# National Milk Producers Federation

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Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061, HFA-305
Rockville, MD 20852

**Re: Opposition to request that FDA issue regulations clarifying how foods may be named by reference to the names of other foods (Docket ID: FDA-2017-P-1298)**

Dear Sir or Madam:

The National Milk Producers Federation (NMPF) submits these comments in opposition to the petition submitted by the Good Food Institute (GFI) on March 2, 2017. The National Milk Producers Federation, based in Arlington, VA, develops and carries out policies to advance the well-being of dairy producers and the cooperatives they own. The members of NMPF's cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of more than 32,000 dairy producers on Capitol Hill and with government agencies.

To ensure product quality and integrity, and to prevent marketing efforts aimed at misleading consumers, NMPF has had a clear, long-standing position on and an ongoing interest in the proper labeling of foods bearing the nomenclature of traditional dairy products. Specifically, NMPF has raised the issue of FDA's lack of enforcement of existing regulations pertaining to the standards of identity for dairy foods through multiple communications over the past 17 years. By referencing those documents here and attaching them to this letter, we respectfully request FDA include them in the current docket before we more specifically address the GFI petition:

- Letter dated February 21, 2017 from Dr. Beth Briczinski, Vice President, Dairy Foods & Nutrition, NMPF to Docket #FDA-2016-D-2343;
- Letter dated May 8, 2015 from James Mulhern, President and CEO, NMPF and Dr. Beth Briczinski, Vice President, Dairy Foods & Nutrition, NMPF to Sylvia Mathews Burwell, Secretary, HHS and Thomas J. Vilsack, Secretary, USDA;
- Letter dated August 1, 2014 from Dr. Beth Briczinski, Vice President, Dairy Foods & Nutrition, NMPF to Docket #FDA-2012-N-1210;
- Letter dated May 5, 2014 from Dr. Beth Briczinski, Vice President, Dairy Foods & Nutrition, NMPF to Docket #FDA-2009-D-0430;
- Letter dated July 28, 2010 from Dr. Beth Briczinski, Director, Dairy Foods & Nutrition, NMPF to Docket #FDA-2010-N-0210;

- Letter dated July 15, 2010 from Dr. Beth Briczinski, Director, Dairy Foods & Nutrition, NMPF to Kathleen Sebelius, Secretary, HHS and Thomas J. Vilsack, Secretary, USDA;
- Letter dated April 28, 2010 from Jerry Kozak, President and CEO, NMPF to Margaret A. Hamburg, Commissioner, FDA;
- Letter dated November 2, 2001 from Dr. Robert Byrne, Vice President, Regulatory Affairs, NMPF to Dr. Christine Lewis, Director of Office of Nutritional Products, Labeling and Dietary Supplements;
- Letter dated February 14, 2000 from Dr. Robert Byrne, Vice President, Regulatory Affairs, NMPF to Joseph Levitt, Director, CFSAN.

**1. Introduction: FDA should summarily reject the GFI petition, which undermines federal standards of identity.**

GFI proposes that the Food and Drug Administration (FDA) amend 21 CFR §102.5[1] in a way that would permit manufacturers of plant-based beverages and products to use product names that employ standardized dairy terms such as "milk." When plant-based beverages use standardized dairy terms, they typically do so to imitate milk and other real dairy products, and to benefit unfairly from the reputation that real dairy foods have for nutritional content and quality, despite the fact that these products are not, in fact, milk and do not have milk's unique nutrient package. If manufacturers of plant-based beverages or products want to use standardized dairy terms in their product names, Congress has created an avenue for them to do so. There already exists an exception to the misbranding rule for products clearly identified as "imitation." GFI's proposal is entirely at odds with the statutory mandate and laws that Congress has established; and is in direct contravention to the current provisions of FDA's regulations in this area.

[1] Specifically, GFI's proposal is to add to 21 CFR §102.5, after subsection (d) the following language:

(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.

GFI characterizes its petition as a "clarification" of existing FDA regulations and policies that would allegedly "reflect consumer understanding and the current realities of products in the marketplace." In fact, it is nothing of the sort. The proposed changes would only serve to further confuse the marketplace by robbing traditional food names of their commonly-understood meaning, by undermining FDA's standards of identity for those traditional food products, and by placing FDA's blessing on the imitation of standardized foods without identification as such, in contradiction to statutory provisions. The GFI petition is plainly inconsistent with Congress's direction to FDA that it establish and enforce standards of identity; and that FDA promulgate regulations, and effectively enforce them, to prevent misleading imitation of standardized foods.

The GFI petition is very long on verbiage, but painfully short on clear answers. In its 39-page petition, GFI never addresses some of the most pertinent questions. For example, What prevents the manufacturer of a plant-based drink or beverage from calling it a "drink" or a "beverage"?; Why are GFI member companies so insistent that they have to market non-dairy products using traditional dairy terms such as "milk"?; If plant-based products are required to be marketed under names that do not contain standardized dairy terms, why would that be "confusing" for consumers who are looking for alternatives to dairy products?

NMPF contends that calling plant-based beverages and drinks what they really are – and not "milks" – is the simplest and most certain way to "promote honesty and fair dealing in the interests of consumers." That is the purpose of the statutes that FDA administers, and the goal that GFI purports to achieve. It is not "anti-competitive" to expect – indeed to require – that a plant-based beverage or product be named in an appropriate manner as to the actual nature of the product, and not in reference to what it is not. That is just common sense, and sound regulation in the interests of consumers.

