability.

[2] The plaintiffs do not allege that the nutrition label contains any misleading information that could lead someone to believe that soymilk has the same nutritional content as cow's milk. Nor, for that matter, do the plaintiffs allege that Trader Joe's misrepresents the nutritional content of its soymilk products in its advertising.

implausible that the use of the word "soymilk" misleads any consumer into believing the product comes from a cow. Soymilk, in short, does not "purport[] to be" from a cow within the meaning of section 343(g).

The plaintiffs cite two FDA "warning letters" in support of the theory that the title "soymilk" violates section 343(g). But even assuming FDA warning letters might sometimes enjoy deference, *see Ang*, 2013 WL 6492353, at *3, the statements in these letters about soymilk labels are entitled to none. The FDA issued these letters to companies in the wake of inspections of food facilities. The letters warned the companies that they were not storing products properly, were not taking adequate precautions against pests, and were generally not keeping things clean. *See* Food & Drug Admin., Warning Letter to Fong Kee Tofu Company (Mar. 7, 2012); Food & Drug Admin., Warning Letter to Lifesoy, Inc. (Aug. 8, 2008). Almost as an afterthought, each of the letters noted that during inspection, the FDA investigators determined that certain food products were misbranded within the meaning of section 343(g), including products that contained the words "soy milk" in their titles. The investigators stated: "we do not consider 'soy milk' to be an appropriate common or usual name because it does not contain 'milk.'" It is difficult to understand what that means. To the extent the letters mean to argue that a product with the word "soymilk" in the title "purports to be or is represented as" cow's milk, 21 U.S.C. § 343(g), they provide no support for that argument, and as explained above, the argument is implausible. To the extent the letters mean to argue that a product with the word "soymilk" in the title violates section 343(g) for some other reason, they do not explain what that reason might be, nor is one apparent from the text of section 343(g), which seems only to forbid a food from "purport[ing] to be" a standardized food, or from being "represented as" a standardized food. *Id*. Either way, there is no conceivable justification for the assertions those letters make about the word "soymilk," so they do not support a claim that products with "soymilk" in their titles violate the federal statute.

Because the Third Amended Complaint does not allege conduct that would amount to a violation of the federal Food, Drug and Cosmetic Act, that is the end of the matter. Any potential claim under state law would be preempted. The motion to dismiss the "soymilk" claims is therefore granted, and dismissal is with prejudice.

With respect to the remaining issues presented by the latest motion to dismiss:

- The motion to dismiss the "newly asserted" claims is unopposed and is therefore granted.
- The motion to dismiss claims based on undisclosed additives in products that the plaintiffs did not purchase is denied in part and granted in part. It is denied with respect to unpurchased products that contain the same additives as the products the plaintiffs purchased and complain of in this lawsuit, because the alleged injuries inflicted on other people by those additives in those unpurchased products are substantially similar to the injuries the named plaintiffs allegedly incurred here. *See, e.g.*, *Garrison*, 2014 WL 2451290, at *5. The motion is granted, however, with respect to products that do not contain the additives that the plaintiffs complain about in the products they purchased. *Id*. In other words, the litigation will proceed only with respect to the additives the plaintiffs complain about in the purchased products (that is, tocopherols, sodium citrate, and citric acid).
- The motion to strike allegations relating to the FDA's "interim position" on evaporated cane juice is denied.
- The motion to strike allegations asserting a theory that Trader Joe's failed to disclose that its products were illegally labeled is granted.

IT IS SO ORDERED.

Dated: December 1, 2015

VINCE CHHABRIA
United States District Judge

IN THE UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

ALEX ANG and KEVIN AVOY, individually and on behalf of all others similarly situated Plaintiffs, v. WHITEWAVE FOODS COMPANY, DEAN FOODS COMPANY, WWF OPERATING COMPANY, and HORIZON ORGANIC DAIRY LLC, Defendants.	Case No. 13-cv-1953 ORDER GRANTING MOTION TO DISMISS

I. INTRODUCTION

Plaintiffs bring this putative class action in connection with Defendants' alleged misbranding of various products containing evaporated cane juice, including soymilk, almond milk, lowfat milk, and yogurt products. ECF No. 1 ("Compl."). Defendants now move to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6). ECF No. 17 ("MTD"). The motion is fully briefed, ECF Nos. 31 ("Opp'n"), 28 ("Reply"),[1] and appropriate for determination without

[1] Plaintiffs filed a "corrected" opposition brief after Defendants filed their reply.

oral argument per Civil Local Rule 7-1(b). For the reasons set forth below, Defendants' motion is GRANTED and this action is DISMISSED WITH PREJUDICE.

II. BACKGROUND

Plaintiffs target two types of products sold by Defendants: the "Silk Products" and the "Horizon Products" (collectively, the "Products"). The Silk Products are a variety of plant-based beverages, including "Silk Vanilla Soymilk," "Silk Pure Almond All Natural Original Almond Milk," and "Silk Pure Coconut Original Coconut Milk" (hereinafter, the "Silk Products"). See Compl. ¶¶ 6, 95. The Horizon Products are a variety of yogurt and milk products, including Organic Whole Vanilla Yogurt, Tuberz yogurt tubes (collectively, the "Horizon Yogurt Products"), and Horizon Organic Vanilla Lowfat Milk. The labels of all of the Products list "All Natural Evaporated Cane Juice" or "Organic Evaporated Cane Juice" (hereinafter, "evaporated cane juice" or "EJC") as an ingredient. Id.

Plaintiffs allege that the Products were misbranded in three ways. First, Plaintiffs claim that, pursuant to US Food and Drug Administration ("FDA") guidelines, Defendants should have used the terms "sugar" or "dried cane syrup" instead of EJC on the Products' labels (the "ECJ Claims"). Second, Plaintiffs claim that Defendants misbranded the Silk Products by using names like "soymilk," "almond milk," and "coconut milk," since the Silk Products are plant-based, and the FDA defines "milk" as a substance coming from lactating cows (the "Milk Claims"). Third, Plaintiffs allege that, pursuant to FDA guidelines, the Horizon Yogurt

Products are mislabeled as yogurt because they contain evaporated cane juice, which is allegedly nothing more than sugar.

Plaintiffs filed this suit on April 29, 2013, and assert claims for (1)-(3) unfair, unlawful, and fraudulent practices in violation of the California Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code § 17200, et seq.; (4) & (5) misleading and deceptive advertising and untrue advertising in violation of the California False Advertising Law ("FAL"), Cal. Bus. & Prof. Code 17500, et seq.; (6) violation of the California Consumers Legal Remedies Act ("CLRA"), Cal. Civ. Code § 1750, et seq.; and (7) restitution based on unjust enrichment/quasi-contract. Plaintiffs bring this action on behalf of themselves and, pursuant to Rules 23(b)(2) and 23(b)(3), all persons in the United States who purchased the Products.

