National Milk Producers Federation

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Via electronic submission through regulations.gov

February 21, 2019

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

On behalf of the National Milk Producers Federation (NMPF),[1] please find the enclosed citizen petition and related attachments and appendix submitted to the Food & Drug Administration (FDA) in accordance with FDA regulations. The Citizen Petition requests that the Commissioner take certain actions to:

- Enforce existing "imitation" labeling requirements against nutritionally inferior non-dairy substitutes for standardized dairy foods that are named and positioned as forms of "milk," "yogurt," "cheese," "ice cream," or "butter," yet fail to provide the "imitation" disclosure statement that is required under the Act and FDA implementing regulations; and

- Amend section 101.3(e) of FDA regulations to codify in more detailed form longstanding FDA policies that permit the name of a standardized dairy food (*e.g.*, "milk," "yogurt," "cheese," "ice cream," "butter") to be used in the statement of identity of a non-dairy substitute for the standardized food only under limited and defined conditions.

These actions are necessary to stem the tide of nutritionally inferior, non-dairy, plant-based foods that are being labeled and marketed in a manner that misrepresents these foods as forms of "milk," "yogurt," "cheese," "ice cream," or "butter," falsely implies that the non-dairy substitutes are equivalent to and interchangeable with standardized dairy foods, and fails to disclose the material facts concerning how these non-dairy substitutes differ from standardized dairy foods or adequately distinguish non-dairy substitutes derived from different plant sources. These actions also are necessary to ensure that consumers are adequately informed concerning the material differences between standardized dairy foods (*e.g.*, milk, yogurt, cheese, ice cream, butter) and the wide variety of non-dairy substitutes that are available in the marketplace which are identified through

[1] The National Milk Producers Federation, established in 1916 and based in Arlington, Virginia, develops and carries out policies that advance the well-being of dairy producers, the cooperatives they own, and the consuming public. The members of NMPF's dairy cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of dairy producers on Capitol Hill and with government agencies. NMPF provides a forum through which dairy farmers and their cooperatives formulate policy on national issues that affect milk production and marketing.

the misappropriation of terms that have been defined by standards of identity to identify standardized foods that meet specified compositional, nutritional, or functional requirements.

As discussed in detail in the petition, the enforcement and regulatory actions sought would advance FDA's mission to protect consumers and the public health, are well supported by the Act and existing FDA implementing regulations and precedents, and are readily justified on First Amendment grounds.

Respectfully submitted,

James Mulhern
President & CEO
National Milk Producers Federation

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

CITIZEN PETITION
SUBMITTED ON BEHALF OF THE
NATIONAL MILK PRODUCERS FEDERATION

FEBRUARY 21, 2019

Submitted via electronic submission through regulations.gov

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CITIZEN PETITION

The undersigned submits this petition on behalf of the National Milk Producers Federation ("NMPF") under Sections 201, 201a, 201c, 301, 401, 402, 403 and 701 of the Federal Food, Drug, and Cosmetic Act ("FDCA" or "Act") to request that the Commissioner take certain actions to (1) enforce existing "imitation" labeling requirements against nutritionally inferior non-dairy substitutes for standardized dairy foods that are named and positioned as forms of "milk," "yogurt," "cheese," "ice cream," or "butter," yet fail to provide the "imitation" disclosure statement that is required under the Act and FDA implementing regulations; and (2) amend section 101.3(e) of FDA regulations to codify in more detailed form longstanding FDA policies that permit the name of a standardized dairy food (*e.g.*, "milk," "yogurt," "cheese," "ice cream," "butter") to be used in the statement of identity of a non-dairy substitute for the standardized food only under limited and defined conditions.[1]

These actions are necessary to stem the tide of nutritionally inferior, non-dairy, plant-based foods that are being labeled and marketed in a manner that misrepresents these foods as forms of "milk," "yogurt," "cheese," "ice cream," or "butter," falsely implies that the non-dairy substitutes are equivalent to and interchangeable with standardized dairy foods, and fails to disclose the material facts concerning how these non-dairy substitutes differ from standardized dairy foods or adequately distinguish non-dairy substitutes derived from different plant sources. These actions also are necessary to ensure that consumers are adequately informed concerning the material differences between standardized dairy foods (*e.g.*, milk, yogurt, cheese, ice cream, butter) and the wide variety of non-dairy substitutes that are available in the marketplace which are identified through the misappropriation of terms that have been defined by standards of identity to identify standardized foods that meet specified compositional, nutritional, or functional requirements.

As discussed further below, the enforcement and regulatory actions this petition asks the Commissioner to undertake would advance FDA's mission to protect consumers and the public health, are well supported by the Act and existing FDA implementing regulations and precedents, and are readily justified on First Amendment grounds.

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[1] Pursuant to 21 C.F.R. § 10.20, NMPF provides copies of materials relied upon in this submission through separate Attachments A through I, and an Appendix of other materials, except as otherwise exempt under that section (*e.g.*, statutes, regulations, and FDA documents).

The National Milk Producers Federation, established in 1916 and based in Arlington, Virginia, develops and carries out policies that advance the well-being of dairy producers, the cooperatives they own, and the consuming public. The members of NMPF's dairy cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of dairy producers on Capitol Hill and with government agencies. NMPF provides a forum through which dairy farmers and their cooperatives formulate policy on national issues that affect milk production and marketing.

PART A – ACTION REQUESTED

This petition requests that the Commissioner take the following actions.

1. Take prompt enforcement action against misbranded non-dairy foods that substitute for and resemble reference standardized dairy food(s) (*e.g.*, milk, yogurt, cheese, ice cream, butter),[2] yet are nutritionally inferior to such reference standardized dairy foods and include the name of the reference standardized dairy food in the statement of identity for the non-dairy substitute food without the required "imitation" disclosure statement, thus misrepresenting the non-dairy substitute food as a form of "milk," "yogurt," "cheese," "ice cream," "butter," or another reference standardized dairy food, and falsely implying that the non-dairy substitute is equivalent to the reference dairy food in material respects.

2. Amend section 101.3(e) of FDA regulations to codify in more detailed form longstanding FDA policies that permit nutritionally inferior "imitation" non-dairy substitutes and nutritionally equivalent non-dairy substitutes for standardized dairy foods to include the name of the reference standardized dairy food (*e.g.*, "milk," "yogurt," "cheese," "ice cream," "butter") in the statement of identity for the non-dairy substitute food only under defined conditions.

The amendments to section 101.3(e) that are proposed by this petition are marked in ***bold, italicized*** text below and explained in Attachment A:

> **PART 101 – FOOD LABELING**
> **Subpart A – General Provisions**
>
> **Sec. 101.3 Identity labeling of food in packaged form.**
>
> (a) The principal display panel of a food in package form shall bear as one of its principal features a statement of the identity of the commodity.
>
> (b) Such statement of identity shall be in terms of:
>
> > (1) The name now or hereafter specified in or required by any applicable Federal law or regulation; or, in the absence thereof,
> >
> > (2) The common or usual name of the food; or, in the absence thereof,
> >
> > (3) An appropriately descriptive term, or when the nature of the food is obvious, a fanciful name commonly used by the public for such food.
>
> (c) Where a food is marketed in various optional forms (whole, slices, diced, etc.), the particular form shall be considered to be a necessary part of the statement of identity and shall be declared in letters of a type size bearing a reasonable relation to the size of the

[2] *See* 21 C.F.R. Part 131 (milk, cream, and yogurt products); 21 C.F.R. Part 133 (cheese and related cheese products); 21 C.F.R. § 135.110 (ice cream and frozen custard); 21 U.S.C. §§ 321a (butter), 321c (nonfat dry milk); *see also* 21 C.F.R. § 130.10 ((requirements for foods named by use of a nutrient content claim and a standardized term). *Cf.* 21 C.F.R. § 101.67 (use of nutrient content claims for butter).

letters forming the other components of the statement of identity; except that if the optional form is visible through the container or is depicted by an appropriate vignette, the particular form need not be included in the statement. This specification does not affect the required declarations of identity under definitions and standards for foods promulgated pursuant to section 401 of the act.

(d) This statement of identity shall be presented in bold type on the principal display panel, shall be in a size reasonably related to the most prominent printed matter on such panel, and shall be in lines generally parallel to the base on which the package rests as it is designed to be displayed.

(e) Under the provisions of section 403(c) of the Federal Food, Drug, and Cosmetic Act, a food shall be deemed to be misbranded if it is an imitation of another food unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.

(1) A food shall be deemed to be an imitation and thus subject to the requirements of section 403(c) of the act if it is a substitute for and resembles another food but is nutritionally inferior to that food.

(2) A food that is a substitute for and resemble***s*** another food shall not be deemed to be an imitation provided it meets each of the following requirements:

(i) It is not nutritionally inferior to the food for which it substitutes and which it resembles.

(ii) Its label bears a common or usual name that complies with the provisions of ***sections 101.3 and*** 102.5 of this chapter and that is not false or misleading, or in the absence of an existing common or usual name, an appropriately descriptive term ***that complies with the provisions of sections 101.3 and 102.5 of this chapter, and that*** is not false or misleading. The label may, in addition, bear a fanciful name ***that complies with the provisions of section 101.3 and 102.5 of this chapter and that*** is not false or misleading.

(3) A food for which a common or usual name is established by regulation (*e.g.*, in a standard of identity pursuant to section 401 of the act, in a common or usual name regulation pursuant to part 102 of this chapter, or in a regulation establishing a nutritional quality guideline pursuant to part 104 of this chapter), and which complies with all of the applicable requirements of such regulation(s), shall not be deemed to be an imitation.

(4) Nutritional inferiority includes:

(i) Any reduction in the content of an essential nutrient that is present in a measurable amount, but does not include a reduction in the caloric or fat content provided the food is labeled pursuant to the provisions of 101.9, and provided the labeling with respect to any reduction in caloric content

complies with the provisions applicable to caloric content in part 105 of this chapter.

(ii) For the purpose of this section, a measurable amount of an essential nutrient in a food shall be considered to be 2 percent or more of the Daily Reference Value (DRV) of protein listed under 101.9(c)(7)(iii) and of potassium listed under 101.9(c)(9) per reference amount customarily consumed and 2 percent or more of the Reference Daily Intake (RDI) of any vitamin or mineral listed under 101.9(c)(8)(iv) per reference amount customarily consumed, except that selenium, molybdenum, chromium, and chloride need not be considered.

(iii) If the Commissioner concludes that a food is a substitute for and resembles another food but is inferior to the food imitated for reasons other than those set forth in this paragraph, he may propose appropriate revisions to this regulation or he may propose a separate regulation governing the particular food.

(5) For the purposes of section 101.3(e), a food shall be deemed to substitute for and resemble another food (i.e., the "reference food") when the food can be used interchangeably as a substitute for or alternative to the reference food under one or more condition(s) of use that are common or customary for human consumption of the reference food. FDA may consider any relevant evidence in determining whether a food substitutes for and resembles a reference food, including

(i) Organoleptic, physical, and functional similarities between the food and the reference food;

(ii) Express or implied representations conveyed on food labels, in labeling, or other communications representing the food to be a substitute for or alternative to a reference food under conditions that are common or customary for human consumption of the reference food; and

(iii) The use of any term that is in whole or part the statement of identity of the reference food to identify another food that substitutes for and resembles the reference food.

(iv) A food that substitutes for and resembles a reference food may be a modified version of a reference food that is a traditional food or may be a distinct food.

(6) <u>Non-Dairy Foods that Substitute for and Resemble Standardized Dairy Foods.</u>

(i) <u>Non-Dairy Food and Non-Dairy Substitute Food</u>. For purposes of this section, a non-dairy food is a food that contains no single dairy

ingredient or combination of dairy ingredients in amounts that are sufficient to constitute major ingredients of the food, and a non-dairy substitute food is a non-dairy food that substitutes for and resembles a food that is a standardized dairy food (i.e., a reference food).

(ii) <u>Reference Food that is a Standardized Dairy Food</u>. For purposes of this section, a reference food that is a standardized dairy food includes any food that is butter or nonfat dry milk within the meaning of sections 201a[3] or 201c[4] of the act respectively, and any dairy food that is subject to any FDA regulation establishing a standard of identity under section 401 of the act, including any FDA regulation in Parts 131, 133, or 135, or in section 130.10 of this chapter.