Why does GFI now propose that FDA amend its regulation so that plant-based products would be allowed to be marketed under names incorporating dairy terms for which standards of identity have long been established? It appears that GFI's members seek to name their products in ways that bask in the halo of the reputation that milk and other dairy products have for providing healthful protein and essential nutrients. Milk and other real dairy products are among the most common foods consumed by humans over many millennia, and have established well-deserved reputations for nutritional value. Congress knew this nearly 80 years ago when it passed laws requiring that the federal government establish standards of identity for common foods, and when it directed federal agencies to prevent mislabeling by

imitation foods. Plant-based drinks and beverages that are marketed using dairy terms are imitation products but, under FDA's current lack of regulatory enforcement in this area, are ones that do not properly acknowledge their imitation status. It is our view that these products are, and for some time have been, misbranded. FDA should reject any proposed amendment to the regulations that would sanction misbranding, and, to the contrary, should enforce existing laws and regulations.

Before explaining why FDA should summarily reject GFI's request, NMPF would like to provide rebuttal to some of the points raised by GFI's petition.

**2a. Plant-based foods and beverages using names of standardized dairy foods are imitation products.**

First, GFI's insistence – that plant-based beverages that use names that include standardized dairy terms such as "milk" are not imitations – is simply untrue. Once again, the fundamental and unanswered question: if a product is not milk, why should it be called "milk"? Anyone who walks into a grocery store or sees an ad for these plant-based products can see that the companies who market them go to great lengths to make their products appear as much as possible like dairy milk. Plant-based beverages or products are processed and colored to look like milk or cheese or the product they aim to imitate, and to have the textures of those products; they are packaged and presented in grocery stores in bottles and cartons designed like those traditionally used for milk, or in shapes and presentation to look like cheese; they are advertised to seem like milk or cheese.

Statements of executives in the plant-based beverage industry have made this imitation strategy clear. For example, Steven Demos, the CEO of WhiteWave, said of his company's soy beverage product in 2001:

> "We also had to figure out how to get this product category to market. Dairy milk is a staple food that we consider a fundamental part of the scenery in a supermarket. Why not position fresh soymilk to be as close as possible?[2]"

In addition to the products and their packaging trying to imitate milk at the point of sale, they are often advertised in the media with imagery evoking the look of traditional dairy milk. A clear example of this is the ads run by "Silk," a manufacturer of plant-based imitation dairy products, which feature the "Silkman" who wears the traditional white outfit and hat of the iconic milkman in our past, and who drives the white step-van truck typical of the home delivery milkman we are all familiar with.

[2] S. Demos. Got Soy. *Hemispheres Magazine*, August 2001, 21-26.

**2b. Imitation dairy products lack the nutritional quality of standardized dairy products.**

Second, GFI incorrectly characterizes the dairy industry's arguments about why product names such as "rice milk" or "almond milk" are misleading to the public. NMPF does not contend that most consumers think that these products come from cows. Many who consume them are certainly aware that these imitation beverages are plant-based products, and NMPF does not claim otherwise. What is completely misleading to the public is the inherent suggestion by the use of word "milk" in these products' names that they have comparable nutritional and food values to those of dairy milk. This is not true, and manufacturers of imitation dairy products are misleading the public through their sleight of hand marketing in this regard. Preventing such marketplace practices is one of the primary reasons for the existence of food standards of identity, and it is imperative that FDA address this issue by enforcing its existing standards.

NMPF conducted a survey of plant-based imitation dairy beverages sold in grocery stores in the Washington, D.C. metropolitan area. NMPF then compared the nutrition facts panels of these products with that of 1% real milk, including the nine essential nutrients for which milk is the #1 source in children's diets[3]. For the purposes of the study, it was assumed that the nutritional values claimed on the products' labels were accurate. Further, NMPF did not factor in decreased nutrient consumption because of poor bioavailability in the fortified products or lesser protein quality compared to milk protein (A University of Illinois study compared digestible indispensable amino acid scores (DIAAS) for both animal and plant protein sources. Results indicated that values for all dairy proteins tested were greater than for proteins from plants[4].) Please see the results of the nutritional profiles of the 244 imitation dairy beverages in the table in Attachment 1.

The results of this comparison study demonstrated that: (1) none of these products is nutritionally equivalent to real milk or delivers those nine essential nutrients as real milk does; and (2) unlike real milk's consistent nutrient package, there was extremely

[3] D.R. Keast, V. L. Fulgoni, T. A. Nicklas, et al. (2013) Food sources of energy and nutrients among children in the United States: National Health and Nutrition Examination Survey 2003-2006. *Nutrients* 5, 283-301.

[4] J.K. Mathai, Y. Liu, and H.H. Stein (2017) Values for digestible indispensable amino acid scores (DIAAS) for some dairy and plant proteins may better describe protein quality than values calculated using the concept for protein digestibility-corrected amino acid scores (PDCAAS). *British Journal of Nutrition* 117, 490-499.

wide variation both within and among the various categories of plant-based beverages.