On April 8, 2013, before Plaintiffs filed the instant action, another food-labeling class action was filed against Defendants in U.S. District Court for the Southern District of Florida.[2] ECF No. 18 ("Defs.' RJN") Ex. 14 ("Singer Compl."). The plaintiff in the Florida action, Barbara Singer ("Singer"), targeted many of the same products as Plaintiffs. Compare Compl.¶ 95 with Singer Compl. ¶ 13. Like Plaintiffs, Singer alleged that these products were misbranded because EJC "is nothing more than sugar, cleverly disguised." Singer Compl. ¶ 2. Singer also relied on many of the same FDA guidelines as Plaintiffs. Compare Compl. 48, 57-61 with Singer Compl. ¶¶ 16-19.

The parties to the Florida action subsequently reached a class

[2] That action is captioned Singer v. WW Operating Company, Case No. 13-cv-2132 (S.D. Fla.) (hereinafter, the "Florida action").

settlement. On April 19, 2013, the Florida court preliminarily approved a settlement, defining the settlement class as all persons who, from January 1, 2005 to the present, purchased Defendants' ECJ-labeled products throughout the United States. RJN Ex. 16. The Court required class notice to be published in USA Today and on a website established for the purpose of providing notice, finding this notice to be the best practicable under the circumstances and to be fully compliant with the requirements of Federal Rule of Civil Procedure 23 and of due process. Id. Plaintiffs, absent class members in the Florida action, did not object to the settlement within the timeline set forth by the Florida court. On June 28, 2013, the Florida court granted final approval of the settlement (hereinafter, the "Singer Settlement").

Plaintiffs subsequently filed a motion to intervene in the Florida action and a motion to set aside the Singer Settlement. Those motions were denied on October 8, 2013. ECF No. 35-1 ("Oct. 8 Order"). Among other things, the Florida court found that Plaintiffs were provided with adequate notice of the Florida action and that Plaintiffs' interests were adequately represented in that action.

III. LEGAL STANDARD

A motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) "tests the legal sufficiency of a claim." Navarro v. Block, 250 F.3d 729, 732 (9th Cir. 2001). "Dismissal can be based on the lack of a cognizable legal theory or the absence of sufficient facts alleged under a cognizable legal theory." Balistreri v. Pacifica Police Dep't, 901 F.2d 696, 699 (9th Cir.

1988). "When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." Ashcroft v. Iqbal, 556 U.S. 662, 679 (2009). However, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Id. (citing Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007)).

IV. DISCUSSION

Defendants now move to dismiss the instant action on the grounds that it is barred by res judicata. Alternatively, Defendants argue that Plaintiffs' claims are preempted or are implausible. As set forth below, the Court finds that the final judgment in the Florida action precludes Plaintiffs from bringing their EJC and Yogurt Claims. Further, the Court finds that Plaintiffs' Milk Claims are either preempted or implausible.

A. Res Judicata

Defendants argue that the Singer settlement is res judicata with respect to Plaintiffs' EJC, Milk, and Yogurt claims. MTD at 8. Res judicata bars relitigation of claims that were raised or could have been raised in a prior action. Owens v. Kaiser Found. Health Plan, Inc., 244 F.3d 708, 713 (9th Cir. 2001). The doctrine is applicable whenever there is (1) identity or privity between the parties in the first and second action, (2) a final judgment on the merits, and (3) an identity of claims. Id.

As to the first requirement, Plaintiffs do not dispute that

they were class members in the Florida action. However, Plaintiffs argue that their interests were inadequately represented in that action and that they were provided with inadequate notice of the proceedings. Opp'n at 6. Both of these arguments were rejected by the Florida court when it denied Plaintiffs motions to intervene and set aside the Singer Settlement. The Court declines to revisit those issues now and finds that the first requirement of res judicata has been met.

With respect to the second requirement, Plaintiffs argue that there was no final judgment in the Florida action because the Florida court did not issue a separate document setting out a final judgment. This argument lacks merit. The Florida court's order approving the class settlement expressly states Defendants may "file the Settlement Agreement and/or this Judgment in any action . . . based on principles of res judicata . . . or any theory of claim preclusion." RJN Ex. 19 ¶ 9. The order refers to itself as a judgment four other times and also uses the phrase "IT IS HEREBY ORDERED, ADJUDGED AND DECREED." Moreover, Plaintiffs have essentially conceded the finality of the order by appealing it to the Eleventh Circuit.

As to the third requirement of res judicata, Plaintiffs do not dispute that there is an identity of claims as to the EJC and Yogurt Claims. Nor could they. The Singer Settlement discharges all claims "arising from, or in any way whatsoever relating to the use of the term evaporated cane juice with respect to [Defendants'] Products . . . ." RJN Ex. 19 § VI. Both the EJC and Yogurt claims are predicated on Defendants' use of the term EJC. Indeed, Plaintiffs' EJC claims are practically identical to Singer's.

While the Yogurt Claims were not raised in the Florida action, they are premised on the same theory -- that EJC is equivalent to sugar -- and thus arise out of the same nucleus of operative facts. See Frank v. United Airlines, Inc., 216 F.3d 845, 851 (9th Cir. 2000) (Central criterion in determining whether there is an identity of claims is whether the two suits arise out of the same transactional nucleus of facts.)

The parties dispute whether there is an identity of claims with respect to the Milk Claims. Defendants argue that the Milk Claims are precluded because they only target products that contain EJC. The Court disagrees. The Singer Settlement bars claims that relate to the use of the term EJC, not claims relating to products that contain EJC. Plaintiffs' Milk Claims are not predicated on Defendants' use of the term EJC. Rather, the Milk Claims are based on the theory that a reasonable consumer could confuse soymilk, almond milk, or coconut milk for dairy milk.

Accordingly, the Court finds that res judicata bars Plaintiffs' EJC and Yogurt Claims, but not their Milk Claims. Accordingly, the Court proceeds to determine whether the Milk Claims are preempted.

B. Preemption

The crux of Plaintiffs' Milk Claims is that Defendants' use of terms "soymilk," "almond milk," and "coconut milk" in the names of Silk Products violates the "standard of identity" for milk. A standard of identity is a requirement that determines what a food product must contain to be marketed under a certain name. The FDCA, as amended, contains a broad preemption provision which prohibits states or other political subdivisions from imposing any

requirements regarding standard of identity that is not identical to the federal requirements. 21 U.S.C. § 343-1(a). Defendants argue that Plaintiffs' Milk Claims attempt to impose new requirements concerning the standard of identity for milk.

The FDCA requires a food to be identified by "the common or usual name of the food, if any there be." 21 U.S.C. § 343(i). FDA regulations require that a "statement of identity" must be in terms of: (1) the name prescribed by federal law or regulation, "(2) [t]he common or usual name of the food; or, in the absence thereof, (3) [a]n appropriately descriptive term, or when the nature of the food is obvious, a fanciful name commonly used by the public for such food." 21. C.F.R. § 101.3(b).

Plaintiffs have not pointed to any statutory or regulatory provision prescribing how the Silk Products must be labeled. However, Plaintiffs do point to 21 C.F.R. § 131.110, which describes Milk as the "lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows." Plaintiffs reason that this regulation bars Defendant from using the name milk in connection with soy-, almond-, coconut-based products since those products do not come from cows. However, § 131.110 pertains to what milk is, rather than what it is not, and makes no mention of non-dairy alternatives such as the Silk Products.