(iii) <u>Non-Dairy Substitute Foods that Are Nutritionally Inferior</u>. Any non-dairy substitute food shall be deemed to be an imitation of a reference food that is a standardized dairy food when the non-dairy substitute food is nutritionally inferior to the reference standardized dairy food within the meaning of section 101.3(e)(6)(vi) and is thus subject to the requirements of section 403(c) of the act; Except that, any such nutritionally inferior non-dairy substitute food shall not be deemed to be an imitation which is subject to the requirements of section 403(c) of the act, provided that the nutritionally inferior non-dairy substitute food complies with the following requirements:

> ***(a) No representation is made on the label or in labeling for the nutritionally inferior non-dairy substitute food that expressly or impliedly represents the food as a form of "milk," "yogurt," "cheese," "ice cream," "butter," or another standardized dairy food, including through use of a standardized term to name the reference standardized dairy food (e.g., "milk," "yogurt," "cheese," "ice cream," "butter," etc.) in the statement of identity of the nutritionally inferior non-dairy substitute food, except as authorized in section 101.3(e)(6)(v) of this chapter;***
>
> ***(b) No representation is made on the label or in labeling for the nutritionally inferior non-dairy substitute food that expressly or***

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[3] 21 U.S.C. § 321a ("For the purposes of the [FDCA] . . . , 'butter' shall be understood to mean the food product usually known as butter, and which is made exclusively from milk or cream, or both, with or without common salt, and with or without additional coloring matter, and containing not less than 80 per centum by weight of milk fat, all tolerances having been allowed for.").

[4] 21 U.S.C. § 321c ("For the purposes of the [FDCA] . . . , nonfat dry milk is the product resulting from the removal of fat and water from milk, and contains the lactose, milk proteins, and milk minerals in the same relative proportions as in the fresh milk from which made. It contains not over 5 per centum by weight of moisture. The fat content is not over 1½ per centum by weight unless otherwise indicated. The term 'milk,' when used herein, means sweet milk of cows.").

impliedly represents the food as nutritionally equivalent or superior to the reference standardized dairy food;

(c) No representation is made on the label or in labeling for the nutritionally inferior non-dairy substitute food that expressly or impliedly suggests that using the nutritionally inferior non-dairy substitute food as a substitute for or alternative to the reference standardized dairy food has nutritional consequences for consumers that are insignificant, or equivalent to or superior to those of consuming the reference standardized dairy food instead with respect to the consumption of essential nutrients, or is otherwise misleading; and

(d) The nutritional inferiority and performance limitations (e.g., "not suitable for frying") of the nutritionally inferior non-dairy substitute food as compared to the reference standardized dairy food are disclosed on the labels and in the labeling of the nutritionally inferior non-dairy substitute food in a prominent and conspicuous manner.

(iv) <u>Non-Dairy Substitute Foods that Are Not Nutritionally Inferior</u>. A non-dairy substitute food shall not be deemed to be an imitation of a reference standardized dairy food, provided that the non-dairy substitute food complies with the following requirements:

(a) The non-dairy substitute food is not nutritionally inferior to the reference standardized dairy food within the meaning of section 101.3(e)(6)(vi) and otherwise complies with section 101.3(e)(2);

(b) No representation is made on the label or in labeling for the non-dairy substitute food that expressly or impliedly represents the food as a form of "milk," "yogurt," "cheese," "ice cream," "butter," or another standardized dairy food, including through use of a standardized term to name the reference standardized dairy food (e.g., "milk," "yogurt," "cheese," "ice cream," "butter," etc.) in the statement of identity of the non-dairy substitute food, except as authorized in section 101.3(e)(6)(v) of this chapter;

(c) The performance limitations (e.g., "not suitable for frying") of the non-dairy substitute food as compared to the reference standardized dairy food are disclosed on the labels and in the labeling of the non-dairy substitute food in a prominent and conspicuous manner.

(v) The statement of identity for a non-dairy substitute food may include the terms, "_____ substitute" or "_____ alternative" with the blank being filled in with the name of the reference standardized dairy food that the non-dairy food substitutes for and resembles (e.g., "Non-dairy Milk Substitute," "Non-dairy Yogurt Alternative,") in type of uniform size and prominence.

(vi) For the purposes of section 101.3(e)(6), nutritional inferiority shall be defined as provided in section 101.3(e)(4) except that nutritional inferiority shall also take into account the protein quality value of the non-dairy substitute food based on the protein digestibility-corrected amino acid score method set forth in section 101.9(c)(7).

(7) Notwithstanding the provisions of section 101.3(e), in no case shall milk or milk products or other dairy foods for human consumption that are derived from the lacteal secretions (practically free of colostrum) of dairy animals other than cows be labeled as "imitation," "substitute," or "alternative" dairy foods, provided that the label for such food --

(i) bears a statement of identity that includes a varietal name which is a common or usual name established for a food derived in full or part from the milk of dairy animal(s) other than cow(s), and the ingredient statement declares the animal source of milk ingredients from dairy animals other than cows (e.g., Ingredients: "Milk, goat milk" or "Cow milk, goat milk"); or

(ii) bears a statement of identity that includes the name(s) of the dairy animal(s) that produced the milk used in the milk or milk product or other dairy food (e.g., "Goat Milk Cheese," "Made with Cow and Goat Milk Cheese," "Buffalo Mozzarella"), and the ingredient statement declares the animal source of milk ingredients from dairy animals other than cows (e.g., Ingredients: "Milk, goat milk," "Water Buffalo Milk").

(iii) Dairy animals include dairy cows, water buffaloes, goats, sheep, camels, yaks, horses, reindeers and donkeys.[5]

* * *

[5] *See* U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. Grade "A" Pasteurized Milk Ordinance (2015 rev.), available at: https://www.fda.gov/downloads/food/guidanceregulation/guidancedocumentsregulatoryinformation/milk/ucm513508.pdf. ("Water buffalo milk is the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one (1) or more healthy water buffalo"; "Goat milk is the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one (1) or more healthy goats"; "Sheep milk is the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one (1) or more healthy sheep"; "Camel milk is the normal lacteal secretion practically free of colostrum, obtained by the complete milking of one (1) or more healthy camels"; "Hooved mammals' milk is the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one (1) or more healthy hooved mammals").

PART B – STATEMENT OF GROUNDS

This Citizen Petition asks FDA to take prompt enforcement and regulatory action to stem the rising tide of misbranded, nutritionally inferior, non-dairy substitutes for standardized dairy foods that are flooding into the U.S. marketplace, and assist consumers in making informed food choices with respect to non-dairy foods that substitute for and resemble standardized dairy foods and the nutritional inferiority and performance limitations that typify these foods, as compared to their reference standardized food counterparts. Non-dairy, plant-based substitutes for standardized dairy foods (*e.g.*, milk, yogurt, cheese, ice cream, butter, and other standardized dairy foods) typically misappropriate and incorporate the name of the reference standardized dairy food (*e.g.*, milk) into the statements of identity for these non-dairy substitute foods (*e.g.*, Almondmilk, Flaxmilk, Hempmilk, Oatmilk, Ricemilk, Soymilk), and do so in a manner that is deceptive and that fails to comply with well-established FDA labeling requirements.

More specifically, the use of standardized dairy terms that have been defined by law and/or FDA regulation to name standardized dairy foods for the disparate purpose of identifying a non-dairy substitute for the reference standardized dairy food completely disregards FDA requirements governing the use of a standardized term to name a nonstandardized food.[6] Such use implies a false equivalence between the respective reference standardized dairy food (*e.g.*, milk) and the non-dairy substitute that bears an identity statement that misappropriates a term from the legal name of the reference standardized food. The implied false equivalence is at least two-fold in nature. First, such use of the standardized term implies a false equivalence with the reference standardized food in material respects (*e.g.*, nutritional value, performance characteristics). Second, the implied false equivalence is likely to extend across a diverse variety of non-dairy substitutes for a given reference standardized food. Standardized dairy terms (*e.g.*, milk) are being used to identify various non-dairy substitutes that are derived from widely different plant-sources (*e.g.*, legumes, nuts, seeds, and grains) that share little in common beyond their common purpose to substitute for and resemble standardized dairy foods and be identified by the name of the reference standardized dairy food (*e.g.*, "Almondmilk," Flaxmilk, Hempmilk," "Oatmilk," "Ricemilk," "Soymilk").[7]

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[6] *See, e.g.*, 21 C.F.R. §§ 130.10, 101.67 and FDA's discussion of its policies in the related rulemaking records, as discussed *infra* Sections I.B.3 (standardized foods modified by nutrient content claims) and Sections I.C.5 (use of standardized food terms in nonstandardized foods).

[7] See Attachment B, "NMPF Releases Fake Milk 'Naughty or Nice List' for Holidays," (Dec. 19, 2018). For example, FDA Commissioner Gottlieb has recognized the diversity of nutritionally inferior products that are being labeled as "milk," and serious adverse health consequences that have been linked to these labeling practices. In July 2018, Dr. Gottlieb gave the following statement: "Many of these plant-based foods use traditional dairy terms (*e.g.*, milk, yogurt, cheese) in the name of the product. . . . For instance, we've seen a proliferation of products made from soy, almond or rice calling themselves milk. However, these alternative products are not the food that has been standardized under the name 'milk' and which has been known to the American public as 'milk' long before the 1938 Federal Food, Drug, and Cosmetic Act . . . was established. In addition, some of these products can vary widely in their nutritional content – for instance in relation to inherent protein or in added vitamin content – when compared to traditional milk. . . There are reports that indication this issue needs examination. . . . For example, case reports show that feeding rice-based beverages to young children resulted in a disease called kwashiorkor, a form of sever protein malnutrition. There has also been a case report of a toddler being diagnosed with rickets, a disease caused by vitamin D deficiency, after parents used a soy-based alternative to cow's milk. Because these

While the identity statements used for such non-dairy substitutes generally include a term that refers to one or more plants from which ingredients have been derived (*e.g.*, almond, flax, hemp, oat, rice, soy), this practice does not adequately identify or describe "the basic nature of the food or its characterizing properties or ingredients," and fails to disclose the material differences that exist between the non-dairy substitute and the reference standardized dairy food, as required by the Act and FDA regulations.[8]

This implied false equivalence that results from noncompliance with applicable FDA requirements has been documented through consumer perception surveys that have found that consumers often believe that non-dairy substitutes are nutritionally equivalent or even nutritionally superior to the reference standardized dairy food, when in fact, the vast majority of non-dairy, substitutes are nutritionally inferior and subject to "imitation" labeling requirements under FDCA section 403(c) and section 101.3(e) of current FDA regulations. The consumer deception and confusion that stems from the violative labeling practices has already been associated with serious adverse health consequences for American consumers,[9] and presents obvious ongoing health risks for consumers, and in the aggregate, for public health more generally.[10] The adverse consumer health and public health consequences that can result when consumers replace standardized dairy foods with non-dairy substitutes in reliance on inadequate information are particularly serious when the non-dairy substitute is nutritionally inferior to the standardized dairy food, as in the case of most, if not all, non-dairy substitutes that currently are being marketed in the United States.[11]

Although some critics of the current regulatory framework governing the dairy standards of identity attempt to disparage the standards by suggesting that they are policies that were adopted in the wake of the Great Depression that no longer are needed, nothing could be further from the truth. The historical FDA record establishes the well-documented need for and benefits of having standards of identity as a result of the notorious loopholes in the 1906 Pure Food and Drug Act,[12] which were exposed over the years and undermined the effectiveness of the ban on economically adulterated foods and failed to adequately protect consumers. The advantages of standards of identity became evident, in part, through the existence of the "butter" standard of identity, which was established by statute in 1923.[13] Indeed, in direct response to the limitations

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dairy alternative products are often popularly referred to as 'milk,' we intend to look at whether parents may erroneously assume that plant-based beverages' nutritional contents are similar to those of cow's milk, despite the fact that some of these products contain only a fraction of the protein or other nutrients found in cow's milk." Statement from FDA Commissioner Scott Gottlieb, M.D., on the process FDA is undertaking for reviewing and modernizing the agency's standards of identity for dairy products (July 26, 2018).

8 *See* 21 U.S.C. §§ 201(n), 343(a), (b), (c), (i), (g); 21 C.F.R. §§ 101.3(e) and 102.5.

9 *See* Statement from FDA Commissioner Scott Gottlieb, M.D., *supra* note 7.

10 *See infra* Section II.B.

11 *See* Attachment C, Survey of Nutritional Profiles of Non-Dairy Plant-Based Substitutes Compared to Reference Standardized Dairy Foods.