Experts in pediatrics and health scientists who have studied these products have arrived at the same conclusions. In a recent medical journal article that looked at the nutritional value of dairy milk versus plant-based beverages, the authors cautioned: "Non-dairy milk beverages vary in their nutritional profiles. These should not be considered a nutritional substitute for cow's milk until nutrient quality and bioavailability is established.[5]" While plant-based beverages may be fortified to contain some additional nutrients, many fall far short in terms of the total nutritional benefits delivered by dairy milk. The most recent *Dietary Guidelines for Americans* also noted this nutritional inferiority: "Other products sold as 'milks' but made from plants (e.g., almond, rice, coconut, and hemp 'milks') may contain calcium and be consumed as a source of calcium, but they are not included as part of the dairy group because their overall nutritional content is not similar to dairy milk and fortified soy beverages…[6]" (emphasis added). Similarly, a spokesperson for the Academy of Nutrition and Dietetics recently acknowledged: "The nutritional profile of these [newer plant-based beverage products] will vary, especially in the protein area, but also in terms of vitamins [and] minerals. Often consumers mistakenly believe [plant-based milks] are healthier, which is not true. This 'health halo' has blurred the lines so much that other plant based milks jumped on the wave and are enjoying the ride.[7]"

The official report of the 2015 Dietary Guidelines Advisory Committee, in addition to noting the lower calcium bioavailability typical of milk alternatives, stated that "vitamin D and potassium amounts vary" among the products, and that "[c]alorie levels also are higher for most of the plant-based alternative milk products for a given calcium intake level. In other words, to obtain a comparable amount of calcium as one cup eq [sic] for non-fat fluid milk, the portion size required to meet the calcium intake need results in higher energy intake…"[8]

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[5] S. Singhal, R. Baker, and S. Baker (2017) A comparison of the nutritional value of cow's milk and non-dairy beverages. *Journal of Pediatric Gastroenterology and Nutrition* 64, 799-805.

[6] U.S. Department of Health and Human Services and U.S. Department of Agriculture. *2015–2020 Dietary Guidelines for Americans*. 8th Edition. December 2015. Available at http://health.gov/dietaryguidelines/2015/guidelines/.

[7] S. Rossman, "Got milk? This is the kind you should be drinking" USA Today. February 28, 2017. Available at https://www.usatoday.com/story/news/nation-now/2017/02/28/got-milk-kind-you-should-drinking/98322592/.

[8] Dietary Guidelines Advisory Committee. *Scientific Report of the 2015 Dietary Guidelines Advisory Committee*. February 2015.

And it is clear that many consumers misunderstand the true nutrient package presented by imitation dairy products. A survey of over 1000 consumers conducted in January 2015 by Mintel/GMI Lightspeed bears this out. Consumers were asked their reasons for consuming non-dairy "milks." The #1 reason, recorded in 49% of the responses, was that they thought it was nutritious. But, as the evidence shows, plant-based milk imitators are uniformly less nutritious than milk.

The #3 reason in the Mintel survey that consumers opted for non-dairy "milks", recorded in 37% of the responses, was that they thought it was a good source of protein. And yet, several of the leading plant-based milk alternatives, "almond milk" (currently ~70% of the imitation dairy beverage market, based on sales volume) and "rice milk", for example, have virtually no protein (≤1 gram per serving). Based on the 244 imitation dairy beverages surveyed by NMPF, the average amount of protein in these products was 2 grams and 1 gram (per serving), respectively. Nearly 80% of the almond beverages, and all of the rice beverages, contained two grams of protein or less. Real milk, in contrast, has 8 grams of naturally-occurring protein per serving.

Clearly, when a large percentage of consumers purchase plant-based imitation "milks," they think they are getting nutritional benefits that they are not. One leading executive within the plant-based beverage industry acknowledged both the nutritional inferiority of many newer plant-based beverages, and the unfairness of their hitching a ride on the fender of the dairy industry by using the word "milk" in their product names. Adam Lowry, the founder of Ripple, recently said: "… I can agree with the gripe of the dairy industry that these alternative milks that don't have nutrition are harvesting unfairly the health halo of milk.[9]"

**2c. Acting on the GFI petition will not increase clarity for consumers.**

Third, GFI's claim that its proposed amendment will allow producers of plant-based products and beverages "to be able to name their new products in a clear commonsense manner consistent with consumer expectations" is false. Naming a new non-dairy product using a traditional dairy name is neither "clear" nor "commonsense." To confuse a thing with something it is not does not heighten clarity. While perhaps not surprising in this era of "fake news", to say that it is acceptable to call things by false names meets no test of common sense.

[9] B. Avery, "Class actions target alt-milk nutritional standards" BevNet. February 8, 2017. Available at https://www.bevnet.com/news/2017/class-actions-target-alt-milk-nutritional-standards.

In addition, what possible expectations do consumers have regarding new or novel food products? The truth is: beyond safety, none whatsoever. And if there are consumer expectations, they do not involve the name of the product. Because FDA has heretofore failed to effectively enforce standards of identity for common and usual foods, there has been a proliferation of plant-based products that incorporate the word "milk." NMPF is aware of at least 23 such sources for imitation beverages in the current marketplace[10]. What possible expectations do consumers have regarding a plant-based drink developed from "algae" or "hemp" or "tiger nut"? And why would consumers have any expectations that these products should have a name that includes the word "milk"?

Some manufacturers of non-standardized imitation dairy products are labeled without resorting to standardized dairy names. The current marketplace includes (as examples) "rice drinks", "almond beverages", or fanciful names that do not have "milk" included in the name of the food on the front of the package. This further demonstrates that such products can be marketed without confusing consumers – and be labeled appropriately – without co-opting standardized dairy terminology.

As one example of the sheer absurdity and tremendous consumer confusion to which the GFI petition would surely lead, NMPF calls attention to a product we have highlighted to the agency in a previous communication[11] – "Blue Magic Milk". Based on the information located on the product's principal display panel, it appears that the name of the food is "Blue Magic Milk"; although according to the product's ingredient statement, the product does not comply with the federal standard of identity for "milk" (21 CFR 131.110). The manufacturer's labeling of the product using the name of a standardized dairy product is likely to mislead consumers, to the extent that they would think the product is a true dairy product (i.e., one that contains real milk). This is one particularly egregious example of the manufacturer of an imitation dairy product blatantly ignoring existing labeling regulations, something which would only worsen with GFI's proposal, while fostering a regulatory climate without true consequences.