Plaintiffs also point to FDA warning letters to soymilk manufacturers, which are referenced in the Complaint. These letters primarily address sanitary conditions at the manufactures' facilities and other labeling issues which are not relevant to this case. See ECF No. 26 ("Pl.'s RJN) Exs. G, H. However, citing 21

C.F.R. § 131.110, the letters also warn two manufacturers that their "soymilk" products are misbranded because they use the term milk. ECF No. 26 ("Pl.'s RJN) Exs. G, H. An agency's reasonable interpretation of its own regulation is entitled to wide deference. Pub. Lands for the People, Inc. v. U.S. Dep't of Agric., 697 F.3d 1192, 1199 (9th Cir. 2012). However, the brief statements in the two warning letters cited by Plaintiffs are far from controlling. This is especially true since the FDA regularly uses the term soymilk in its public statements, see, e.g., FDA Enforcement Report, 2011 WL 6304352 (Dec. 14, 2011); FDA Enforcement Report, 2007 WL 4340281 (Dec. 12, 2007), suggesting that the agency has yet to arrive at a consistent interpretation of § 131.110 with respect to milk substitutes.

As the FDA has yet to prescribe a name for the Silk Products, the Court considers the "common or usual name[s]" for those foods. See 21 U.S.C. § 343(i). FDA regulations provide that the common or usual name of a food "shall accurately identify or describe, in as simple terms as possible, the basic nature of the food or its characterizing properties or ingredients." 21 C.F.R. § 102.5(a). "Each class or subclass of food shall be given its own common or usual name that states, in clear terms, what it is in a way that distinguishes it from different foods." Id. Moreover, the common or usual name may be established by common usage. Id. § 102.5(d).

Here, the Court agrees with Defendants that the names "soymilk," "almond milk," and "coconut milk" accurately describe Defendants' products. As set forth in the regulations, these names clearly convey the basic nature and content of the beverages, while clearly distinguishing them from milk that is derived from dairy

cows. Moreover, it is simply implausible that a reasonable consumer would mistake a product like soymilk or almond milk with dairy milk from a cow. The first words in the products' names should be obvious enough to even the least discerning of consumers. And adopting Plaintiffs' position might lead to more confusion, not less, especially with respect to other non-dairy alternatives such as goat milk or sheep milk.

Accordingly, the Court finds that Plaintiffs' Milk Claims are preempted.

C. Plausibility

Plaintiffs' Milk Claims fail for the additional reason that they are simply not plausible. False advertising claims under the UCL, FAL, and CLRA are governed by the reasonable consumer standard, whereby a plaintiff must show that members of the public are likely to be deceived. Williams v. Gerber Products Co., 552 F.3d 934, 938 (9th Cir. 2008). The question of whether a business practice is deceptive is generally a question of fact not amenable to determination on a motion to dismiss. Id.

However, in certain situations a court may assess, as a matter of law, the plausibility of alleged violations of the UCL, FAL, and CLRA. For example, in Werbel ex rel. v. Pepsico, Inc., C 09-04456 SBA, 2010 WL 2673860, at *3 (N.D. Cal. July 2, 2010), the plaintiff alleged that he believed "Cap'n Crunch's Crunch Berry" cereal derived its nutrition from actual fruit because of its label's reference to berries and because its cereal balls were shaped like berries. The Court found such allegations to be "[n]onsense." Id. The court reasoned that the word "berries" was always preceded by the word "crunch" to form the term "crunch berries," and that the

image of crunch berries on the label did not even remotely resemble any naturally occurring fruit of any kind. Id.

Plaintiffs' Milk Claims fail for similar reasons. The crux of the claims is that a reasonable consumer might confuse plant-based beverages such as soymilk or almond milk for dairy milk, because of the use of the word "milk." The Court finds such confusion highly improbable because of the use of the words "soy" and "almond." Plaintiffs essentially allege that a reasonable consumer would view the terms "soymilk" and "almond milk," disregard the first words in the names, and assume that the beverages came from cows. The claim stretches the bounds of credulity. Under Plaintiffs' 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.

Thus, even if Plaintiffs Milk Claims were not preempted, they would still fail under the reasonable consumer test, as well as plausibility standard set forth in Iqbal and Twombly.

V. CONCLUSION

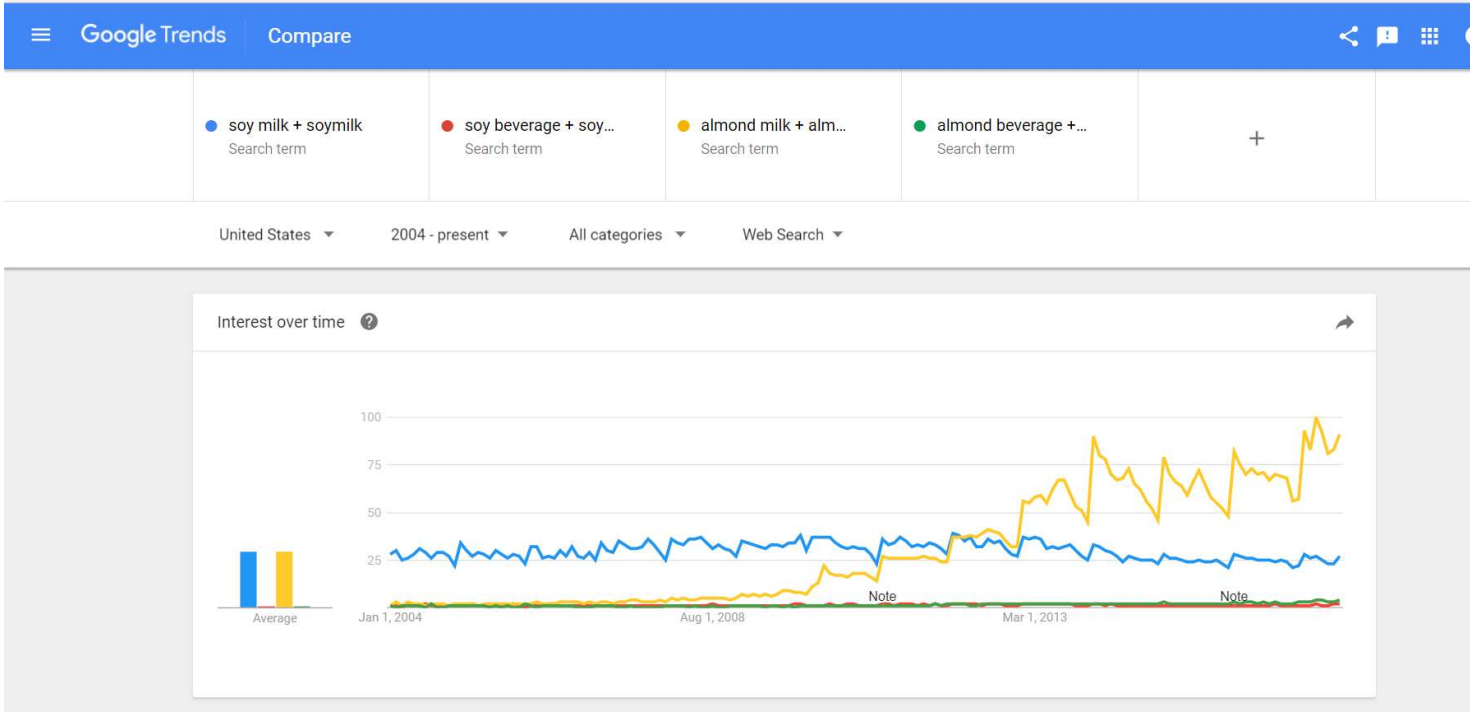
For the reasons set forth above, Defendants' motion to dismiss is GRANTED, and Plaintiffs Alex Ang and Kevin Avoy's claims are DISMISSED WITH PREJUDICE.