12 Pure Food and Drug Act of 1906, ch. 3915, 34 Stat. 768 (1906).

13 Mar. 4, 1923, ch. 268, 42 Stat. 1500; *see also* Ruth de Forest Lamb, AMERICAN CHAMBER OF HORRORS: THE TRUTH ABOUT FOOD AND DRUGS (1936), at 149-173 (describing the difficulties the Agency faced prior to the 1938 Act in targeting misleading, cheap and debased foods).

of the economic adulteration provisions of the 1906 statute, which largely stemmed from the absence of food standards, FDA was granted authority under FDCA section 401 pursuant to the enactment of the FDCA in 1938 to establish standards of identity for traditional dairy foods, as well as other foods.[14] Over the years since that time, FDA has relied on its section 401 authority to establish and enforce standards of identity for both traditional dairy foods (*e.g.*, "milk," "lactose-free milk," "yogurt," "cheddar cheese," "chocolate ice cream") and modified standardized dairy foods (*e.g.*, "fat free milk," "low fat yogurt," "reduced fat cheddar cheese," "low fat chocolate ice cream," "whipped butter").

FDA's establishment and enforcement of standards of identity for dairy foods have played critical roles in ensuring that foods that are identified as "milk," "yogurt," "cheese," "ice cream," "butter," or as other standardized dairy foods, consistently meet consumer expectations with respect to chemical composition (*e.g.*, essential nutrients) and organoleptic and performance characteristics, and in preventing nutritionally inferior foods from being passed off under a name that is regulated by a standard of identity. In addition, standards of identity for dairy foods and other categories of foods that are widely consumed by American consumers have laid the regulatory foundations for fortification policies that are responsible for significant consumer health benefits and, in the aggregate, huge public health gains. For example, the fortification of standardized dairy foods with vitamin D has virtually eliminated the nutritional deficiency disease known as rickets, and more recently, the fortification of grain foods with folic acid has resulted in dramatic reductions in neural tube defects in infants.[15]

The continued vitality of the dairy standards of identity coupled with FDA's continued vigilance in enforcing these standards and the labeling requirements that apply to foods that do not comply with these standards is of critical importance to protect consumers from misbranded and nutritionally inferior substitutes for standardized dairy foods, and to protect public health. In addition, FDA's adoption of the generic standard of identity regulation in section 130.10, authorizing nutritionally modified versions of traditional standardized dairy foods, as well as the parallel rule authorizing nutritionally modified nonstandardized "butter" products, amply demonstrate that there is no need to dispense with FDA policies that fully respect standards of identity to support and promote product innovations that are beneficial for consumers and protective of public health. These regulations permit use of standardized food terms in defined,

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[14] *See* 21 U.S.C. § 341; *see also* Frederick H. Degnan, *What is in a Name? The Legal Effect of Food Standards*, 45 FOOD DRUG COSM. L.J. 263, 264 (1990) ("In fashioning section 401, Congress explicitly rejected reliance on informative labeling as the means of ensuring that foods meet the expectations of consumers. Informative labeling alone could not be counted on to combat the practices and frauds described in Upton Sinclair's *The Jungle* and Ruth Lamb's *American Chamber of Horrors.*").

[15] *See* 21 C.F.R. §§ 131.110 (fluid milk), 131.111 (acidified milk), 131.112 (cultured milk), 131.115 (concentrated milk), 131.127 (nonfat dry milk fortified with A and D), 131.130 (evaporated milk, fortified), 131.147 (dry whole milk), 131.200 (yogurt), 131.203 (low fat yogurt), 131.206 (nonfat yogurt); *see also* Calvo, M. S., S Whiting, C.N. Barton, "Vitamin D fortification in the United States and Canada; current status and data needs," 80(6) Am. J. of Clin. Nutrition 1710S-1716S (December 1, 2004) (https://doi.org/10.1093/ajcn/80.6.1710S); *see also* Holick, Michael F, "Resurrection of vitamin D deficiency and rickets," 116(8) J. Clin. Invest. 2062-2072 (August 1, 2006), (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1523417/) (concluding that the fortification of milk [beginning in the 1930s] with vitamin D eradicated rickets as a major public health problem in the United States, but rickets is reemerging in some U.S. subpopulations that have inadequate vitamin D intakes).

limited circumstances where the modified food can still be "fairly described" as the standardized food, including by requiring dairy ingredients to be major ingredients of nutritionally modified foods that are identified using a standardized dairy term in the statement of identity (*e.g.*, milk, yogurt, cheese, ice cream, butter, or another standardized dairy food). These regulations not only function to ensure the nutritional integrity of a modified dairy food, but incentivize the development of innovative foods that substitute for and resemble traditional dairy foods that offer nutritional attributes that are not provided by the traditional dairy foods, expanding the range of food options for consumers without undermining the integrity of foods labeled with standardized dairy terms.

There is no need to disregard the dairy standards of identity or the related labeling requirements that apply to non-standardized, non-dairy substitutes for standardized dairy foods for FDA policies to foster the responsible development and marketing of non-dairy alternatives to standardized dairy foods. NMPF does not seek to prevent non-dairy substitutes from being marketed and sold, but rather asks that FDA ensure that the products are labeled consistent with longstanding law and prevent labeling that falsely suggests the foods to be nutritionally equivalent substitutes of the same basic nature, characterizing properties, and nutritional profile of their dairy counterparts. As shown in Attachment B, a number of manufacturers in the United States are already doing just that – thereby affirming that enforcing and codifying existing FDA precedent will not result in stifling innovation or deterring the marketing and sale of non-dairy substitutes. At the same time, failing to uphold and enforce these historical requirements in the context of non-dairy substitutes for standardized dairy foods threatens to turn back the clock, inviting a return of the food misbranding and adulteration practices that were so prevalent before the FDCA was enacted in 1938.

As discussed in more detail below, the Actions Requested ask FDA to take certain actions to enforce the existing "imitation" labeling requirements established under FDCA section 403(c) against nutritionally inferior non-dairy substitutes for standardized dairy foods that are named and positioned as forms of "milk," "yogurt," "cheese," "ice cream," or "butter," yet fail to provide the "imitation" disclosure statement that is required by the act and section 101.3(e) of FDA regulations. In addition, the Actions Requested ask FDA to adopt amendments to section 101.3(e) to codify in more detailed form longstanding FDA policies that permit the name of a standardized dairy food (*e.g.*, "milk," "yogurt," "cheese," "ice cream," "butter,") to be used in the statement of identity of a non-dairy substitute for the reference standardized food only under limited and defined conditions. The requested amendments would codify requirements that already exist under FDCA sections 403(a), 403(c) and 201(n) and related FDA policies in the specific context of non-dairy substitutes for standardized dairy foods in new section 101.3(e)(6), entitled "Non-Dairy Foods that Substitute for and Resemble Standardized Dairy Foods."

The Actions Requested are necessary to protect the consumer and public health objectives underlying FDCA's statutory authority to establish standards of identity and related food labeling requirements that have been reaffirmed consistently over the years. The Actions Requested are also carefully tailored and align with First Amendment principles. While it is well-established that commercial speech is entitled to protection under the First Amendment, it is equally well-established that regulations that compel factual and uncontroversial information to help consumers make informed decisions comport with First Amendment requirements. The speech effects of the Actions Requested have been carefully tailored such that they apply in limited

contexts where manufacturers of non-dairy substitutes have affirmatively elected both to formulate and label a product as a substitute for a standardized dairy product, and to explicitly reference the standardized dairy product they are intending to substitute for and resemble as part of the statement of identity for that product. For decades, and in response to well-documented consumer deception and public health risks, FDA has held that such misleading references do not align with its mission to protect consumers and public health.

I. Legal and Regulatory Framework Governing the Naming of Foods

The FDCA and related FDA implementing regulations establish the framework under which all foods manufactured, distributed, and sold in the United States must be labeled with a statement of identity providing the name of the food, and requiring such names to be truthful and not misleading.[16] In addition to this overarching requirement, the FDCA and FDA implementing regulations establish more specific requirements that help ensure that consumers are informed about the basic nature of a food and material features that distinguish the food from other foods. For example, FDCA sections 403(b) and 403(g) prohibit a food from being identified with a name that passes the food off under the name of another food, or from representing the food as a standardized food when it does not comply with the relevant standard of identity.[17] FDCA section 403(c) requires a food that "is an imitation of another food" to be labeled with "the word 'imitation' and, immediately thereafter, the name of the food imitated" and specifies that this imitation disclosure statement appear on the label in a type of uniform size and prominence.[18] In addition, FDCA section 401 directs the Agency to "promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity" whenever such an action "will promote honesty and fair dealing in the interest of consumers."[19]

This framework was established with the enactment of the Federal Food, Drug and Cosmetic Act in 1938 ("the 1938 Act"), and designed to address loopholes that were exposed in the preexisting Pure Food and Drug Act of 1906 ("the 1906 Act"),[20] which had enabled manufacturers of innovative products to label inferior substitute products for traditional foods "under meaningless 'distinctive' names" that failed to accurately convey to consumers the basic nature and characterizing properties of a food.[21] By directing the Agency to establish standards of identity and prescribing "imitation" labeling for certain foods, through the 1938 Act Congress sought to

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16 21 U.S.C. §§ 321(n), 343(a), (i); *see also* 21 C.F.R. §§ 101.3, 102.5.

17 21 U.S.C. § 343(b) (providing that a food is misbranded if it is offered for sale under the name of another food); 21 U.S.C. § 343(g) (providing that a food is misbranded if it purports to be or is represented as standardized food and does not comply with the requirements of the standard of identity).

18 21 U.S.C. § 343(c) (providing that a food is misbranded if it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated).

19 21 U.S.C. § 341.

20 Pure Food and Drug Act of 1906, ch. 3915, 34 Stat. 768 (1906).

21 Food Standards of Identity, Quality and Fill of Container; Common or Usual name Regulations; Request for Comments on Existing Regulations, 60 Fed. Reg. 67,492, 67,493-67,494 (Dec. 29, 1995).

protect consumers and the public health.[22] Over the course of several rulemakings following the enactment of the 1938 Act and subsequent amendments to the FDCA, the Agency continually and consistently reaffirmed that standardized food terms could only be used in limited circumstances.[23]

The proliferation of nutritionally inferior, non-dairy substitutes for standardized dairy foods that are identified through the misappropriation and incorporation of the reference standardized dairy food name in the statement of identity for the non-dairy substitutes fails to comply with the requirements of the governing legal framework, and fundamentally undermines the consumer protection and public health protection goals the legal framework is designed to serve.

A. Overview of Framework

The FDCA and FDA regulations set forth the manner in which food products must be named and direct the Agency to establish standards of identity whenever it "will promote honesty and fair dealing in the interest of consumers."[24] Congress directed the Agency to establish standards of identity precisely because "[t]he absence of definitions and standards of identity has seriously handicapped the effective operation of the present law in maintaining the integrity of our food supply."[25] While the 1906 Act established definitions for adulteration and misbranding, and authorized the Agency to prevent false and misleading labeling, loopholes allowed manufacturers to pass off innovative foods with similar functional and organoleptic qualities but that were inferior in other material respects, under "meaningless 'distinctive' names" that undermined the integrity of the food supply.[26]

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[22] Degnan, *supra note* 14, at 264 ("In fashioning section 401, Congress explicitly rejected reliance on informative labeling as the means of ensuring that foods meet the expectations of consumers. Informative labeling alone could not be counted on to combat the practices and frauds described in Upton Sinclair's *The Jungle* and Ruth Lamb's *American Chamber of Horrors.*"); William W. Goodrich, *Food Standardization Past, Present, and Future*, 24 FOOD DRUG COSM. L.J. 464, 466 (1969) (citing statement from Congressman Chapman that "[t]he most important economic provision in this bill is the authorization of standards of identity and quality for foods. Without such a provision the integrity of our food cannot be maintained, nor can purchasers have any definite knowledge of the grade value of the article offered on the grocers' shelves.").

[23] *See infra* Sections I.B.3, I.C.5.

[24] 21 U.S.C. § 341.

[25] S. Rep. 493 to Accompany S. 2800, 73rd Cong. (Mar. 15, 1934).

[26] Food Standards of Identity, Quality and Fill of Container; Common or Usual Name Regulations; Request for Comments on Existing Regulations, 60 Fed. Reg. at 67,493-67,494 ("Section 7 of the 1906 act was intended to prevent adulteration in the form of dilution of substitution of a valuable ingredient, concealment of inferiority, or use of harmful ingredients in foods. It deemed that a food was adulterated if, among other things, the food's strength or quality had been lowered, or if it had been cheapened. However, the 1906 act contained no provision requiring foods to bear a statement of ingredients on the label and, thus, offered no means of comparing foods to determine whether dilution or substitution had occurred. The misbranding provisions of the 1906 act actually contributed to the proliferation of cheap or debased foods that could be sold legally by reason of its so called 'distinctive name proviso.' This provision permitted the marketing of foods that would have been adulterated and misbranded if sold under the name of the food they purported to be by allowing their sale under meaningless 'distinctive' names such as 'Bred-Spred.'").