In contrast to the brazen labeling tactics of manufacturers of imitation dairy products, dairy foods manufacturers do formulate and market non-standardized dairy products without resorting to inappropriate use of standardized dairy terminology. Consumers are not confused when they purchase products labeled as "dairy beverage", "frozen

[10] Algae, Almond, Banana, Barley, Cashew, Flax, Green Pea, Hazelnut, Hemp, Macadamia, Oat, Peanut, Pecan, Pistachio, Potato, Quinoa, Rice, Sesame, Soy, Sunflower, Tiger Nut, Walnut and Wheat.

[11] Letter dated June 7, 2017 from Dr. Beth Briczinski, Vice President, Dairy Foods & Nutrition, NMPF to Ms. Felicia Billingslea, Director Food Labeling and Standards, FDA.

dairy dessert", "cultured dairy snack", "dairy snack", "processed cheese product", or "pizza cheese". Clearly there is a need for a level playing field, which means proper enforcement of current standards of identity for dairy foods across the breadth of the food industry.

**2d. Asking for enforcement of current standards of identity for dairy foods is not anti-competitive.**

Finally, GFI's claim that NMPF's opposition to their use of standardized dairy names in non-dairy products is an attempt to stifle competition is also groundless. It is not anti-competitive behavior to seek enforcement of longstanding laws and regulations.

The dairy industry is not trying to prevent plant-based drinks and beverages from being sold in the marketplace. America's dairy farmers understand and embrace full and fair competition. If companies want to develop plant-based products and market them, they are free to do so. There are consumers who want to purchase these products for various reasons, and NMPF and its members believe in the right of American consumers to have access to the widest array of food choices. If an American consumer wants to purchase a plant-based beverage, so be it. But a product should not be named for what it really is not. That contention is not anti-competitive; it is pro-fairness, pro-honesty, and pro-transparency.[12]

[12] GFI's accusations that U.S. dairy industry's regulatory and legislative efforts are "anticompetitive" (GFI Petition, p. 15 and fns. 33, 34 & 35) are wholly without merit. The examples of allegedly "anticompetitive" behavior cited by GFI are letters from NMPF to government officials, comments in government proceedings, and legislative proposals. As a trade association itself, GFI is certainly aware that the right of any group of citizens, including the members of a trade association like NMPF, to petition the government is constitutionally protected under the First Amendment. There is no liability under any law of competition for attempting to influence the passage or enforcement of law. *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.,* 365 U.S. 127, 135 (1961); *United Mine Workers v. Pennington*, 381 U.S. 657, 670 (1965). This doctrine is grounded in First Amendment protection of political speech, and "upon a recognition that the antitrust laws…are not at all appropriate for application in the political arena*." City of Columbia v. Omni Outdoor Advertising, Inc.,* 499 U.S. 365, 380 (1991), *quoting Noerr, supra,* 365 U.S. at 141. NMPF's efforts to maintain the integrity of the federal standards of identity for milk and other dairy products through the legislative and regulatory processes are constitutionally protected, and therefore cannot be characterized as "anticompetitive" in any legal sense.
Even less responsible are GFI's charges that Members of Congress who propose legislation or who make their views known to regulators are "anticompetitive" or assisting in "anticompetitive goals." Members of Congress are elected to represent the interests of the people in their States

**3. The underlying statutory and regulatory scheme.**

Nearly 80 years ago, Congress determined that the federal government should "promote honesty and fair dealing in the interest of consumers by promulgating regulations fixing and establishing for foods, under their common or usual names, reasonable definitions or standards of identity." Congress has left this question – whether doing so would "promote honesty and fair dealing in the interest of consumers" – to the judgment of the Secretary, 21 U.S.C. § 341. That authority, and that judgment, have been duly delegated to FDA. Pursuant to that statutory authority, FDA has promulgated regulations, including general principles, to guide this process (21 CFR 102.5). FDA regulations specifically provide that:

> …common or usual name of a food may be established by common usage or by establishment of a regulation in subpart B of this part, in part 104 of this chapter, in a standard of identity, or in other regulations of this chapter. 21 CFR 102.5(d).

Once FDA has established a standard of identity to define a common or usual food, then **any product that uses that food name, but does not conform to the established standard of identity, is deemed by law to be misbranded** (emphasis added). 21 U.S.C. §343(g). In the case of milk and nearly one hundred other dairy products, federal standards of identity have been long established (See 21 CFR Parts 131, 133, and 135). As a matter of law, therefore, the legal determination was made that it is in the interests of consumers that "milk", "yogurt", named varieties of specific cheeses, and many dairy common or usual food names be specifically defined, and that those dairy terms be used only in conjunction with products that conform to specific standards.

In fact, FDA has so ruled on a number of occasions, issuing warning letters to several manufacturers who have misbranded foods by misusing names of standardized dairy

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and Districts, and to write the laws of this country. The exercise of those constitutional duties is not subject to the antitrust laws or any law of competition. Senators and Congressmen propose legislation or speak out in the best interests of their constituents, and it cannot be termed "anticompetitive" in any sense. As the Court said in the *Noerr* decision, the antitrust laws simply do not apply in the political arena. GFI's suggestion that a Senator's legislative proposal or a Congressional letter to the FDA is an anticompetitive act totally misunderstands the democratic form of government, is insulting to those elected officials, and is simply wrong as a matter of law.

products[13]. Adding the name of a plant material in front of the word "milk" does not result in appropriate names for non-dairy products, as these products do not contain milk or milk ingredients, the plant-based liquids are not permitted ingredients in milk, nor do they represent the common or usual names of these beverages.