IT IS SO ORDERED.

December 10, 2013

UNITED STATES DISTRICT JUDGE

ATTACHMENT 2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Compare
soy milk + soymilk
Search term
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Search term
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Web Search
Interest over time
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50
25
Note
Note
Average
Jan 1, 2004
Aug 1, 2008
Mar 1, 2013

ATTACHMENT 3

[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 16-12049

D.C. Docket No. 4:14-cv-00621-RH-CAS

OCHEESEE CREAMERY LLC,

Plaintiff - Appellant,

versus

ADAM H. PUTNAM,
in his official capacity as Florida Commissioner of Agriculture,
ZACH CONLIN,
in his official capacity as Chief of Florida Bureau of Dairy Industry,

Defendants - Appellees.

Appeal from the United States District Court
for the Northern District of Florida

(March 20, 2017)

Before ROSENBAUM, BLACK and SENTELLE,[*] Circuit Judges.

BLACK, Circuit Judge:

Ocheesee Creamery, LLC (the Creamery) appeals the district court's grant of summary judgment to the Florida Commissioner of Agriculture and the Chief of the Florida Bureau of Dairy Industry, parties to this lawsuit in their official capacities (together, the State), and the court's denial of the Creamery's motion for summary judgment on the question of whether the State improperly forbade the Creamery from selling unfortified skim milk. The Creamery contends the State violated its First Amendment right to free speech by prohibiting the Creamery from using the words "skim milk" to describe its product. After review, we vacate the judgment of the district court.

I. BACKGROUND

The Creamery is a small dairy creamery located on its owners' farm in rural Calhoun County, Florida. It sells all-natural dairy items, including whole milk, cream, and related items such as ice cream. It also sells all-natural skim milk, which is a byproduct of its cream production. Consistent with standard practice, the Creamery produces cream by causing it to rise to the top of the milk and then

[*] Honorable David Bryan Sentelle, United States Circuit Judge for the District of Columbia, sitting by designation.

skimming it off. The leftover product is skim milk: milk that has had the fat removed through skimming.

Incidentally, the skimming process depletes almost all the vitamin A naturally present in whole milk because vitamin A is fat-soluble and is thus removed with the cream. Vitamin A levels can be restored by introducing an additive to the resulting skim milk. The Creamery prides itself on selling only all-natural, additive-free products, and therefore refuses to replace the lost vitamin A in its skim milk. Its product contains no ingredients other than skim milk. The Creamery only sells its skim milk in Florida.[1]

Florida law prohibits the sale of milk and milk products that are not Grade "A," which requires, among other things, that vitamin A lost in the skimming process must be replaced. *See* Fla. Stat. § 502.091 ("Only Grade 'A' pasteurized milk and milk products . . . shall be sold at retail to the final consumer."); Fla. Stat. § 502.014(5) (authorizing Florida Department of Agriculture to adopt rules); Fla. Admin. Code r. 5D-1.001(1) (adopting and incorporating by reference "Grade A Pasteurized Milk Ordinance ('PMO'), 2005 Revision, Public Health Service/Food and Drug Administration, its Appendices and notes"); U.S. Dep't of Health & Human Servs., *Grade "A" Pasteurized Milk Ordinance*, at App'x O (2005) ("[V]itamins A and D must be added to dairy products from which fat has been

[1] This case concerns only its intrastate sales and no challenge is made to any federal action or regulation.

removed; such as, reduced fat, lowfat, and nonfat dairy products, in an amount necessary to replace the amount of these vitamins lost in the removal of fat."). The Creamery sold its skim milk in Florida for nearly three years, beginning in 2010. In October 2012, the State issued two stop sale orders with respect to the Creamery's skim milk, stating the milk lacked vitamin A. That left the Creamery with two alternatives: add vitamin A to its skim milk or cease to sell the product. The Creamery opted for the latter and began discarding the skim milk left over from its cream production rather than incorporate the additives. Meanwhile, it attempted to procure a permit to sell the unenhanced milk under Florida's imitation milk statute. *See* Fla. Stat. § 502.165. The State began negotiating with the Creamery for the issuance of an imitation milk permit.

Initially, the State told the Creamery it could sell its product without adding vitamin A so long as it bore the label "imitation milk product," but the Creamery objected to describing its all-natural product this way. The Creamery and the State entered into discussions with the object of finding a more suitable label for the product that addressed the Creamery's concerns but did not mislead consumers into thinking the milk was Grade "A" skim milk with replenished vitamin A. By letter dated December 11, 2013, the State informed the Creamery that "Florida law provides that only Grade 'A' pasteurized milk and milk products shall be sold at retail within the state." It nevertheless added that it had "determined that Florida

law would allow [the Creamery] to offer this product for retail sale within the state" pursuant to the imitation milk statute if certain conditions were met, among them that the product label read as follows: "Non-Grade 'A' Milk Product, Natural Milk Vitamins Removed." Replying in September 2014, the Creamery insisted that the State's proposed label was misleading because the product was in fact skim milk, and should be labeled as such. It submitted five alternative labels, each of which included the words "skim milk."[2] The State responded on October 23, 2014, rejecting the Creamery's suggestions and insisting that the skim milk be sold under a different name. It offered a counterproposal that mirrored one of the Creamery's suggestions except that it substituted the term "milk product" in place of "skim milk."[3]

[2] The Creamery offered the following labels: (1) "PASTEURIZED SKIM MILK, NO VITAMIN A ADDED;" (2) "PASTEURIZED SKIM MILK, NO LOST VITAMIN A REPLACED;" (3) "PASTEURIZED SKIM MILK, MOST VITAMIN A REMOVED BY SKIMMING CREAM FROM MILK;" (4) "NON-GRADE 'A' SKIM MILK, SOME MILK VITAMINS REDUCED BY SKIMMING CREAM FROM ALL-NATURAL PASTEURIZED MILK;" and (5) "THE STATE REQUIRES US TO CALL THIS: 'NON-GRADE "A" MILK PRODUCT, NATURAL MILK VITAMINS REMOVED.' IT IS ALL-NATURAL SKIM MILK WITH SOME VITAMIN A REMOVED BY SKIMMING CREAM FROM MILK."

[3] The State proposed the following label, based on the Creamery's earlier suggestion: "The State requires us to call this: 'Non Grade "A" Milk Product, Natural Milk Vitamins Removed.' All natural milk product with vitamins removed by separating cream from milk." In the Creamery's version, the second sentence used the term "skim milk" in place of "milk product." The Creamery asserts in its initial brief that it would "happily use" a disclaimer stating that its skim milk does not have the same vitamins as whole milk. Brief of Appellant at 21–22 & n.16.