To address these substitute products, protect consumers, public health, and the integrity of the food supply, Congress directed the Agency to adopt standards of identity and required "imitation" labeling. By establishing standards for traditionally consumed foods that would be required to be met in order to be labeled as that traditional food and requiring "imitation" labeling for inferior substitute foods, Congress established compositional and quality benchmarks for commonly consumed foods that could be used to prevent consumer deception and provide information through product labeling that supports informed purchase decisions, thereby helping to protect consumers from uninformed consumption of diluted or otherwise nutritionally inferior foods, and in the aggregate, protecting public health.

B. Foods Subject to a Standard of Identity

1. Generally

Prior to the FDCA's enactment in 1938, the 1906 Act established definitions for adulteration and misbranding but failed to include a mechanism to compare foods to determine whether new products made in the semblance of traditional products were actually the same, whether the new products were wholly distinct, or whether they had been economically adulterated through dilution of valuable ingredients or other unlawful methods.[27] Despite the fact that the 1906 Act had been intended to bring such fraudulent practices to an end,[28] the limitations of the 1906 Act "actually contributed to the proliferation of cheap or debased foods that could be sold legally by reason of its so called 'distinctive name proviso,' [which] permitted the marketing of foods that would have been adulterated and misbranded if sold under the name of the food they purported to be by allowing their sale under meaningless 'distinctive' names such as 'Bred-Spread.'"[29] As FDA would later explain:

> The lack of a provision to establish mandatory standards under the 1906 act handicapped the Government in its attempts to maintain the integrity of the food supply by making it difficult for the Government to proceed *against a debased food product, particularly a fabricated food* . . . . Eventually the government and the industry came to the conclusion that a new statute was needed to ensure the integrity of food by keeping economically adulterated foods off the market. This recognition resulted in inclusion of three key provisions (sections 401, 403, and 701 of the act) (21 U.S.C. 341, 343, and 371) for standardization of foods.[30]

Notably, as evidence for the need for a new statute, the Agency cited a case involving a food that did not purport to be a standardized food through its statement of identity but rather was labeled by a "meaningless distinctive" name – "Bred-Spred," a product resembling jam, but containing

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[27] Food Standards of Identity, Quality and Fill of Container; Common or Usual Name Regulations; Request for Comments on Existing Regulations, 60 Fed. Reg. at 67,493-67,494.

[28] *See, e.g.*, Ilysse D. Barkan, *Industry Invites Regulation: The Passage of the Pure Food and Drug Act of 1906*, 75 AM. J. PUB. HEALTH 18 (Jan. 1985).

[29] Food Standards of Identity, Quality and Fill of Container; Common or Usual Name Regulations; Request for Comments on Existing Regulations, 60 Fed. Reg. at 67,493.

[30] *Id.* (emphasis added).

substantially less fruit than traditional fruit jams or preserves. This underscores that the FDCA food standard provisions were not intended solely to prevent consumer deception, which the Agency was already authorized to address under the 1906 Act, but rather to protect the integrity of the food supply by establishing compositional and quality benchmarks for commonly consumed foods.[31] To address this shortcoming, the FDCA directs the Secretary to "promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity" and to do so when it "will promote honesty and fair dealing in the interest of consumers."[32] As a corollary, FDCA Section 403(c) provides that imitation foods must be labeled as such to prevent misleading substitute products like "Bred-Spred" from simply being labeled through "meaningless distinctive" names.

Over time FDA has established standards of identity for many different types of foods. As a general matter, the requirements that are established under a standard of identity are designed to relate to the defining characteristics of the specific type of food. FDA explained this policy in the context of standardized dairy foods in 2005:

> Individual FDA food standards vary widely in their content. These variations have developed because of the different aspects of food technology that are responsible for providing the defining characteristics of a food. Some foods are defined and distinguished by their ingredients. The standards for these foods set specific limits on the levels of ingredients that may be used. . . . *Other food standards focus on compositional characteristics of the food, rather than on the specific ingredients. For example, the standards of identity for milk products (part 131) list the minimum levels of milkfat and milk solids (excluding fat) that must be contained in these foods. Still other foods owe their distinctive characteristics to the manner in which they are produced, and the standards for these foods reflect this fact. For example, the standards of identity for cheese products (part 133) specify the manufacturing process, in addition to compositional characteristics, to distinguish one cheese from another*.[33]

While the establishment of standards of identity to "promote honesty and fair dealing in the interest of consumers" in accordance with FDCA section 401 has always required standards to be designed in a manner that is helpful in preventing consumer deception and helping to ensure that standardized foods meet consumer expectations (*e.g.*, organoleptically, chemically (including nutritional composition), and in terms of performance characteristics), the establishment of

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[31] Degnan, *supra note* 14, at 264 ("In fashioning section 401, Congress explicitly rejected reliance on informative labeling as the means of ensuring that foods meet the expectations of consumers. Informative labeling alone could not be counted on to combat the practices and frauds described in Upton Sinclair's *The Jungle* and Ruth Lamb's *American Chamber of Horrors*."); Goodrich, *supra note* 22, at 466; Peter Barton Hutt, *The 1940s: Initial Implementation of the New Statute*, 45 FOOD DRUG COSM. L.J. 21, 25 (1990); Richard A. Merrill, Earl M. Jr. Collier, *Like Mother Used to Make: An Analysis of FDA Food Standards of Identity*, 74 COLUMBIA LAW REV. 561, 564-567 (1974); J. Kenneth Kirk, *Standard Setting—FDA*, 24 FOOD DRUG COSM. L.J. 408, 411(1969) ("[I]t is essential that we consider nutritional values in the establishment of standards").

[32] 21 U.S.C. § 341.

[33] Food Standards; General Principles and Food Standards Modernization. 70 Fed. Reg. 29,214, 29,216 (May 20, 2005) (emphasis added).

standards of identity for basic foods that are important sources of essential nutrients in the overall diet, such as standardized dairy foods, also plays an important role in protecting and promoting consumer health and public health more generally. For example, because dairy foods are standardized, consumers are able to make informed purchase decisions that allow them to choose dairy foods that align with the recommendations of the Dietary Guidelines for Americans.[34] The Dietary Guidelines currently recommend three daily servings of dairy products for Americans nine and older, 2.5 servings for children ages four through eight, and two servings for children ages two through three years old. Notably, as discussed further in Section II.B, the Dietary Guidelines distinguish dairy foods from plant-based dairy substitutes (except for fortified soy beverages) because the "overall nutritional content" of plant-based dairy substitutes "is not similar to dairy milk and fortified soy beverages."[35]

As such, standards of identity for dairy foods in particular have long been among the most important food standards based on the widespread and frequent consumption of standardized dairy foods, and the importance of the nutrient contributions that are made by standardized dairy foods to a healthy diet. Cheaper, nutritionally inferior non-dairy substitutes for standardized dairy foods began to emerge many years ago, prompting the Agency (and the states) to address the consumer protection and public health issues in various ways. The Agency has sought to address these issues through various approaches, including by prohibiting confusingly similar names, prescribing imitation labeling, and promulgating new standards like that for margarine.[36]

Additionally, in response amendments to the FDCA under the Nutrition Labeling and Education Act of 1990 ("NLEA") designed to authorize nutrient content claims for foods, including standardized foods, FDA adopted sections 130.10 and 101.67 to authorize nutritionally modified versions of standardized foods that are named using the standardized term combined with the FDA-approved nutrient content claim (*e.g.*, "low fat milk," "fat-free ice cream," "light butter"), provided a host of requirements are met. As discussed more fully *infra* Section I.B.3, section 101.30 establishes a generic standard of identity for standardized foods that have been modified to qualify for a nutrient content claim. The regulation advances the goals of Section 401 by permitting certain deviations from the formulation requirements of the reference standard for the traditional food to meet the nutritional criteria necessary to qualify for a nutrient content claim (which align with public health nutrition goals), but also by limiting these deviations to the "minimum necessary," including by requiring authorized dairy ingredients to be used in substantial amounts, such that the modified food can still be fairly described as a standardized dairy food and be identified by using the name of the traditional reference standardized food in its statement of identity (*e.g.*, "low fat milk," "fat-free ice cream," *etc.*).[37]

As the Agency would later explain:

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[34] U.S. Department of Health Services and Human and U.S. Department of Agriculture. 2015-2020 Dietary Guidelines for Americans, 8th Edition. December 2015, at 23, available at http://health.gov/dietaryguidelines/2015/guidelines/.

[35] *Id.*

[36] *See* 21 C.F.R. §§ 166.40, 166.110.

[37] 21 C.F.R. § 130.10.

> This one standard (§130.10) has provided enormous flexibility in the manufacture of foods that deviate from the traditional standards and in providing many healthful and informatively labeled food products to consumers. It has also eliminated the need for use of complex alternative names for foods, as well as the need for industry to request establishment of new standards or TMPs [temporary marketing permits] to deviate from existing standards to make new foods to meet consumers' needs and desires.[38]

2. Dairy Standards

The FDCA and FDA regulations establish standards of identity for dairy products – specifically milk, yogurt, cheese, ice cream, and butter products. In each of these cases, the standards make clear that dairy products must be produced from and/or contain milk or cream, and that milk and/or milk-derived ingredients must be major ingredients, and the food must meet other nutritional and compositional requirements in order to meet the relevant standard and qualify for use of the standardized term as part of the statement of identity for a food.

- ***Milk***. "Milk is the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows."[39] If added, vitamins A and D shall be present in such quantity that each quart of milk contains not less than 2,000 International Units and 400 International Units, respectively.[40] FDA has also adopted standards for a number of related milk and cream products including acidified milk, cultured milk, concentrated milk, evaporated milk, dry cream, heavy cream, light whipping cream, sour cream, eggnog, and half-and-half.[41] Without exception, each of these foods is made from a lacteal secretion and the differences between products relate to how the food is produced such that the ultimate composition and nature of the food may vary in certain defined respects but the basic nature of each food is the same in that they are all derived from milk.

- ***Yogurt***. "Yogurt is the food produced by culturing one or more of the optional dairy ingredients specified in paragraph (c) [*i.e.*, cream, milk, partially skimmed milk, or skim milk] with a characterizing bacterial culture that contains the lactic acid-producing bacteria, *Lactobacillus bulgaricus* and *Streptococcus thermophiles.*"[42] If added, vitamins A and D shall be present in such quantity that each quart contains not less than 2,000 International Units and 400 International Units, respectively.[43]

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38 Food Standards of Identity, Quality and Fill of Container; Common or Usual Name Regulations; Request for Comments on Existing Regulations, 60 Fed. Reg. at 67,497.

39 21 C.F.R. § 131.110(a).

40 21 C.F.R. § 131.110(b)(1)-(2).

41 21 C.F.R. Part 131.

42 21 C.F.R. § 131.200(a).

43 21 C.F.R. § 131.200(b)(1)-(2).

- ***Cheese***. Different cheeses have different standards of identity, each of which specify how the cheese is produced, mandatory and optional ingredients, minimum milk fat, and maximum moisture content, amongst other requirements. In every case, relevant standards make clear that a cheese begins with a dairy product such as cream or milk and is produced by coagulating the milk protein casein through specified methods.[44]

- ***Ice Cream***. "Ice cream is a food produced by freezing, while stirring, a pasteurized mix consisting of one or more of the optional dairy ingredients specified in paragraph (b) of this section [*e.g.*, cream, butter oil, milk, concentrated milk, evaporated milk], and may contain one or more" other optional ingredients.[45]

- ***Butter***. Butter "is made exclusively from milk or cream, or both, with or without common salt, and with or without additional coloring matter, and containing not less than 80 per centum by weight of milk fat, all tolerances having been allowed for."[46]

As new products have emerged that are labeled and marketed as substitutes to traditional dairy products, Congress and FDA have responded to ensure that consumers are not deceived as to the basic nature of these substitute products. For example, Congress passed the Oleomargarine Amendments in response to the increasing prevalence of colored oleomargarine and margarine and to prevent such products from being deceptively sold as "butter" products.[47] Following the passing of the Oleomargarine Amendments and FDA's promulgation of a standard of identity for margarine, products that meet the standard for margarine must be labeled as such.[48] Notably, Congress and the Agency concluded that "margarine" should be labeled as a wholly new product notwithstanding that it was initially required to contain dairy ingredients.[49] This determination was made precisely to avoid a confusingly similar name to butter and promote consumer understanding of the organoleptic, chemical, performance and physical differences between the products.[50]

While the standard of identity for margarine initially required the use of skim milk or a similar ingredient derived from milk, the Agency subsequently revised the standard based on its conclusion that it was reasonable "to provide that mixtures of water and finely ground soybean may be used in lieu of an ingredient derived from cow's milk," provided the label discloses that the essential ingredients are vegetable fats, water, and finely ground soybeans.[51] Notably, the standard of identity for margarine prescribes that the finished margarine product contain not less

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44 21 C.F.R. Part 133.