**4. GFI's proposal would render standards of identity meaningless, and would be inconsistent with the underlying statute.**

Congress directed that federal authorities develop reasonable definitions and standards of identity for common food names such as milk and named varieties of cheese, to create some certainty for consumers who desired to purchase these products. Now, GFI petitions the FDA to promulgate a regulation that would permit its members to render those definitions and standards totally meaningless simply by adding a word or two in front of the common food name. GFI invites FDA to add confusion to the names of standardized foods, and that is not in the interests of consumers.

GFI's proposal is to amend 21 CFR § 105 by adding a new section (e) that would permit manufacturers of new products to use common food names simply by adding virtually any word or phrase before that common name. The only alleged limitation in GFI's proposal is that the name must "effectively notify consumers that the product is distinct from such other food." But it is not clear what GFI intends or means by "distinct from such other food," and GFI makes no attempt to explain the meaning.

GFI's proposal effectively requests FDA to adopt a regulation that would negate two statutory provisions and a portion of its own regulations. First, GFI's amendment would render 21 U.S.C. §341 meaningless. Congress has directed that FDA promulgate standards of identity to promote honesty and fair dealing in the interests of consumers; and that once there is a standard of identity for a food term, a product using that food term that does not conform is misbranded. But there would be little purpose in establishing a standard of identity for a food like milk, if the word could be

[13] FDA Warning Letter dated June 29, 2011 from Barbara Cassens, District Director, FDA San Francisco District to Mr. Michael Pickett, CytoSport, Inc.;
FDA Warning Letter dated August 8, 2008 from Alonza E. Cruse, District Director, FDA Los Angeles District to Mr. Long H. Lai, Lifesoy, Inc.;
Letter dated July 18, 1985 from Lillie Taylor, Assistant to the Director, Division of Regulatory Guidance, CFSAN to C. Hwang, Dr. Chung's Foods Company, Ltd.;
Letter dated September 29, 1983 from James R. Taylor, Jr., Assistant to the Director, Division of Regulatory Guidance, Bureau of Foods to Mr. Kok Ee Lynn, Senior Officer, Singapore Institute of Standards and Industrial Research.

subsequently used in combination with virtually any other word to mean any other type of product. GFI's proposal would render all existing standards of identity meaningless because the allowance for other products is so broad, and the limitations so vague, that standardized food terms will be overused and become meaningless.

Second, the proposed amendment would render ineffective 21 U.S.C. §343(g). Congress has determined that a product is misbranded if "it purports to be or is represented as a food for which a standard of identity has been prescribed by regulations." GFI's petition would interpret this provision away. Under GFI's proposal, a manufacturer could stick any other word in front of a common food name and avoid Congress' rule against misbranding, subject only to an alleged "reasonable consumer standard," which (as will be discussed below) is unclear and inapplicable in a regulatory context.

GFI's argument that "by their own terms, standards of identity govern only *unqualified* food names" is unsupported and incorrect. The only case cited by GFI on this point is *62 Cases of Jam v. United States*, 340 U.S. 593 (1951), and GFI quotes only some dicta in that case. The actual holding of the case does not support GFI's position. GFI contends that if you simply add another word in front of a food name that has a standard of identity, then anything goes. That is not what *62 Cases of Jam* says.

*62 Cases of Jam* involved a product that was being marketing as "Delicious Brand Imitation Jam." The case was an *in rem* action brought by the government alleging that the product was misbranded because it did not conform to the federal definition of fruit jam. The trial court dismissed the case on the grounds that the statute expressly allowed the use of a standard food name if the manufacturer clearly used the word "imitation" in the brand name. See 21 U.S.C. § 343(c). The Tenth Circuit disagreed with the trial court, but the Supreme Court reversed and reinstated the verdict for the defendant. The actual holding in that case was that Congress had created an express exception for products that used the word imitation, where that word is the same size as the usual food name, and immediately preceded it. As Justice Frankfurter said in his opinion that the Court's job was "to construe what Congress has written. After all, Congress expresses its purpose by words. It is for us to ascertain – neither to add nor to subtract, neither to delete nor to distort." 340 U.S. at 596.

GFI is mistaken to cite *62 Cases of Jam* as undermining the integrity of federal usual food names or standards of identity – or to argue that it stands for the proposition that manufacturers may circumvent the statute simply by pairing a common food name with any other term that comes to mind. *62 Cases of Jam* is a case of very straightforward statutory construction. The Court said simply that Congress wrote a

clear exception in the statute for products marketed as "imitation", and a company could not be charged with misbranding if it placed the word "imitation" immediately before the usual food term.

In this situation, GFI argues that "by their own terms, standards of identity govern only *unqualified* food names." Nothing in the statute authorizing the promulgation of standards of identity, nothing in either 21 U.S.C. §341 or in 21 U.S.C. §343(g) so indicates; the word "unqualified" appears in neither statute. Inserting a word such as "unqualified" into the statute when it is not actually there, as GFI attempts to do, runs directly contrary to the tenet announced by the Court in *62 Cases of Jam* – that in reading a statute, we are "neither to add nor to subtract, neither to delete nor to distort."

Congress created the single exception for use of food names for which a standard of identity has been developed – the "imitation" exception in 21 U.S.C. §343(c). GFI now asks FDA to promulgate regulations that will create additional exceptions for added words or hyphenated phrases – exceptions that would literally swallow the rule. But legally, FDA may not do so. It must read the statute as Congress has written it, and neither add nor subtract.