Negotiations ceased and the Creamery filed its complaint on November 20, 2014, contending the State's refusal to allow it to call its product "skim milk" amounted to censorship in violation of the First Amendment.[4] Cross-motions for summary judgment, responses, and replies were filed on June 22, July 27, and August 10, 2015, respectively. The district court granted summary judgment in favor of the State on March 30, 2016. It reasoned that it is inherently misleading to call a product "skim milk" if that product does not have the same vitamin content as whole milk. The State's refusal to allow the Creamery to use the term "skim milk" thus withstood scrutiny under the threshold inquiry of the *Central Hudson* test for commercial speech regulations. *See Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 563–64, 100 S. Ct. 2343, 2350 (1980). The

[4] The Creamery also asserted the State unconstitutionally compelled the Creamery to use a confusing and misleading label in violation of the First Amendment. The district court ruled the issue was not ripe. On appeal, however, the Creamery has only argued that the State has censored its use of the term "skim milk." Although its statement of issues does mention the compelled speech claim, its brief does not argue the question. The only mention of purportedly compelled labels (the Creamery is unspecific as to which labels the State allegedly forced it to use) takes place in furtherance of the Creamery's argument that the State's ban on the use of "skim milk" fails the last two prongs of *Central Hudson*, discussed *infra*. To the extent it has actually asserted the compelled speech claim in this litigation, it has abandoned it by failing to argue it in its brief. *See Access Now, Inc. v. Sw. Airlines Co.*, 385 F.3d 1324, 1330 (11th Cir. 2004) ("[T]he law is by now well settled in this Circuit that a legal claim or argument that has not been briefed before the court is deemed abandoned and its merits will not be addressed.").

In addition, the Creamery and the State nearly agreed on a proposed label, the only difference being that the State would have forbidden the use of the term "skim milk." *See supra* n.3. It is not clear a dispute over compelled speech would still exist, then, because there is no remaining disagreement about the label once we have determined whether the State may prohibit the Creamery from using the term "skim milk."

court also found that the regulation passed muster under the three remaining prongs of *Central Hudson* as well.

The sole issue on appeal is whether the State's actions prohibiting the Creamery's truthful use of the term "skim milk" violate the First Amendment.[5] We hold that they do.

II. STANDARD OF REVIEW

"This court reviews *de novo* the question of whether state restrictions on commercial speech are constitutional." *Mason v. Fla. Bar*, 208 F.3d 952, 955 (11th Cir. 2000). In reviewing a grant of summary judgment, we apply the same

[5] Throughout the proceedings, the Creamery has litigated this case as an as-applied challenge, notwithstanding passing references to a facial challenge in its complaint. The Creamery appears to seek the narrowest as-applied relief available to it. *See Am. Fed'n of State, Cty. & Mun. Emps. Council 79 v. Scott*, 717 F.3d 851, 863 (11th Cir. 2013) (distinguishing as-applied and facial challenges). It does not specifically cite the offending Florida statutes or regulations, nor explain how the statutes themselves are invalid; rather, its arguments concern only the State's treatment of the Creamery. *See* Complaint for Declaratory and Injunctive Relief at ¶ 6 ("Plaintiff Creamery seeks declaratory and injunctive relief against Florida restrictions on . . . the labeling of skim milk, as well as related actions taken by [the State]. These restrictions and requirements are found in Chapter 502, Florida Statutes, and Florida Administrative Code Chapter 5D-1."); *id.* at ¶¶ 80, 91 (challenging "Florida law and the action of [the State]"); Brief of Appellant at 11 ("The relevant Florida statutes are located in Chapter 502 and are supplemented by Florida Administrative Code Section 5D-1."); *id.* at 12 n.9 ("The meanings of these state statutes and state regulations are not in dispute, and the statutes and regulations themselves are long and complex. For a detailed explanation of the manner in which the numerous relevant state statutes and state regulations fit together, *see* [the Creamery's brief in support of its motion for summary judgment]."). The closest indication of which actual provisions of Florida law are at issue are found in the Creamery's memorandum of law accompanying its motion for summary judgment. There, it references Fla. Stat. §§ 502.165 and 502.181, which are Florida's imitation milk statute and general enforcement provisions, respectively. *See* Plaintiff's Memorandum of Law in Support of Plaintiff's Motion for Summary Judgment at 6–7, 11. No argument has been advanced as to how these statutes are unconstitutional; the Creamery only disputes the State's refusal to allow it to use the term "skim milk." Thus the only challenge is to the action of the State with respect to the Creamery in this case, and our decision is limited to that issue.

standards as the district court and view all facts and reasonable inferences in the light most favorable to the nonmoving party. *Borgner v. Brooks*, 284 F.3d 1204, 1208 (11th Cir. 2002) (citing *Parks v. City of Warner Robins*, 43 F.3d 609, 612–13 (11th Cir. 1995)).

III. DISCUSSION

"Commercial speech, expression inextricably related to the economic interests of the speaker and audience, is undeniably entitled to substantial protection under the First and Fourteenth Amendments of the United States Constitution."[6] *Mason*, 208 F.3d at 955 (collecting cases). But it was not always so. *See Metromedia, Inc. v. City of San Diego*, 453 U.S. 490, 505, 101 S. Ct. 2882, 2891 (1981) (plurality opinion) ("The extension of First Amendment protections to purely commercial speech is a relatively recent development in First Amendment jurisprudence. Prior to 1975, purely commercial advertisements of services or goods for sale were considered to be outside the protection of the First Amendment." (citing *Valentine v. Chrestensen*, 316 U.S. 52, 62 S. Ct. 920 (1942))). In *Virginia State Board of Pharmacy v. Virginia Consumer Council, Inc.*, 425 U.S. 748, 96 S. Ct. 1817 (1976), the Supreme Court decisively repudiated

[6] Commercial speech is "a narrow category of necessarily expressive communication that is related solely to the economic interests of the speaker and its audience . . . or that does no more than propose a commercial transaction." *Dana's R.R. Supply v. Att'y Gen.*, 807 F.3d 1235, 1246 (11th Cir. 2015) (quotations omitted). The parties agree the Creamery's use of the term "skim milk" to describe its product is commercial speech.

the notion that commercial speech receives no First Amendment protection. *Id.*; *cf. Valentine*, 316 U.S. at 54, 62 S. Ct. at 921 ("[T]he Constitution imposes no . . . restraint on government as respects purely commercial advertising."). Since that decision and those that followed, some, but not all, commercial speech has been held to be entitled to the protection of a form of intermediate scrutiny.