45 21 C.F.R. § 135.110.

46 21 U.S.C. § 321a.

47 Oleomargarine Amendments of 1950, ch. 61, § 3(a), 64 Stat. 20 (1950).

48 21 C.F.R. §§ 166.40, 166.110 .

49 *See, e.g.*, Labeling of Oleomargarine, 15 Fed. Reg. 2081 (1950).

50 In re Public Hearing for the Purpose of Receiving Evidence upon the Basis of Which Regulations May Be Promulgated Fixing and Establishing a Standard of Identity for Oleomargarine, 6 Fed. Reg. 1990 (1931).

51 Oleomargarine: Definition and Standard of Identity, 16 Fed. Reg. 10,492, 10,493-10,494 (Oct. 13, 1951).

than 15,000 international units per pound of Vitamin A in order to meet the margarine standard and be labeled as "margarine" – further emphasizing that the Agency has used standards to protect consumers and the public health by requiring fortification of substitutes to prevent nutritional inferiority when the food substituted for has historically provided important nutrient contributions to the diet.[52]

As discussed in detail in Section I.C.3, the Agency subsequently considered additional standards for dairy substitute products but ultimately declined to adopt new regulations based on concern "that the proposed names [such as "low fat milk substitute" or "cheddar cheese substitute product"] are confusingly similar to those of traditional dairy products, and as such, have the potential for misleading consumers, particularly when the substitute foods are packaged in materials similar to those of traditional dairy products and are displayed in close proximity to dairy products in super markets."[53] That the Agency found even these references in carefully circumscribed contexts too close to the standardized dairy products they substitute for and resemble is compelling, and demonstrates just how far current non-dairy substitutes have strayed from longstanding law.

3. Standardized Foods Modified by Nutrient Content Claim

The NLEA amendments to the FDCA authorized the Agency to adopt regulations defining nutrient content claims, such as "reduced fat," "low fat," and "fat free." To implement these provisions, the Agency proposed and subsequently promulgated sections 130.10 and 101.67, which prescribe the limited conditions under which a food that does not meet a standard of identity and that substitutes for a standardized food can use the name of a standardized food in the statement of identity.[54] Section 130.10 of FDA regulations prescribes a general definition and standard of identity for substitute foods named by use of a nutrient content claim in conjunction with a traditional standardized name. The Agency created section 101.67 as a separate provision in addition to 130.10 applicable to modified butter products based on butter's unique positioning under the statutory standard of identity under 21 U.S.C. § 321a.[55] In both cases, the rulemaking records that foods named by reference to a standardized food in combination with a nutrient content claim must contain the same "major ingredients" and "must comply with the relevant standard in all other respects," except specifically authorized

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52 21 C.F.R. § 166.110(a)(3).

53 Substitutes for Milk, Cream, and Cheese; Withdrawal of Proposed Standards of Identity, 48 Fed. Reg. 37,666 (Aug. 19, 1983) (withdrawing proposed rule that would have established standards of identity for milk and cream substitutes and cheese and cream cheese product substitutes).

54 21 C.F.R. § 130.10 prescribes a general definition and standard of identity for substitute foods named by use of a nutrient content claim in conjunction with a traditional standardized name, whereas 21 C.F.R. § 101.67 applies to modified butter products since FDA was precluded by a preexisting statutory standard of identity from establishing a regulatory standard of identity for butter.

55 FDA was initially prohibited from establishing a regulatory standard of identity for butter under the statutory standard for butter but concluded that the NLEA "clearly evidence[s] an intent by Congress to permit nutrient content claims like 'light' to be made for butter," thus authorizing the use of nutrient content claims for nonstandardized modified butter products in the carefully defined circumstances of section 101.67. *See* Food Labeling: Use of Nutrient Content Claims for Butter, 56 Fed. Reg. 60,523, 60,526 (Nov. 27, 1991).

deviations.[56] Indeed, in promulgating the final rule, the Agency emphasized that "the major ingredients of a category of products should be from that variety of food (*e.g.*, the major ingredients in dairy products should be dairy ingredients), and some ingredients are not appropriate to add to some modified foods that use the traditional standardized dairy name."[57]

The rulemaking record further explains that the Agency had previously "taken regulatory action against some of these uses" of nutrient content claims in combination with standardized food terms because the Agency had not defined how such terms could be used generally, or much less in combination with standardized food terms, and "[t]hus, the use of these nutrient content claims [in combination with standardized food terms] had the effect of undermining consumer confidence in the labeling of standardized foods."[58] FDA reasoned therefore that the regulations were necessary to restore consumer confidence in standards by expressly defining and limiting the contexts in which such terms could be used in connection with standardized foods. Notably, FDA expressly considered and rejected a more flexible approach that would have permitted the use of standardized dairy food names in non-dairy products, concluding that such an approach, for example, "would be misleading because consumers expect sour cream to be a dairy product."[59]

The agency instead adopted a requirement "that a required ingredient or component of an ingredient that is specifically required by the traditional standard *shall not be replaced or exchanged with a similar ingredient unless the traditional standard provides for the use of such ingredient*."[60] Therefore, for example, "a manufacturer who used vegetable oil to replace or substitute for milkfat in a modified sour cream product would not be able to take advantage of [section] 130.10" and use the term "sour cream" as part of the statement of identity.[61] As such, under section 130.10, an ingredient required by a standard (such as dairy and dairy-derived ingredients for standardized dairy products) "shall be present in the product in a significant amount" in the finished food and "the major ingredients of a category of products should be from that variety of food (*e.g.*, the major ingredients in dairy products should be dairy ingredients)."[62]

The rulemaking record is replete with references that make clear that the provisions of section 130.10 were intended to protect standards of identity and limit their use to clearly defined situations where the food was fundamentally the same but had been nutritionally modified to

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56 Food Standards: Requirements for Foods Named by Use of a Nutrient Content Claim and a Standardized Term, 58 Fed. Reg. 2,431 (Jan. 6, 1993).

57 *Id.* at 2,441.

58 Food Standards: Requirements or Substitute Foods Named by Use of a Nutrient Content Claim and a Standardized Term, 56 Fed. Reg. 60,512, 60,513 (Nov. 27, 1991).

59 *Id.* at 60,520 ("FDA believes that replacing the milkfat in sour cream with vegetable oil to make a product labeled as 'cholesterol free sour cream' would be misleading because consumers expect sour cream to be a dairy product.").

60 *Id.* (emphasis added).

61 *Id.*

62 21 C.F.R. § 130.10(d)(4); Food Standards: Requirements for Foods Named by Use of a Nutrient Content Claim and a Standardized Term, 58 Fed. Reg. at 2,441.

achieve public health benefits.[63] For example, the rulemaking record explains that "[t]he agency agrees that general requirements as to how far a modified food may deviate from the standard of identity and still use the standardized name are necessary."[64] The final rule therefore carefully circumscribed the conditions under which a food could be labeled under section 130.10, including by:

- Requiring that "mandated ingredients [by the standard of identity] must be present in a significant amount if the food is to be considered a modified version of the traditional standardized food" to align with consumer expectations and "promote honesty and fair dealing in the interest of consumers [by] ensur[ing] that a § 130.10 food will bear an appropriate relationship to the traditional standardized food."[65]

- Requiring that "deviations from ingredient and noningredient provisions of the standard must be the minimum necessary to achieve this effect or the food will be deemed to be adulterated under section 402(b) of the act."[66]

- Requiring that "[a]n ingredient or component of an ingredient that is specifically prohibited by the standard . . . shall not be added to a substitute food under this section."[67]

- Explaining that "the § 130.10 food should resemble the standardized food in as many ways as possible" and that "any differences in the performance characteristics must be clearly stated on the principal display panel of the label."[68]

Similarly, in promulgating section 101.67 governing nutrient content claims for substitute butter products, the Agency reiterated that the provision could only be relied upon to use the term "butter" when a product could "be fairly described as 'butter,' [meaning it is] . . . made from cream or milk, or their constituents, with only those safe and suitable ingredients added as necessary to improve texture, add flavor, prevent syneresis, improve shelf life, improve appearance, and add sweetness."[69] The Agency considered and again rejected comments suggesting that products be permitted to use the standardized term "butter" with minimal limitations, noting that "FDA disagrees with a comment that urged FDA to allow the use of safe and suitable non-dairy ingredients without restriction."[70] Instead, FDA emphasized that:

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63 *Id.* at 2,431-2,447.

64 *Id.* at 2,433.

65 *Id.* at 2,433 (explaining the addition of new subsection 130.10(d)(2)); *see also* 58 Fed. Reg. at 2441 (requiring that such ingredients be "major ingredients" "(*e.g.*, the major ingredients in dairy products should be dairy ingredients)").

66 *Id.* at 2,445 (explaining the addition of new subsection 130.10(d)(3)).

67 *Id.* at 2,445 (explaining the addition of new subsection 130.10(c)).

68 *Id.* at 2433 (explaining the addition of new subsection 130.10(c)).

69 *Id.* at 2,451 (Jan. 6, 1993).

70 *Id.* at 2,451.

> [D]eviations from ingredient provisions of 21 U.S.C. 321a must be the minimum necessary to achieve this effect, or the food will be deemed to be adulterated under section 402(b) of the act. The agency advises that products with non-dairy ingredients in excess of these amounts fall outside of new § 101.67 and must be labeled as imitation butter if nutritionally inferior to regular butter, as butter alternatives or substitutes if not nutritionally inferior to butter, or, if appropriate, as margarine, a margarine product, or a spread.[71]

Unlike the carefully circumscribed instances addressed in sections 130.10 and 101.67, non-dairy substitutes are not "fairly described" as the standardized dairy foods referenced as part of their statements of identity – they contain no butter, milk, cream, or other dairy ingredients, and are comprised wholly of various plant-based ingredients and are simply blended with water and other additives in a manner that leads consumers to believe the product is equivalent to its reference standardized dairy food in material respects (e.g., nutritional value, performance characteristics). FDA regulations such as sections 130.10 and 101.67 would be nonsensical and rendered meaningless if manufacturers could simply create new substitute products as they please, and misappropriate the name of the respective reference standardized food in the statement of identity for the substitute in any manner that suits them.

4. FDA Consideration of Alternative Approaches to Standards

FDA has considered changes to its approach to food standards over time, and has consistently reaffirmed the basic importance and purpose of food standards. For example, in 1995, FDA issued an Advance Notice of Proposed Rulemaking (ANPR) announcing its intention to review regulations governing standards of identity and consider a range of options for potential improvements.[72] The ANPR summarizes the evolution of food standards and explains that the authority came about when "the Government and the industry came to the conclusion that a new statute was needed to ensure the integrity of food by keeping economically adulterated foods off the market."[73] The ANPR elaborated on the success of food standards as follows:

> Congress directed FDA to establish and implement food standards because there was a real need to protect consumers from economic fraud and to promote honesty and fair dealing in the interest of consumers. Food standards have been beneficial through their long history of *providing assurance to consumers of product uniformity, with the resulting expectation and belief by consumers that all* products bearing a particular name will possess the same characteristics irrespective of where they are purchased, or by whom they are manufactured or distributed. Food standards have also been an efficient mechanism for addressing public health problems through mandatory fortification requirements. In addition, standards have provided manufacturers with guidance in the production, naming,

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71 *Id.* at 2,451-2,452.

72 Food Standards of Identity, Quality and Fill of Container; Common or Usual Name Regulations; Request for Comments on Existing Regulations, 60 Fed. Reg. at 67,492.

73 *Id.* at 67,494.