*62 Cases of Jam* stands for the very reading of FDCA law that NMPF has long been advocating – you are permitted to market an imitation product, but only if you clearly identify it as an imitation. NMPF contends that the plant-based beverages produced and marketed by GFI's members are imitations of real dairy products, and clearly intended to be. So-called "soy milk" or "almond milk" or "rice milk" are not naturally white in color like real dairy milk; they have been processed or colored to look like dairy milk. These imitations do not have the same natural consistency or texture of milk; they have been formulated and processed to feel like real dairy milk. NMPF would have no complaint – indeed, legally could have no complaint – if these manufacturers called their products "Soy Imitation Milk" or "Almond Imitation Milk" or "Rice Imitation Milk." The statute permits this, as the Supreme Court affirmed in *62 Cases of Jam*.

**5. GFI's proposal would create greater confusion in the marketplace.**

Congress left the question of whether standards of identity were needed to protect the interests of the consumer to the judgment of the Secretary. GFI now asks FDA to promulgate a regulation that would allegedly apply a "reasonable consumer" standard in instances where a company included a common food term in the name of its product. Specifically, GFI proposes this amendment to 21 CFR 102.5:

> 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 Petition at 2)

This part of GFI's proposal is patently flawed in that it would significantly change the way in which FDA conducts its business. Is it GFI's intention that FDA would no longer apply its own judgment to these matters, but would in some unspecified process discern and apply the judgment of the "reasonable consumer"? If that is GFI's intention, it is clearly contrary to law as it has been repeatedly held that an agency cannot, by regulation, adopt implementing regulations or administrative constructions that are inconsistent with the language of the underlying statute. See *Brown v. Gardner*, 513 U.S. 115 (1994); *Davis County Solid Waste Mgmt. v. EPA*, 101 F.3d 1395 (D.C.Cir.1996). Congress had directed these decisions "to the judgment of the Secretary."

Or is GFI saying that FDA should, in exercising its own judgment as the statute requires, apply this "reasonable consumer" standard? If so, how is this any different from what FDA already does? FDA is directed by the statute to determine whether, in its judgment the establishment of standards of identity would "promote honesty and fair dealing in the interests of consumers." How is this different from the determination whether a name "serves to notify a reasonable consumer that the product differs…"? GFI doesn't explain what difference there is between FDA's judgment in the interests of consumers and the judgment of the reasonable consumer. It is certainly not clear from the language itself; and in any case, presumably FDA already makes this type of judgment. How else would FDA do what the statute requires?

Or does GFI contemplate that FDA will go through some legal or public process to determine what the "reasonable consumer" was so notified. Perhaps GFI has become enamored of the phrase "reasonable consumer" because it has been a standard applied in several recent California class action lawsuits applying federal and state consumer protection laws. See *e.g., Swearingen v. Late July Snacks*, Case No. 13-cv-04324-EMC (N.D. Cal.) (Order dated May 5, 2017 at 6) ("California courts have adopted the 'reasonable consumer' standard for adjudicating materiality of an alleged misrepresentation.") Reading *Swearingen* and the other recent California cases, it becomes clear that the "reasonable consumer" standard is simply the common law "reasonable person" standard applied in the context of a consumer protection lawsuit. It is essentially a jury instruction; it is the standard that the judge reads to the

twelve ordinary citizens called to jury duty who serve as the finder of fact in jury trial. What application does it have in this context where there is no jury process, and no mechanism or authority to develop one? GFI doesn't explain this. Is FDA supposed to issue this instruction to itself[14]?

The determination whether consumers are being misled by a food name has been delegated by statute to the FDA. Whether a food name misleads consumers because it leads them to believe it is a different product, or because the food does not have the same nutritional value that the name suggests, is a question for the FDA and the courts. Previously, courts have found "it is appropriate to defer to the authority of the expertise of the FDA to say what the appropriate rules should be…" *Hood v. Wholesoy & Co.,* Civil No. 12-cv-5550-YGR (N.D.Cal. July 12, 2013), *available at* 2013 U.S. Dist.LEXIS 97836.

GFI's suggestion that the use of terms like "soy milk" or "rice milk" have become accepted in other countries is also incorrect. Just recently, the European Court of Justice ("ECJ") ruled that for the proper application of EU food marketing standards, which take into account "the interests of producers, traders and consumers," the use of the word "milk" is precluded in food names used to market purely plant-based products. *Verband Sozialer Wettbewerb eV v. TofuTown.com GmbH*, Case No. C-422/16 (European Court of Justice, Seventh Chamber, 14 June 2017), *available at* http://curia.europa.eu/juris/documents. In that decision, the ECJ noted: "In the absence of such limits, those designations would not enable products with the particular characteristics related to the natural composition of animal milk to be

[14] The law is clear that the issues of "misbranding" of food and determining whether food names or labeling are false or misleading are relegated to the judgment of the Secretary, with that judgment subject to appellate review under the ordinary standards of deference. FDA has primary jurisdiction over these matters and the courts will not interfere with its decisions. In *Swearingen,* for example, plaintiffs brought a class action lawsuit because Late July Snacks LLC had identified one of the ingredients in its snack cracker products as "evaporated cane juice." (hereinafter, "ECJ"). Plaintiffs were consumers seeking to avoid added sugars in their food, and they asserted that ECJ was, in actuality, sugar. The action was brought under the federal Food Drug & Cosmetic Act and several state law claims. At the time the case was being brought, FDA was undertaking regulatory proceedings concerning the use of ECJ. Significantly, the court stayed the action pending completion of FDA proceeding on the grounds of primary jurisdiction. It was only after FDA completed its proceeding and issued final guidance that the court allowed the litigation to proceed. *Swearingen, supra,* at 3-4. The "reasonable consumer" standard is a jury instruction, and FDA would do well to avoid any inference that its judgments on these issues can be challenged in a trial court. If that is the idea behind this proposal, FDA should certainly avoid taking the bait and summarily reject it.

identified with certainty, which would be contrary to the protection of consumers because of the likelihood of confusion that would be created." *Id*.