Challenges to restrictions on commercial speech are evaluated according to the rubric set forth by the Court in *Central Hudson Gas & Electric Corp. v. Public Service Commission.*[7] 447 U.S. 557, 100 S. Ct. 2343 (1980). The *Central*

[7] There is some question as to whether under the Supreme Court's decisions in *Sorrell v. IMS Health Inc.* and *Reed v. Town of Gilbert* an analysis to determine if the restriction is content based or speaker focused must precede any evaluation of the regulation based on traditional commercial speech jurisprudence, and if so, whether this would alter the *Central Hudson* framework. *See Sorrell v. IMS Health Inc.*, 564 U.S. 552, 131 S. Ct. 2653 (2011); *Reed v. Town of Gilbert*, 135 S. Ct. 2218 (2015). In *Sorrell*, the Supreme Court found the restriction at issue to be content based but nevertheless cited, articulated, and applied the *Central Hudson* test. *See Sorrell*, 564 U.S. at 572, 131 S. Ct. at 2667–68 ("To sustain the targeted, content-based burden § 4631(d) imposes on protected [commercial] expression, the State must show at least that the statute directly advances a substantial governmental interest and that the measure is drawn to achieve that interest." (citing *Bd. of Trs. of the State Univ. of N.Y. v. Fox*, 492 U.S. 469, 480–81 109 S. Ct. 3028, 3035 (1989); *Central Hudson*, 447 U.S. at 566, 100 S. Ct. at 2351)); *accord Dana's R.R. Supply*, 807 F.3d at 1246 ("Content-based restrictions on certain categories of speech such as commercial and professional speech, though still protected under the First Amendment, are given more leeway because of the robustness of the speech and the greater need for regulatory flexibility in those areas."). And in *Reed*, the Court arguably broadened the test for determining whether a law is content based. *See Reed*, 135 S. Ct. at 2227, 2230 (noting no exceptions in stating that laws that "single[ ] out specific subject matter" are facially content based and thus subject to strict scrutiny); *see also id.* at 2236–39 (Kagan, J., concurring in the judgment) (warning that the majority's approach glosses over exceptions in the Court's case law regarding the content-based determination). This Court's recent decision in *Wollschlaeger v. Governor of Florida* underscores the uncertainty. ___ F.3d ___, No. 12-14009, 2017 WL 632740 (11th Cir. Feb. 16, 2017) (en banc). There, we determined that the regulations at issue were speaker focused and content based but ultimately applied intermediate scrutiny. *Id.* at *6–*7, *10–*13 (citing and applying the *Central Hudson* line of cases, though not citing *Central Hudson* itself). We need not wade into these troubled waters, however, because the State cannot

Hudson analysis consists of a threshold question followed by a three-prong test.[8] The threshold question asks "whether the expression is protected by the First Amendment" at all because, as noted above, some commercial speech remains unprotected. *Central Hudson*, 447 U.S. at 566, 100 S. Ct. at 2351. Commercial speech does not merit First Amendment protection and may be regulated or even banned if (1) the speech concerns unlawful activity or (2) the speech is false or inherently misleading. *See Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 638, 105 S. Ct. 2265, 2275 (1985) ("The States and the Federal Government are free to prevent the dissemination of commercial speech that is false, deceptive, or misleading or that proposes an illegal transaction." (citations omitted)); *Cable/Home Commc'n Corp. v. Network Prods., Inc.*, 902 F.2d 829, 849 (11th Cir.

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survive *Central Hudson* scrutiny, and in any event the Creamery does not argue the State's restriction was content based or speaker focused. Brief of Appellant at 27 n.19.

[8] *Central Hudson* sometimes has been characterized as consisting of a four-prong test and other times as a three-prong test following a threshold question. *Compare Fla. Bar v. Went For It, Inc.*, 515 U.S. 618, 624, 115 S. Ct. 2371, 2376 (1995) ("Commercial speech that falls into neither of those categories [misleading speech or speech concerning unlawful activity], like the advertising at issue here, may be regulated if the government satisfies a test consisting of three related prongs . . . ."), *and Harrell v. Fla. Bar*, 608 F.3d 1241, 1269–70 (11th Cir. 2010), *with City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 435, 113 S. Ct. 1505, 1519–20 (1993) (Blackmun, J., concurring) ("Under the analysis adopted by the *Central Hudson* majority, misleading and coercive commercial speech and commercial speech proposing illegal activities are addressed in the first prong of the four-part test."), *and Borgner v. Brooks*, 284 F.3d 1204, 1210 (11th Cir. 2002). We think *Central Hudson* is best characterized as consisting of a threshold question and a three-prong test, and we adopt this terminology throughout this opinion. The threshold question is really a separate inquiry, for it examines the *speech* to determine whether it is protected at all, whereas the three-prong test scrutinizes the *restriction* to ascertain whether it survives the intermediate scrutiny afforded to protected commercial speech. *But cf. Alexander v. Cahill*, 598 F.3d 79, 88 n.5 (2d Cir. 2010) (recognizing the terminological split but adopting the four-part locution).

1990) ("[C]ommercial speech, accorded lesser protection than other constitutionally guaranteed expression, may be banned if it relates to illegal activity." (citing *Central Hudson*, 447 U.S. at 563–64, 100 S. Ct. at 2350)); *Borgner*, 284 F.3d at 1210 ("Inherently misleading or false advertising . . . may be regulated by the state at will." (citing *In re R.M.J.*, 455 U.S. 191, 203, 102 S. Ct. 929, 937 (1982))).

If the speech neither concerns unlawful activity nor is inherently misleading, satisfying the threshold criterion and thus meriting First Amendment protection, then the government may only regulate the speech if its restriction satisfies intermediate scrutiny under *Central Hudson*'s three-prong test. In the first prong, "we ask whether the asserted governmental interest is substantial." *Central Hudson*, 447 U.S. at 566, 100 S. Ct. at 2351. In the remaining two prongs, "we must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest." *Id.* A regulation that fails to pass muster violates the First Amendment.

With respect to both the threshold question and the three-prong test, the burden is on the government to produce evidence to support its restriction. *Edenfield v. Fane*, 507 U.S. 761, 770, 113 S. Ct. 1792, 1800 (1993) ("It is well established that the party seeking to uphold a restriction on commercial speech carries the burden of justifying it." (quotation omitted)); *see also Ibanez v. Fla.*

Dep't of Bus. & Prof'l Regulation, 512 U.S. 136, 143, 114 S. Ct. 2084, 2089 (1994) ("The State's burden is not slight; the 'free flow of commercial information is valuable enough to justify imposing on would-be regulators the costs of distinguishing the truthful from the false, the helpful from the misleading, and the harmless from the harmful.'" (quoting *Zauderer*, 471 U.S. at 646, 105 S. Ct. at 2279)). The requirement to produce evidence is essential, "otherwise 'a State could with ease restrict commercial speech in the service of other objectives that could not themselves justify a burden on commercial expression.'" *Miller v. Stuart*, 117 F.3d 1376, 1382 (11th Cir. 1997) (quoting *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 487, 115 S. Ct. 1585, 1592 (1995)). With these precepts in mind, we turn to *Central Hudson*.