> and labeling of products and with assurance that competitors will have to meet the same guidelines for the same foods.[74]

While acknowledging that "[s]ome critics have suggested that the agency revoke all food standards and allow market forces to control the composition of the products that are currently regulated by standards," the Agency rejected this approach and responded that the adoption of the generic standard in section 130.10 for foods named by the use of a nutrient content claim and a standardized term was an approach that provided appropriate flexibility.[75] After consideration of comments in response to the ANPR, the Agency reaffirmed its commitment to food standards generally and proposed a rule that would be used to evaluate existing and potential new food standards.[76] The Agency explained the prospective benefit of the proposed rule as follows:

> The proposed rule would establish a system by which we intend to revise, eliminate, or establish standards in response to petitions submitted by external parties or on our own initiative and would generate benefits by encouraging external parties to submit such petitions. External parties may already submit such petitions, and we already consider them. However, by stating that such petitions will henceforth be the primary means for initiating changes to the standards' regulations, we are making it clear to interested parties that they should submit petitions if they desire changes in the standards.[77]

Notably, the principles FDA proposed to codify as subsection 130.5(b) advance the same goals of protecting consumers and public health and preventing consumer deception that constituted the basis for the statutory authorization of food standards in the first place. In addition to meeting the statutory standard of promoting honesty and fair dealing in the interest of consumers, the Agency proposed to codify, *inter alia*, that:

- "The food standard should describe the basic nature of the food to ensure that consumers are not misled by the name of the food and to meet consumers' expectations of product characteristics and uniformity."

- "The food standard should reflect the essential characteristics of the food. The essential characteristics of a food are those that define or distinguish a food or describe the distinctive properties of a food. The essential characteristics of a food may contribute to achieving the food's basic nature or may reflect relevant consumer expectations of a food product. For example, foods may be defined or distinguished by their ingredients, compositional characteristics, nutrient levels, or the manner in which they are produced."

- "The food standard should ensure that the food does not appear to be better or of a greater value than it is. The food standard may be used as a vehicle to improve the overall nutritional quality of the food supply."

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74 *Id.* at 67,499 (emphasis added).

75 *Id.*

76 Food Standards; General Principles and Food Standards Modernization, 70 Fed. Reg. at 29,227.

77 *Id.*

- "The food standard should take into account any other relevant regulations in this chapter. For example, a proposed new or revised food standard should be consistent with common or usual name regulations for related commodities or products."

- "Names of ingredients and functional use categories in a food standard should be consistent with other food standards and relevant regulations in this chapter, and, when appropriate, incorporate current scientific nomenclature."[78]

As explained more fully below, these principles are fundamentally undermined through the use of standardized dairy terms in non-dairy substitute food names because those terms do not reflect the basic nature, essential characteristics, or nutritional profile of the food, nor do such names account for longstanding regulations that prohibit use of those terms outside of carefully defined situations. In contrast, the Actions Requested by this petition align with the principles and priorities of the FDA proposed rule outlined above.

C. Nonstandardized Foods

1. Generally

Under FDCA section 403(i)(1), a food product must be identified by "common or usual name . . . , if any there be." FDCA section 403(b) prohibits a food from being "offered for sale under the name of another food," and section 403(c) prohibits a food that "is an imitation of another food, unless its label bears . . . 'imitation' and, immediately thereafter, the name of the food imitated." FDCA section 403(a) further prohibits a food for which labeling is "false or misleading in any particular."

FDA regulations governing the statement of identity required on food labels implement and expand upon these statutory requirements. Section 101.3(b)(2) provides that, when the name of the food is not assigned by law or regulation, the "common or usual name of the food" must be used when one exists. When an established common or usual name does not exist for a product, section 101.3(b)(3) requires that the statement of identity name the food using "[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." In this regard, section 102.5(a) further specifies:

> *The common or usual name of a food, which may be a coined term, 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. The name shall be uniform among all identical or similar products and may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name. 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.*[79]

2. Imitation Foods

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[78] *Id.* at 29,234-29,235.

[79] 21 C.F.R. § 102.5(a) (emphasis added).

FDCA section 403(c) prohibits a food that "is an imitation of another food, unless its label bears. . . 'imitation' and, immediately thereafter, the name of the food imitated." Imitation labeling requirements work in tandem with standards of identity to ensure that imitation foods are not passed off as standardized foods and are clearly and conspicuously labeled to prevent consumer deception and protect consumers and public health by safeguarding the integrity of the food supply.

Given the lack of a statutory definition for "imitation," the Agency ultimately proposed and promulgated current section 101.3(e) to more clearly define when "imitation" labeling is required for substitute foods. Specifically, section 101.3(e) specifies that a food that substitutes for and resembles another food is not required to bear "imitation" labeling, provided: (i) it is not nutritionally inferior to the food for which it substitutes and resembles; and (ii) its label bears a common or usual name that complies with the provisions of 102.5 of this chapter and that is not false or misleading, or in the absence of an existing common or usual name, an appropriately descriptive term that is not false or misleading.[80] The regulation defines "nutritional inferiority" as any reduction in an essential nutrient[81] in a substitute food compared to the food it resembles that amounts to two percent or more of the Daily Value for the nutrient on the basis of the "reference amount customarily consumed" (RACC) that has been established for the food in section 101.12(b) of FDA regulations.

By defining "imitation" foods by reference to nutritional inferiority, the Agency sought to "discourage the gradual nutritional degradation of the American diet through the introduction of products that replace traditional products but are nutritionally inferior to them."[82] In promulgating the regulation, the Agency responded to comments suggesting that the definition was overly narrow by explaining that the regulation would continue to require "imitation" labeling for many substitute products:

> The Commissioner concludes that the definition of "imitation" set forth in this regulation is fully consistent with the court opinions in the Jam and Chil-Zert cases, cited above, both of which discussed factors of resemblance, substitution, and inferiority in concluding that the products involved were imitations. There have been several State court cases in the past 10 years holding that a vegetable oil substitute for cream, which looks like, tastes like, and is intended to replace

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[80] 21 C.F.R. § 101.3(e). In addition to an appropriate common or usual name, the label may, in addition, bear a fanciful name which is not false or misleading as set forth under 21 C.F.R § 102.5(e).

[81] Under 21 C.F.R. § 101.3(e)(4), the determination of whether a substitute food is nutritionally inferior to the food it resembles does not consider calories, fat, selenium, molybdenum, chromium, or chloride.

[82] Peanut Spreads: Proposed Common or Usual Name, 40 Fed. Reg. 51,052, 51,053 (Nov. 3, 1975) ("Under § 1.8(e) the requirement for nutritional equivalence applies only when a food resembles another food, in addition to substituting for it. The Commissioner concludes that all spreadable peanut products resemble peanut butter within the meaning of § 1.8(e) since the dominant physical characteristics of both peanut spread and peanut butter are their spreadable form and peanut flavor. The Commissioner notes that the effect of section 403(c) of the act and § 1.8(e) of the regulations is to discourage the gradual nutritional degradation of the American diet through the introduction of products that replace traditional products but are nutritionally inferior to them. When a nutritionally inferior product is introduced, it's being labeled as an imitation in accordance with the provisions of § 1.8(e) will alert consumers to the food's inferiority.").

> cream, is not an "imitation cream" but rather is a separate and distinct product that should bear its own common or usual name. These cases represent the most current and definitive judicial interpretation of the term "imitation."[83]

FDA emphasized in the rulemaking process that "imitation" labeling requirements were not limited to cheap counterfeit products, but instead applied broadly to any substitute product. Indeed, the Agency even cited as examples of "imitation" products those that were not counterfeits but rather labeled as distinct substitute products. For example, in *United States v. 651 Cases*, a case cited approvingly by FDA in the rulemaking record, the court addressed a "Chocolate ChilZert" product that "contains the usual ingredients of chocolate-flavored ice cream in approximately the same proportions, except that soy fat and soy protein are used therein in place of milk fat and milk protein."[84] The court held that the product was a nutritionally inferior substitute that was required to be labeled as "imitation" notwithstanding that it was labeled "in prominent letters" "not an ice cream" and "contains no milk or milk fat," and notwithstanding that the statement of identity used a uniquely distinct common or usual name.[85] Contrastingly, the Agency distinguished a Coffee-Rich product that was marketed as a separate and distinct vegetable oil product that would was not required to bear "imitation cream" labeling but "should bear its own common or usual name" consistent with other naming requirements.

By drawing a distinction, In addition to expressly acknowledging that "imitation" requirements would apply to all nutritionally inferior substitute products – and not just counterfeit or modified products – the Agency also responded to concerns that the new regulation would weaken protection for food standards:

> This regulation will not reduce in any way the protection afforded by standards of identity to the consumer, or to persons who manufacture standardized foods. Any food which purports to be or is represented as a standardized food but which does not conform to the standard of identity is deemed to be misbranded under section 403(g) of the act. *See, e.g., 62 Cases Jam v. United States*, 340 U.S. 593 (1951). A substitute for a standardized food may be properly labeled with *a distinctive common or usual name or a descriptive term or phrase if it is sufficiently informative to prevent confusion with the standardized product*. The Commissioner finds that it is neither necessary nor practical to require prior approval of all such common or usual names. The present way by which common or usual names may be established . . . provides adequate consumer protection.[86]

Under this framework, substitute products must be labeled in one of two ways: (1) as "imitation" products if nutritionally inferior to the product they resemble and for which they substitute; or

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83 Imitation Foods: Application of the Term "Imitation," 38 Fed. Reg. 20,702 (Aug. 2, 1973) (citing *Coffee-Rich, Inc. v. Kansas City State Bd. of Health*, 338 P.2d 582 (Kan. 1964); *Coffee-Rich, Inc. v. Mich. Dept. of Agric.*, 135 N.W. 2d 594 (Mich. 1965)).

84 *United States v. 651 Cases*, 114 F. Supp. 430, 432 (N.D.N.Y. 1953).

85 *Id.*

86 Imitation Foods: Application of the Term "Imitation," 38 Fed. Reg. at 20,702-20,703 (emphasis added).

(2) if not nutritionally inferior, then with an appropriately descriptive common or usual name that is not false or misleading that complies with section 102.5.

3. Non-Imitation Substitute Foods

Substitute foods that are not nutritionally inferior are subject to distinct but related requirements under the FDCA and FDA regulations. Section 102.5 of FDA regulations requires all nonstandardized products to bear a common or usual name that "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. The name shall be uniform among all identical or similar products and may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name. 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."[87] Section 102.5(b) of FDA regulations further requires that a common or usual name "include the percentage(s) of any characterizing ingredient(s) or component(s) when the proportion of such ingredient(s) or component(s) in the food has a material bearing on price or consumer acceptance or when the labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient(s) or component(s) is present in an amount greater than is actually the case." The provisions operate concurrently to ensure that consumers are not misled about the basic nature of a food and its characterizing properties or ingredients, and to protect consumers by ensuring that names are not confusingly similar to the name of any other food.

In promulgating regulations elaborating on "imitation" labeling requirements, the Agency explained the importance of naming requirements for non-standardized, non-imitation foods:

> *The consumer, however, must be protected from unwitting purchase of a product which is different, although not inferior, from what he may reasonably expect*. The Commissioner concurs with the further recommendation of the White House Conference that the "name of a food should accurately describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients." Accordingly, *in order to avoid "imitation" status, a substitute food product which is not nutritionally inferior must also bear a label which clearly states the common or usual name of the product and which is not false or misleading.*[88]

4. Imitation and Substitute Milk and Cheese Products

The Agency previously considered adopting regulations specific to imitation and substitute dairy products – in recognition of the important role that dairy foods play in human nutrition and the desire to protect standardized dairy foods from debasement and consumer confusion. Specifically, FDA considered and proposed standards of identity for substitute milk, cream, and cheese products, which would have established compositional and nutritional requirements for substitutes and required them to be named either "substitute" or "product substitute," depending on whether the product conformed to the established fat and moisture levels.

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87 21 C.F.R. § 102.5(a).