**6. The proposed amendment is unnecessary: Plant-based imitations of dairy products may use dairy terms if they are fairly and honestly identified as imitations.**

Manufacturers of plant-based beverages have several legal options for labeling their products. They can choose unique names that describe their products by reference to actual content, or creatively or whimsically, without any reference to common food names for which standards of identity have been established; or, if they want to use a standardized food term, such as milk or a named cheese, in the product name, they may do so by taking advantage of the exception created by Congress for imitation products, and fairly and accurately label it as "imitation" in accordance with 21 U.S.C.§ 343 (c). The "imitation" exception was created by Congress and it is FDA's duty to read the statute as it was written –"neither to add nor to subtract, neither to delete nor to distort."*62 Cases of Jam, supra* at 596.

**7. FDA's effective enforcement of the statutory provisions regarding standards of identity and misbranding raise no constitutional issues.**

The final 10 pages GFI's petition (pp.28-38), wherein GFI hectors FDA about alleged Constitutional issues of commercial speech, appear to have absolutely nothing to do with the specific subject of GFI's petition. The petition seeks a regulatory amendment; there is nothing in the petition, nor as far as NMPF is aware, in any other current docket, about an alleged "ban on names." As such, the arguments GFI makes in pages 28-38 really are specious and off-point.

NMPF, however, feels obligated to set the record straight regarding some of GFI's legal contentions. We believe that GFI badly misrepresents the law in this area, and in particular the holding in *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 (1980). NMPF disagrees completely with GFI's suggestion that the *Central Hudson* decision would in any way prevent the effective enforcement of federal law involving common food names, standards of identity and misbranding.

*Central Hudson* involved a challenge to an order of the New York Public Service Commission that all public utilities in that State cease all advertising to promote the use of electricity. The Public Service Commission issued its order in an attempt to promote conservation, a purpose that the Court found to be a legitimate government

objective. The issue in the case was whether a total ban on all advertising was necessary to achieve this goal.

From GFI's rendition of the case, one might think that a government agency walked on a very thin edge in regulating the content of commercial speech. But that is not at all what *Central Hudson* holds. In rendering its decision, the Supreme Court began its analysis by noting that the protections afforded commercial speech are much more limited than for other forms of speech, and that the government plays an important role in regulating commercial speech. "[T]he Constitution…affords a lesser protection to commercial speech than to other constitutionally guaranteed forms of expression." *Id.* at 563, citing *Ohralik v. Ohio State Bar Ass'n,* 436 U.S. 447, 456-57 (1978). "The protection available for particular commercial expression turns on the nature both of the expression and the government's interest served by its regulations." *Id.* at 563. "There can be no constitutional objection to the suppression of commercial messages that do not accurately inform the public about lawful activity. The government may ban forms of communication more likely to deceive the public than to inform it." *Id.* at 563, citing *Friedman v. Rogers*, 440 U.S. 1, 13, 15-16 (1979) and *Ohralik, supra* at 464-65.

The holding in *Central Hudson* was simply that the State Public Utilities Commission had failed to show its interests in conserving energy required a <u>total</u> ban on <u>all</u> advertising. "The Commission has also not demonstrated that its interests…cannot be protected adequately by more limited regulation of commercial expression…<u>the Commission could attempt to restrict the format and content</u> of Central Hudson's advertising." *Id*. at 570-71 (emphasis added). Thus, the constitutional defect that the Court identified in *Central Hudson* was the complete ban on all advertising; the Court found no fault whatsoever with effective regulation of format or content of commercial speech in order to achieve legitimate government interests.

GFI's suggestion that FDA regulation of common food names and enforcement of standards of identity could not survive judicial scrutiny under *Central Hudson* is unsupported by the case law. Simply put, *Central Hudson* has not been interpreted and applied by the courts in the absurd fashion that GFI suggests. The Supreme Court has subsequently explained that *Central Hudson* does not require the satisfaction of a "least-restrictive-means standard" but rather requires "a fit between the legislature's ends and the means chosen to accomplish those ends…a fit that is not necessarily perfect, but reasonable…. *Board of Trustees of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 477, 480 (1989); *see also Retail Digital Network LLC, v. Prieto*, Civil No. 13-56069 (9th Cir., June 14, 2017), *available on* Google Scholar. As the court very recently observed in *Nicopure Labs, LLC v. FDA,* Civil No. 16-0878 (ABJ) (D.D.C.,July 21, 2017), *available at* 2017 U.S. Dist. LEXIS 113583, the FDA and other federal administrative agencies are

entitled to great deference in determining whether one option is better than another for advancing the statutory directive, and that courts may "rely on an agency's 'reasonable, common sense determination' that the option chosen is preferable". *Id*. at 59, *citing Nat'l Cable & Telecomms Ass'n v. FCC*, 555 F.3d 996, 1002 (D.C. Cir. 2009).

The courts have recognized that where Congress has enacted food safety and labeling legislation, determinations "require both specialized expertise and uniformity in administration" and that "[b]oth the food industry and consumers will benefit from the uniformity that comes from agency determination." *See e.g., Red v. General Mills, Inc.*, Civil No. 2:15-cv-02232-ODW(JPR) (C.D.Cal., December 29, 2015), *available at* 2015 U.S. Dist. LEXIS 172671).