A. Threshold Question

1. Speech related to unlawful activity

The first question under the threshold inquiry is whether the restriction is permissible as a regulation of speech relating to unlawful conduct. The State asserts it is because the Creamery's skim milk is simply prohibited for sale in Florida. If the only legal way to sell skim milk in Florida were to add vitamin A so that the milk met the standards for a Grade "A" milk product, then banning the use of the term "skim milk" for non-complying milk would be lawful as a restriction of

speech relating to the unlawful activity of selling non-Grade "A" milk.[9] *See Fla. Bar v. Went For It, Inc.*, 515 U.S. 618, 623–24, 115 S. Ct. 2371, 2376 (1995) ("[T]he government may freely regulate commercial speech that concerns unlawful activity."); *Pittsburgh Press Co. v. Pittsburgh Comm'n on Human Relations*, 413 U.S. 376, 389, 93 S. Ct. 2553, 2561 (1973) ("Any First Amendment interest which might be served by advertising an ordinary commercial proposal . . . is altogether absent when the commercial activity itself is illegal and the restriction on advertising is incidental to a valid limitation on economic activity."); *Central Hudson*, 447 U.S. at 563–64, 100 S. Ct. at 2350; *see also Cable/Home Commc'n Corp.*, 902 F.2d at 849–50 (holding that copyright infringement suit against publisher of advocacy campaign newsletter advertising illegal de-scrambling devices does not violate First Amendment). Put another way, the State's action would be a regulation of illegal conduct, not speech. *See Dana's R.R. Supply v. Att'y Gen.*, 807 F.3d 1235, 1241–46, 1249 (11th Cir. 2015) (finding a law that permitted a price differential to be charged to customers if called a discount but that prohibited such a disparity if referred to as a surcharge regulated speech rather

[9] If an imitation milk permit were unavailable for skim milk, it would simply be illegal to sell the milk without replenishing the lost vitamin A, because without additives the skim milk is not Grade "A" and as such cannot be sold in Florida. *See* Fla. Stat. § 502.091 ("Only Grade 'A' pasteurized milk and milk products . . . shall be sold at retail to the final consumer"); Plaintiff's Response to Defendant's Motion for Summary Judgment at 2 ("Defendants state that the fact the Creamery's skim milk 'is not Grade "A"' is an undisputed material fact in this case. This fact is indeed undisputed . . . .").

than conduct and was not exempt from *Central Hudson* scrutiny as a restriction on speech relating to illegal conduct).

However, the State and the Creamery agree that in Florida vitamin-deficient skim milk can lawfully be sold as "imitation" milk. Furthermore, the State demonstrated its willingness to issue an imitation milk permit to the Creamery subject to its desired labeling and has acknowledged throughout these proceedings that the Creamery's skim milk can be sold as imitation milk. Because all that is being challenged is the State's action with respect to the Creamery, we accept the State's contention.[10]

As a result, the State has presented the Creamery with two options given the Creamery's unwillingness to add vitamin A: (1) sell the milk (pursuant to the

[10] If it were illegal to sell skim milk without additives at all, then restricting the use of the words "skim milk" would be legitimate with respect to non-complying milk because such branding would constitute speech incidental to unlawful conduct. *See Went For It*, 515 U.S. at 623–24, 115 S. Ct. at 2376; *Pittsburgh Press*, 413 U.S. at 389, 93 S. Ct. at 2561. To that end, an argument could be made that under Florida law, the Creamery is not entitled to an imitation milk permit for its skim milk. *See* Fla. Stat. § 502.012(13) (defining "milk products" to include skim milk); *id.* § 502.012(10) (defining "imitation milk and milk products" as expressly excluding items that qualify as "milk products"); *id.* § 502.165(3) (authorizing permits for imitation milk and milk products). If the Creamery could not sell its skim milk as imitation milk, there would be no way around Florida's prohibition on the sale of non-Grade "A" skim milk. *See id.* § 502.091. The State could thus ban the Creamery's use of the words "skim milk" on its illegal product.

However, throughout this proceeding, the State has maintained both that the Creamery's use of the term "skim milk" was speech incident to unlawful conduct *and* that the Creamery's skim milk can be sold under the imitation milk statute. When questioned at oral argument whether an imitation milk permit is even issuable for a milk product such as skim milk, the State conceded it was something of "a square peg in a round hole," but insisted a permit could be issued, refusing to adopt the above argument.

imitation milk statute) but do not call it "skim milk;" or (2) call the product "skim milk" but face sanctions for violating Fla. Stat. § 502.091.[11] The State's action is a speech regulation because the only difference between the two courses of conduct is the speech. *See Dana's R.R. Supply*, 807 F.3d at 1241–46. The Creamery's speech "is the only behavior being targeted." *Id*. at 1249; *see also Abramson v. Gonzalez*, 949 F.2d 1567, 1574 (11th Cir. 1992) ("Clearly the statutes do place restrictions on speech, for apparently *anyone* may currently *practice* psychology . . . in Florida, but only those who have met the examination/academic requirements of the statutes can *say* that they are doing so or hold themselves out as psychologists . . . ."). As a result, the State cannot escape full *Central Hudson* scrutiny by characterizing its restriction as a regulation of speech relating to unlawful conduct because the Creamery's conduct is not unlawful, only its speech is.

[11] It should be noted that Florida law does not appear to require the State to prohibit the Creamery from using the term "skim milk;" if an imitation permit is sought, additional disclosure is all that is needed. *See* Fla. Stat. § 502.181 ("It is unlawful for any person in this state to . . . [a]dvertise, package, label, sell, or offer for sale, or cause to be advertised, packaged, labeled, sold, or offered for sale, any imitation or substitute milk or milk product in a manner that is untrue, deceptive, or misleading and which could cause consumers to think they are purchasing a Grade A milk or milk product."). This fact underscores that what we decide here is whether the *action* of the State in this case is constitutional. We make no determination here as to the constitutionality of any statute or regulation.

2. False or inherently misleading speech

The remaining focus of our analysis under the threshold question of *Central Hudson* is whether in using the term "skim milk" the Creamery's speech is inherently misleading or merely potentially misleading.[12] If it is inherently misleading, the speech is not entitled to constitutional protection. *See Borgner*, 284 F.3d at 1210. Regulations of speech that is only potentially misleading must pass the three-prong *Central Hudson* test. *Id*.

The district court held the Creamery's use of the term "skim milk" to describe its product was inherently misleading because it conflicted with the State's definition of "skim milk," according to which the product would include replenished vitamin A. *See* U.S. Dep't of Health & Human Servs., *Grade "A" Pasteurized Milk Ordinance*, at App'x O (2005) ("[V]itamins A and D must be added to dairy products from which fat has been removed; such as, reduced fat, lowfat, and nonfat dairy products, in an amount necessary to replace the amount of these vitamins lost in the removal of fat."). The court asserted that "[a] state can recognize—and indeed deliberately create—a standard meaning of a term used to describe a food product, including, in this instance, skim milk."

It is undoubtedly true that a state can propose a definition for a given term. However, it does not follow that once a state has done so, any use of the term

[12] The State does not argue the Creamery's speech is false.

inconsistent with the state's preferred definition is inherently misleading. Such a per se rule would eviscerate *Central Hudson*, rendering all but the threshold question superfluous. All a state would need to do in order to regulate speech would be to redefine the pertinent language in accordance with its regulatory goals. Then, all usage in conflict with the regulatory agenda would be inherently misleading and fail *Central Hudson*'s threshold test. Such reasoning is self-evidently circular, and this Court has already had occasion to refute it.