88 Imitation Foods: Application of Term "Imitation," 38 Fed. Reg. 2,138 (Jan. 19, 1973) (emphasis added).

In considering the proposal, the Agency explained:

> The Commissioner maintains that, *if the name of the substitute food includes the name of the traditional food it simulates, the substitute food should be reasonably similar to the traditional food.* Thus, the substitute food should be nutritionally equivalent to the traditional food and should have similar levels of fat and moisture, as well as similar physical attributes such as color, body, and texture.[89]

The rulemaking record, therefore, provides yet another example of the Agency affirming that substitute foods can only refer to the name of the traditional food it simulates under limited and carefully defined circumstances.[90] The initial proposal sought to limit the capacity for consumer confusion and undermining the integrity of the food supply by: (1) reaffirming that all nutritionally inferior milk and cheese substitute products must be labeled as "imitation" products; (2) only allowing use of the term "substitute" when the food conforms to the established fat and moisture content levels of relevant milk or cheese substitute product; (3) only allowing use of the term "product substitute" when in defined situations and requiring the name to be "accompanied by an additional statement, as applicable, which identifies other nonmilk ingredients used to replace milk protein in the manufacture of the cheese substitute."[91]

And yet even these carefully circumscribed instances where the manufacturer would have only been permitted to use the standardized term in connection with a qualifier such as "substitute" or "product substitute" were rejected because the names were found to be too close to traditional dairy names. The Agency ultimately withdrew the proposed rule and explained:

> *The principal objection to the proposal was to the use of the names of traditional and standardized dairy foods in the names of the milk, cream, cheese, and cheese product substitutes. Most of these comments contended that the proposed names are confusingly similar to those of traditional dairy products and, as such, have the potential for misleading consumers, particularly when the substitute foods are packed in materials similar to those of traditional dairy products and are displayed in close proximity to dairy products in supermarkets*. Some comments stated that all such foods should be labeled 'imitations," whether or not they are nutritionally equivalent to the foods simulated. Others stated that substitute foods should be marketed under their own distinctive names which make no reference to the foods simulated as is done in the case of mellorine and margarine.[92]

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89 Substitutes for Milk, Cream, and Cheese: Standards of Identity, 43 Fed. Reg. 42,118, 42,121-42,122 (Sept. 19, 1978) (emphasis added).

90 *See also supra* Section I.B.3, *infra* Section I.C.5.

91 Substitutes for Milk, Cream, and Cheese: Standards of Identity, 43 Fed. Reg. at 42,122.

92 Substitutes for Milk, Cream, and Cheese; Withdrawal of Proposed Standards of Identity, 48 Fed. Reg. at 37,666 (emphasis added).

Because of potential confusion surrounding use of standardized food names in names for substitute foods, even under carefully defined situations, the Agency ultimately determined that "honesty and fair dealing are best served by the withdrawal of the proposal and termination of the rulemaking proceedings."[93] The Agency explained that existing regulations would continue to govern substitute products as follows:

> Milk, cream, and cheese substitutes will continue to be governed by the regulations in 21 CFR 101.3(e) regarding the use of the term 'imitation' and in 21 CFR 102.5 that set forth the general principles for common or usual names for nonstandardized foods. *A food made in semblance of a milk, cream, or cheese product will be deemed to be an imitation and thus subject to the requirements of section 403(c) of the Federal Food, Drug, and Cosmetic Act if it is nutritionally inferior to the milk, cream, cheese, or cheese product simulated. If it is not nutritionally inferior, it must bear a common or usual name that complies with the provisions of 21 CFR 102.5 which is not false or misleading in any particular, or, in the absence of an existing common or usual name, an appropriately descriptive name which is not false or misleading.*
>
> *To ensure that the name of a substitute food is not misleading, the name should ordinarily not include the name of a product subject to a standard of identity unless (1) it complies with the standard of identity, or (2) it is nutritionally inferior to the food simulated and is labeled with the term 'imitation.' However, in some cases, it may be reasonable and appropriate to include the name of a standardize [sic] 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 material 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.*[94]

The Agency has never contemplated haphazard and indiscriminate use of standardized food names as part of common or usual names for other foods. This is particularly the case for substitute products that simulate foods that are longstanding bedrocks of the food supply like dairy products since consumers substituting nutritionally inferior products could result in significant consumer and public health issues. Indeed, that the Agency expressly considered permitting standardized food names in conjunction with qualifiers such as "substitute" and "product substitute" for dairy products and rejected the proposal because even that qualified reference was confusingly similar underscores the egregiousness of the ongoing violations by non-dairy substitute foods.

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93 *Id.* at 37,667.

94 *Id.* (emphasis added).

5. Use of Standardized Terms as Part of Common or Usual Name

The Agency has also acknowledged – in the milk and cheese substitute rulemaking and in other instances – that use of a standardized food in the common or usual name for another food "may be reasonable and appropriate" if the term is necessary "in order to provide the consumer with an accurate description."[95] Of course, this does not mean that standardized food terms can be used in conditions where they do not accurately describe the basic nature and characteristics of the substitute food and fail to adequately disclose the material differences between the substitute and reference standardized food. The Agency has cautioned that standardized terms should only be used "in order to provide the consumer with an accurate description."[96]

Those instances are inherently limited, however. For example, FDA concluded that it was permissible to establish a standard for certain dried milk products like "nonfat dry milk":

> Lactose-reduced milk products differ in composition from dry milk products. As the objectors recognize, the lactose-reduced foods cannot bear the same name as dry milk products but must instead be named to indicate their distinctive feature. However, they do not have to be labeled with obscure names as suggested by the objectors. Furthermore, as the Commissioner has previously advised in the Federal Register of August 2, 1973 (38 FR 20703), the existence of a standard of identity for a particular food does not necessarily preclude the use of the standardized name in connection with the name of a nonstandardized food, and 'in some cases it may be necessary to include a standardized name in the name of a substitute food in order to provide the consumer with accurate, descriptive, and fully informative labeling.' In other words, the standards of identity to which objections are made do not by themselves affect the objecting parties' ability to market accurately labeled lactose-reduced milk products using the standardized nomenclature, to the extent appropriate, as part of the name of the new foods.[97]

The agency has also allowed enriched standardized foods to use standardized nomenclature provided the food name is qualified to convey how the product has been modified. For example, the Agency has approvingly referenced food names such as "raisin bread made with enriched flour,"[98] "enriched macaroni with fortified protein,"[99] and "tomato juice enriched with vitamin C."[100] In each of these cases, the Agency explained that the food did not purport to be the same as the standardized referenced product and instead clearly explained how the food differed in

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95 *Id.*

96 *Id.*

97 Nonfat Dry Milk, Lowfat Dry Milk, Dry Whole Milk, and Dry Cream; Standards of Identity; Confirmation of Effective Date and a Further Amendment, 44 Fed. Reg. 3,964, 3,965 (Jan. 19, 1979).

98 Revocation of Stayed Standard for Enriched Raisin Bread, 43 Fed. Reg. 43,456 (Sept. 26, 1978).

99 Standard of Identity for Enriched Macaroni Products with Fortified Protein; Stay of Effective Date of Standard, 43 Fed. Reg. 11,695 (Mar. 21, 1978).

100 Tomato Juice; Stay of Effective Date of Order Amending Identity Standards, 39 Fed. Reg. 31,898 (Sept. 3, 1974).

material respects. None of these precedents support the use of a standardized term in a manner that misleadingly conveys the basic nature and characterizing properties of the food.

Importantly, however, the Agency has determined that in certain cases it is not appropriate to allow use of a standardized term even if the standardized term is qualified in a way that accurately characterizes the modification. For example, in *Federal Security Administrator v. Quaker Oats Co.*, the Supreme Court upheld the Agency's standard of identity for "farina" and "enriched farina," which together operated to preclude the plaintiff from labeling its "farina with Vitamin D" product as "farina."[101] The Court explained "[t]he text and the legislative history of the Act show that its purpose was not confined to requiring informative labeling, *but was to authorize the Administrator to promulgate definitions and standards of identity 'under which the integrity of food products can be effectively maintained*,'" and therefore "[t]t was not unreasonable to prohibit the addition to 'farina' of vitamin D as an optional ingredient, while permitting its addition as an optional ingredient to 'enriched farina.'"[102]

The case underscores that the FDCA standards authority is important not only in preventing consumer deception but also in protecting consumer and public health by providing meaningful benchmarks that could be used to maintain the integrity of the food supply.

II. Statement of Problem

A. The Proliferation of Misbranded Non-Dairy Substitutes Misappropriating Standardized Dairy Terms

Non-dairy, plant-based foods formulated and labeled to substitute for and resemble standardized dairy products have been on the market for some time, but they are increasingly labeled and marketed as nutritionally equivalent or even superior substitutes, notwithstanding that they are almost uniformly nutritionally inferior to their standardized dairy counterparts.[103] In addition to new and more brazen labeling campaigns, these non-dairy substitutes are now derived from a vast and nutritionally diverse array of plant-derived ingredients (*e.g.*, hemp, oat, pea, pecan, rice, quinoa, cashew, hazelnut, pistachio, flax), and include random combinations thereof (*e.g.*, "coconut hemp milk"). Additionally, manufacturers of non-dairy substitutes have also expanded their offerings to target replacement of additional dairy products subject to standards of identity, such as yogurt and ice cream. These products are intentionally formulated with added colors, flavors, and other additives to resemble dairy products, and are labeled through use of the standardized dairy term reserved for the product they are intended to substitute for and resemble, notwithstanding that they do not contain that food as a primary or even subsidiary ingredient.

NMPF respectfully submits that FDA's failure to enforce existing regulations and policies against these non-dairy substitutes has emboldened the industry and contributed to the current disarray of non-dairy substitutes purporting to be something they are not. Attachment B

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101 *Fed. Sec. Adm'r v. Quaker Oats Co.*, 318 U.S. 218, 219 (1943).

102 *Id.* at 219 (emphasis added).

103 Attachment C, Survey of Nutritional Profiles of Non-Dairy Plant-Based Substitutes Compared to Reference Standardized Dairy Foods.

provides examples of products that are named to capitalize on the healthy halo associated with dairy foods through use of standardized dairy terms in the statement of identity, notwithstanding that the non-dairy substitute does not contain the reference dairy food in any amount. These products are unmistakably manufactured, labeled, and marketed to resemble dairy products and thus constitute "substitute" products subject to "imitation" labeling requirements if nutritionally inferior under section 101.3(e) of FDA regulations, and the vast majority of these products are nutritionally inferior.[104] Some labeling for these products are more egregious than others – with terms such as "non-dairy" or "vegan" haphazardly and inconsistently used to varying degrees of effectiveness. Irrespective of whether these modifiers are included on the labels, these products are misbranded because they are held out as nutritionally equivalent substitutes in violation of the FDCA and FDA implementing regulations and to the detriment of public health.[105]

Importantly, and contrary to the assertion of some in the non-dairy, substitute foods industry, these misleading names are not accepted or used consistently internationally or even here in the United States. Indeed, as shown in Attachment B, certain non-dairy substitutes manufactured and sold in the United States by Trader Joe's, Quaker Oats, Pacific Foods, and Kirkland are already labeled to comply with longstanding FDA regulations and precedent and refrain from referencing the standardized food they substitute for and resemble as part of the statement of identity. These products affirm that enforcing and codifying existing FDA precedent will not result in stifling innovation or deterring the marketing and sale of non-dairy substitutes.

In addition to those manufacturers of certain non-dairy substitutes already complying with the relevant law and precedent in the United States, other manufacturers who do not use compliant statements of identity here use different product names such as "soy beverage" or "almond drink" in Canada, the United Kingdom, and the European Union to comply with applicable legal requirements and avoid enforcement. The European Court of Justice recently considered this precise issue and found that "the relevant legislation *reserves the term 'milk' only for milk of animal origin [and] . . . reserves designations like 'cream,''chantilly,' 'butter,' 'cheese,' and 'yoghurt' solely for milk products, that is products derived from milk.*"[106] The Court further explained "that the addition of descriptive or clarifying additions indicating the plant origin of the product concerned . . . has no influence on that prohibition [and] . . . cannot completely exclude the likelihood of confusion on the part of consumers."[107] The same legal requirements and public policy rationale applies in the United States.

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104 Attachment C.

105 *See supra* Sections I.C.2-3.

106 Press Release, Court of the European Union, Judgment in Case C-422/16, Verband Sozialer Wettbewerb eV v TofuTown.com GmbH, Purely plant-based products cannot, in principle, be marketed with designations such as 'milk', 'cream', 'butter', 'cheese' or 'yoghurt', which are reserved by EU law for animal products (June 14, 2017) (available at: https://curia.europa.eu/jcms/upload/docs/application/pdf/2017-06/cp170063en.pdf) (emphasis added); *see also* General Standard for Use of Dairy Terms Codex Standard 206-1999 (defining "milk" as "the normal mammary secretion of milking animals obtained from one of more milkings without either addition to it or extraction from it, intended for consumption as liquid milk or for further processing").