And, without a doubt, the question of whether an item of food is misbranded or a name used for a food is misleading are technical questions that Congress has directed to the scientific and nutritional expertise of the FDA. Whether products that contain no milk but are labeled using the word milk mislead consumers simply because they use the word milk, or because the products "do not have the same nutritional value," is a question for the FDA, and the courts will find that "it is appropriate to defer to the authority of the expertise of the FDA to say what the appropriate rules should be…" *Hood v. Wholesoy & Co.,* Civil No. 12-cv-5550-YGR (N.D.Cal. July 12, 2013), *available at* 2013 U.S. Dist.LEXIS 97836. The courts will defer to the expertise of the FDA, because in the absence of that expert judgment, a court "would find itself in a position of having no set standard to apply, or announcing a standard and thereby overstepping its proper role." *Id.*

Protection of usual food names, federal standards of identity, and federal regulations regarding misbranding are not <u>total bans on all advertising</u>, the kind of restriction overturned in *Central Hudson*. To the contrary, they are effective <u>regulation of format and content</u> to meet the specific governmental interests Congress identified in the underlying statutory authority – i.e., protection of consumer interests. This is the precise type of government oversight of the marketplace that the *Central Hudson* court expressly approved.

Much of GFI's argument is based on hyperbole and fundamental mischaracterizations both regarding what is at issue in this matter, as well as what the Supreme Court has held. For example, GFI claims that "proposals to ban common names for dairy alternatives would run afoul of the First Amendment, failing to withstand scrutiny under *Central Hudson*."[15] But, as explained above, the constitutional defect in *Central Hudson* was the State's ban on <u>all</u> advertising. GFI concocts the phrase "ban on names" to suggest that FDA's regulation of food terms is somehow factually similar to

[15] GFI Petition at 34.

*Central Hudson*. FDA's regulation of food terms is not a "ban on names" – it is regulation of the content of commercial speech that *Central Hudson* expressly acknowledges and permits. In addition, GFI's argument is also premised on another invented phrase – "common names for dairy alternatives." It is not clear what that phrase precisely means or covers.

There has been no proposal made by anyone, to NMPF's knowledge, to ban "common names for dairy alternatives," (whatever that phrase means). This is more hyperbole. NMPF's position is, and has been, that dairy alternatives can be marketed under any name that the manufacturer chooses so long as that name does not violate federal law with respect to standards of identity, imitation or misbranding.

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In conclusion, NMPF strongly encourages FDA to reject the GFI petition. The arguments presented by GFI to initiate a new food naming protocol are without merit and, if FDA were to act on the petition as described, the agency would be acting in a manner contrary to both the statutory mandate and laws established by Congress and its own labeling regulations. Further, NMPF again requests the FDA to significantly increase enforcement efforts to prevent the mislabeling of imitations of standardized dairy products. The current marketplace is characterized by an "anything goes" attitude, where misbranding and mislabeling run rampant, and consumers are consistently short-changed through the purchase of products bearing nomenclature that deceptively promises a certain level of nutrients to be expected with terms like "milk", "cheese" and "yogurt", but in reality delivers far less.

NMPF appreciates the opportunity to provide comment on this issue. Please feel free to contact us with any questions or for additional information.

Respectfully submitted,

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Senior Vice President, Environmental and Regulatory Affairs & Staff Counsel

**Attachments**

Attachment 1 – Nutrient Composition of Imitation Dairy Beverages Compared to Milk, Marketplace survey conducted by NMPF, August 29, 2017.

Attachment 2 – Letter dated June 7, 2017 from Dr. Beth Briczinski, Vice President, Dairy Foods & Nutrition, NMPF to Ms. Felicia Billingslea, Director Food Labeling and Standards, FDA.

Attachment 3 – Letter dated February 21, 2017 from Dr. Beth Briczinski, Vice President, Dairy Foods & Nutrition, NMPF to Docket #FDA-2016-D-2343.

Attachment 4 – Letter dated May 8, 2015 from James Mulhern, President and CEO, NMPF and Dr. Beth Briczinski, Vice President, Dairy Foods & Nutrition, NMPF to Sylvia Mathews Burwell, Secretary, HHS and Thomas J. Vilsack, Secretary, USDA.

Attachment 5 – Letter dated August 1, 2014 from Dr. Beth Briczinski, Vice President, Dairy Foods & Nutrition, NMPF to Docket #FDA-2012-N-1210.

Attachment 6 – Letter dated May 5, 2014 from Dr. Beth Briczinski, Vice President, Dairy Foods & Nutrition, NMPF to Docket #FDA-2009-D-0430.

Attachment 7 – Letter dated July 28, 2010 from Dr. Beth Briczinski, Director, Dairy Foods & Nutrition, NMPF to Docket #FDA-2010-N-0210.

Attachment 8 – Letter dated July 15, 2010 from Dr. Beth Briczinski, Director, Dairy Foods & Nutrition, NMPF to Kathleen Sebelius, Secretary, HHS and Thomas J. Vilsack, Secretary, USDA.

Attachment 9 – Letter dated April 28, 2010 from Jerry Kozak, President and CEO, NMPF to Margaret A. Hamburg, Commissioner, FDA.

Attachment 10 – Letter dated November 2, 2001 from Dr. Robert Byrne, Vice President, Regulatory Affairs, NMPF to Dr. Christine Lewis, Director of Office of Nutritional Products, Labeling and Dietary Supplements.

Attachment 11 – Letter dated February 14, 2000 from Dr. Robert Byrne, Vice President, Regulatory Affairs, NMPF to Joseph Levitt, Director, CFSAN.