In *Abramson*, Florida's professional licensure regime permitted the practice of psychology by both licensed and unlicensed professionals, but only allowed those holding licenses to publicly hold themselves out as such. *Abramson*, 949 F.2d at 1572. The defendants there made the same argument the State makes here, namely, that "any commercial speech describing the plaintiffs as psychologists would be false and therefore unprotected by the first amendment since the statute defines a psychologist as someone who is licensed by the state to be a psychologist." *Id.* at 1576. We pointed out the resemblance to *Peel v. Attorney Registration and Disciplinary Commission*, in which the Supreme Court rejected Illinois' identical argument that its definition of the term "specialist" rendered a lawyer's use of the term inherently misleading. *Id.* We explained that "[b]y finding that the attorney in that case could legally hold himself out as a specialist in trial practice, the Court [in *Peel*] necessarily held that the state's own definition of

a specialist—or here a psychologist—cannot bar those who truthfully hold themselves out as specialists or psychologists from doing so." *Id.* (citing *Peel v. Att'y Registration and Disciplinary Comm'n*, 496 U.S. 91, 103–105, 110 S. Ct. 2281, 2289–90 (1990) (plurality opinion)). Accordingly, we concluded in *Abramson* that we were "not bound by Florida's definition of a psychologist." *Id.*

The same analysis applies to the State's definition of "skim milk." Indeed, *Peel* indicates that statements of objective fact, such as the Creamery's label, are not inherently misleading absent exceptional circumstances. *Peel*, 496 U.S. at 101–102, 110 S. Ct. at 2288 (concluding the phrase "Certified Civil Trial Specialist" was not inherently misleading in part because "[a] lawyer's certification by NBTA is a verifiable fact, as are the predicate requirements for that certification," though "if the certification had been issued by an organization that had made no inquiry" into the matter, "the statement, even if true, could be misleading"); *see also Ibanez*, 512 U.S. at 144, 114 S. Ct. at 2089 ("[A]s long as Ibanez holds an active CPA license from the Board we cannot imagine how consumers can be misled by her truthful representation to that effect."); *Parker v. Commonwealth of Ky., Bd. of Dentistry*, 818 F.2d 504, 510 (6th Cir. 1987) ("We cannot agree that such terms [as orthodontics, brackets, and braces] are inherently misleading. Such terms are not false, but actually describe procedures which a general practicing dentist is permitted to perform under state law."). Calling the

Creamery's product "skim milk" is merely a statement of objective fact. *See*, *e.g.*, *Skim milk*, Webster's Third New International Dictionary (1986) (defining "skim milk" as "milk from which the cream has been taken").

This is not to say that a state's definition of a term might not become, over time and through popular adoption, the standard meaning of a word, such that usage inconsistent with the statutory definition could indeed be inherently misleading. But the state must present evidence to that effect, and that has not been done here. *See Edenfield*, 507 U.S. at 770–71, 113 S. Ct. at 1800; *Peel*, 496 U.S. at 106, 110 S. Ct. at 2290 ("Given the complete absence of any evidence of deception in the present case, we must reject the contention that petitioner's letterhead is actually misleading."); *Miller*, 117 F.3d at 1382–83 (holding that state had not introduced evidence to show CPA's truthful information was in fact misleading). *But see Zauderer*, 471 U.S. at 652–53, 105 S. Ct. at 2282 (holding that where a contingency fee advertisement stated that "if there is no recovery, no legal fees are owed by our clients," but did not make a distinction between "legal fees" and "costs," state was not required to produce evidence where "the possibility of deception is as self-evident as it is in this case"). To the contrary, the district court went as far as to concede that it "is undoubtedly true that a typical consumer would think 'skim milk' is simply milk from which the cream has been skimmed." Nevertheless, it maintained, the State produced a study in which

consumers indicated they would "expect skim milk to include the same vitamin content as whole milk." But this evidence about what consumers believe to be skim milk's attributes does not make the Creamery's representation that it is selling skim milk misleading; "[u]nfamiliarity is not synonymous with misinformation." *Mason*, 208 F.3d at 957. The State's study provides no evidence that consumers expected anything other than skim milk when they read those words on the Creamery's bottles, the State's alternative definition notwithstanding. We are not bound by such a definition. *See Abramson*, 949 F.2d at 1576. The Creamery's use of the words "skim milk" to describe its skim milk is not inherently misleading.

B. Intermediate Scrutiny

As the Creamery's label does not concern unlawful activity and is not inherently misleading, the Creamery's commercial speech merits First Amendment protection. Accordingly, the State's speech restriction is subject to intermediate scrutiny under the remainder of the *Central Hudson* test.

As to the first prong, the State and the Creamery agree the State has a substantial interest in combating deception and in establishing nutritional standards for milk. We assume, without deciding, that such interests are valid under intermediate scrutiny. In addition, we do not address the second prong of *Central Hudson*, regarding whether the State has shown its restriction directly and

materially advances its interests, because the measure is clearly more extensive than necessary to achieve its goals.

Indeed, the State has introduced no evidence at all on the third prong of *Central Hudson*. The record makes clear that numerous less burdensome alternatives existed and were discussed by the State and the Creamery during negotiations that would have involved additional disclosure without banning the term "skim milk."[13] *See Abramson*, 949 F.2d at 1577 ("[W]hen the first amendment is at issue, 'the preferred remedy is more disclosure, rather than less.'" (quoting *Bates v. State Bar of Ariz.*, 433 U.S. 350, 375, 97 S. Ct. 2691, 2704–2705 (1977))). There can be little question the State failed to show its remedy was "not more extensive than is necessary to serve [its] interest." *Central Hudson*, 447 U.S. at 566, 100 S. Ct. at 2351.

It is true, as the State contends, that the final prong of *Central Hudson* does not require it to show its measure was the least restrictive means of achieving its goal. *See Borgner*, 284 F.3d at 1213 ("We do not require that the regulation at issue be the least restrictive means available to accomplish the state's objective. Rather, we merely require 'a fit between the legislature's ends and the means chosen to accomplish those ends—a fit that is not necessarily perfect, but

[13] For example, the Creamery indicated it was amenable to a label that would have included the following disclaimer: "It [the milk] is all-natural skim milk with some vitamin A removed by skimming cream from milk." *See supra* n.2.

reasonable.'" (quoting *Bd. of Trs. of the State Univ. of N.Y. v. Fox*, 492 U.S. 469, 480, 109 S. Ct. 3028, 3035 (1989))). Nevertheless, the State was unable to show that forbidding the Creamery from using the term "skim milk" was reasonable, and not more extensive than necessary to serve its interest. It "disregard[s] far less restrictive and more precise means"—for example, allowing skim milk to be called what it is and merely requiring a disclosure that it lacks vitamin A. *Fox*, 492 U.S. at 479, 109 S. Ct. at 3034 (quotation omitted). The State's mandate was clearly more extensive than necessary to serve its interest in preventing deception and ensuring adequate nutritional standards.

IV. CONCLUSION

For the foregoing reasons, the State has not carried its burden and is not entitled to summary judgment with respect to its prohibition of the Creamery's use of the term "skim milk." We therefore **VACATE** the judgment and **REMAND** to the district court.