107 *Id.*

These products marketed and sold in the United States and elsewhere across the world that comply with existing FDA regulations and policy demonstrate that manufacturers of non-dairy substitutes could easily revise their labels to avoid using standardized food terms in the statement of identity in a misleading fashion. Yet some in the non-dairy substitute industry continue to audaciously attempt to frame the issue as one of embracing versus stifling innovation and consumer choice. This could not be farther from the case. NMPF recognizes that there are consumers who prefer to include non-dairy substitutes in their diet in addition to or in lieu of their standardized dairy counterparts. NMPF does not seek to prevent these products from being marketed and sold, but rather asks that FDA ensure that the products are labeled consistent with longstanding law and prevent labeling that falsely suggests the products to be nutritionally equivalent substitutes of the same basic nature and characterizing properties of their dairy counterparts that have comprised a central food group of American nutrition for centuries.

B. Serious Public Health Consequences Associated with the Misbranding Violations

The harms associated with naming food products in violation of the FDCA and FDA regulations are not purely hypothetical or academic. As discussed above in Section I, these regulations are grounded in important consumer and public health protection objectives that "discourage the gradual nutritional degradation of the American diet through the introduction of products that replace traditional products but are nutritionally inferior to them."[108] These public health goals are directly at stake here. Specifically, because non-dairy substitutes are almost uniformly nutritionally inferior to the standardized dairy products they resemble and substitute for, consumers may unknowingly reduce consumption of nutrients vital to a healthy diet based on the false assumption that the non-dairy substitute is nutritionally equivalent to the reference standardized dairy food. Notably, the risk applies irrespective of whether a consumer understands that the non-dairy substitute food is not comprised in whole or in part of the reference standardized dairy food.[109]

At the same time, even surveys funded by the non-dairy substitute industry have found that a significant proportion of consumers either affirmatively believe or do not know whether non-dairy substitutes contain dairy. For example, an October 2018 industry funded survey conducted by the International Food Information Council Foundation (IFICF) found that between 7 and 9 percent of consumers believe that non-dairy, plant-based beverages contain cow's milk and

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[108] Peanut Spreads: Proposed Common or Usual Name, 40 Fed. Reg. at 51,053.

[109] Certain courts considering false advertising actions related to the labeling of non-dairy substitutes have focused on whether a reasonable consumer could believe the substitute food to be comprised of the reference dairy food. These cases are inapposite generally because the standards under state laws prohibiting unfair and deceptive acts and practices differ from applicable FDCA standards, and thus these decisions have not addressed the broader consumer protection considerations that form the bases for FDA's food standards authority and related labeling requirements (*i.e.*, the false equivalencies presented by use of a reference standardized food term as part of the statement of identity for a substitute product intended to substitute for and resemble that reference food). *See, e.g., Gitson v. Trader Joe's Co.*, No. 13-CV-01333-WHO, 2013 U.S. Dist. LEXIS 144917, at *2 (N.D. Cal. Oct. 4, 2013). Moreover, the standard applied by courts in false advertising cases is fundamentally different than the standard applied by FDA, given the Agency is tasked with protecting public health and not merely preventing false advertising.

between 16 and 20 percent of consumers report not knowing whether they contain cow's milk.[110] While the study was touted as finding "a low level of consumer confusion over nomenclature and basic differences" between non-dairy substitutes and their standardized dairy counterparts, longstanding Federal Trade Commission precedent holds that a threshold of 10-20 percent of consumers is sufficient to establish deception from an implied claim.[111] More fundamentally, the survey failed to ask consumers about their perception of the nutritional and performance characteristics of non-dairy substitutes compared to their reference standardized dairy counterparts.

Even if consumers did understand that non-dairy substitutes do not contain the reference standardized dairy food misleadingly used in their names, FDA regulatory requirements governing food standards and names of foods are grounded not only in preventing consumer deception but also protecting consumer and public health by establishing nutritional, quality, and compositional benchmarks.[112] This is precisely why the Agency long ago decided to define "imitation" products by reference to nutritional inferiority; consumers are likely to assume that substitute products are nutritionally equivalent to the products they resemble and substitute for. This is especially the case here because non-dairy substitutes are marketed as healthy, nutritious alternatives to their dairy counterparts and are labeled with explicit references to the traditional standardized dairy food.

Studies confirm that consumers wrongly assume that non-dairy, plant-based substitutes are nutritionally equivalent or even superior to their dairy counterparts. According to a 2018 survey by IPSOS, a global market research and consulting firm, 62% of plant-based beverage buyers cite nutrition as important to their purchase decision.[113] Additionally, more than 70% of consumers thought plant-based, non-dairy substitutes have the same or more protein than dairy milk.[114] However, an actual comparison of nutritional profiles shows that non-dairy substitutes are nearly uniformly nutritionally inferior to their nutrient-dense dairy counterparts.[115] To evaluate, NMPF surveyed non-dairy substitute beverages sold in grocery stores in the Washington, D.C. metropolitan area, and then compared the nutrition facts panels of these

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110 Politico Pro, "Survey: Most consumers not confused by plant-based milk labeling" (Oct. 12, 2018) (citing International Food Information Council Foundation Report, Consumer Attitudes about Labeling Cow's Milk Plant Based and Non-Dairy Alternatives (October 2018), available at: https://foodinsight.org/wp-content/uploads/2018/10/Milk-Nomenclature_PDF_1.pdf.

111 *Firestone Tire & Rubber Co. v. FTC*, 481 F.2d 246, 249 (6th Cir. 1973).

112 *See supra* Section I.A.

113 Attachment D, Consumer Perceptions: Dairy Milk and Plant-based Milk Alternatives. These findings were reiterated by a Phase II survey also conducted by IPSOS. *See* Attachment E, Consumer Perceptions, Dairy and Plant-based Milks Phase II (Jan. 14, 2019).

114 *Id.*

115 As noted in the Foreword to the Grade "A" Pasteurized Milk Ordinance, "of all foods, none surpasses milk as a single source of those dietary elements needed for the maintenance of proper health, especially in children and older citizens." U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration Grade "A" Pasteurized Milk Ordinance (2015 rev.), available at: https://www.fda.gov/downloads/food/guidanceregulation/guidancedocumentsregulatoryinformation/milk/ucm513508.pdf.

products with that of 1% milk, including the nine essential nutrients for which milk is the number one source in children's diets.[116] The results are summarized in Attachment C and show that of the 244 beverages examined: (1) none of these products are nutritionally equivalent to real milk or deliver those nine essential nutrients in the same proportions as dairy milk; (2) many of these products lack key essential nutrients provided by milk such as protein and Vitamin D; and (3) unlike real milk's consistent nutrient profile, there was extremely wide variation both within and among the various categories of non-dairy, plant-based beverages.

The inconsistency between consumer perception and reality of the nutritional profiles of dairy and plant-based substitutes has potentially grave consequences given the important role that dairy plays in contributing to human nutritional needs.[117] Many scientists, doctors, and even some in the non-dairy substitute industry have recognized the risks to consumer health and public health that are presented by the proliferation of these misbranded imitation products.[118] The most recent Dietary Guidelines for Americans addressed the nutritional inferiority issue by grouping products separately and explaining that "[o]ther 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."[119]

While experts and industry know that non-dairy substitutes are generally nutritionally inferior to their dairy counterparts, consumers are not so informed, and misleading labels reinforce the false perception that nutritionally inferior imitations are equivalent or even superior to their dairy counterparts. Indeed, there have been a number of reports of health incidents such as malnutrition associated with replacement of dairy beverages with nutritionally inferior

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[116] 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.

[117] Attachment F, Contribution of Dairy Foods to Nutrient Intakes by Americans; Attachment G Dairy servings by ethnicity and age group; Attachment H, Average Contribution of Dairy Foods to Calorie and Nutrient Intakes; Attachment I, National Dairy Council. NHANES 2011-2014. Data Source: Centers for Disease Control and Prevention, National Center for Health Statistics, National Health and Nutrition Examination Survey Data. Hyattsville, MD: U.S. Department of Health and Human Services. http://www.cdc.gov/nchs/nhanes.htm.

[118] 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 ("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"); Sean Rossman, *Got milk? This is the kind you should be drinking*, USA Today (Feb. 28, 2017), https://www.usatoday.com/story/news/nation-now/2017/02/28/got-milk-kind-you-should-drinking/98322592/ ("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.'"); Brad Avery, *Class actions target alt-milk nutritional standards*, BevNet (Feb. 8, 2017), https://www.bevnet.com/news/2017/class-actions-target-alt-milk-nutritional-standards (citing statement by Adam Lowry, the founder of Ripple, "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").

[119] U.S. Department of Health Services and Human and U.S. Department of Agriculture. 2015-2020 Dietary Guidelines for Americans, 8th Edition. December 2015, at 23, available at http://health.gov/dietaryguidelines/2015/guidelines/.

imitations.[120] These potentially grave public health consequences are precisely why the FDCA and FDA regulations require truthful and non-misleading common or usual names, and require nutritionally inferior substitutes to be labeled as "imitation" products.

III. The Actions Requested Fall Well Within the Confines of Acceptable First Amendment Limitations

The Actions Requested ask FDA to enforce existing "imitation" labeling requirements established under FDCA section 403(c) against nutritionally inferior non-dairy substitutes for standardized dairy foods that are named and positioned as forms of "milk," "yogurt," "cheese," "ice cream," or "butter," yet fail to provide the "imitation" disclosure statement that is required by the Act and section 101.3(e) of FDA regulations. In addition, the Actions Requested ask FDA to adopt amendments to section 101.3(e) to codify in more detailed form longstanding FDA policies that permit the name of a standardized dairy food (*e.g.*, "milk," "yogurt," "cheese," "ice cream," "butter") to be used in the statement of identity of a non-dairy substitute for the reference standardized food only under limited and defined conditions. The requested amendments would codify requirements that already exist under FDCA sections 403(a), 403(c) and 201(n) and related FDA regulations (*e.g.*, section 101.3) and policies in the specific context of non-dairy substitutes for standardized dairy foods in new section 101.3(e)(6), entitled "Non-Dairy Foods that Substitute for and Resemble Standardized Dairy Foods."

This provision would apply to non-dairy foods that substitute for and resemble standardized dairy foods including milk, yogurt, cheese, ice cream and butter products, and would codify distinct requirements for nutritionally inferior and nutritionally equivalent non-dairy substitutes for standardized dairy foods. In both cases, new section 101.3(e)(6) would prohibit claims that are already prohibited by FDCA sections 403(a) and 201(n), and to specify disclosures that are already required under FDCA sections 403(c) and/or sections 403(a) and 201(n).[121]

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[120] Mary Hui, *An Italian baby raised on a vegan diet is hospitalized for severe malnutrition and removed from parents*, The Washington Post, (July 11, 2016), https://www.washingtonpost.com/news/morning-mix/wp/2016/07/11/italian-baby-fed-vegan-diet-hospitalized-for-malnutrition/?noredirect=on&utm_term=.fd48490d2d2e; Raf Casert, *Parents convicted over baby killed by 'alternative' diet*, Independent (June 15, 2017), https://www.independent.co.uk/news/world/europe/baby-dies-diet-parents-convicted-lucas-dendermonde-belgium-malnutrition-dehydration-a7790916.html; Michele Mandel, *Parents of toddler whose vegan diet led to death sentenced to 30 months*, Ottawa Sun (Apr. 10, 2015), https://ottawasun.com/2015/04/10/parents-of-toddler-whose-vegan-diet-led-to-death-sentenced-to-30-months/wcm/64f62d5b-8e45-4ebd-b1d5-4be4d2fb1c7c; Associated Press, *Vegan Couple Sentenced to Life Over Baby's Death*, NBC News (May 9, 2007), http://www.nbcnews.com/id/18574603/ns/us_news-crime_and_courts/t/vegan-couple-sentenced-life-over-babys-death/#; Koen Berghuis & Kara O'Neill, *Health food is out of control': Doctors warning over vegan diets as more malnourished children seen in hospitals*, Mirror (Aug. 22, 2017), https://www.mirror.co.uk/news/world-news/health-food-out-control-doctors-11033265.

[121] 21 U.S.C. §§ 321(a), 343(a), 343(c). *See, e.g.*, Food Standards: Requirements for Foods Named by Use of a Nutrient Content Claim and a Standardized Term, 58 Fed. Reg. at 2,432-2,433 ("A modified food that does use a traditional standardized term but that does not comply with the traditional standard of identity or with new § 130.10 must be labeled either as an 'imitation,' if it is nutritionally inferior, or as a 'substitute,' 'alternative,' or other appropriate term, if it is not nutritionally inferior, as specified in § 101.3(e) which will remain in effect. For example, a mozzarella cheese product made with skim milk and vegetable oil does not comply with the standard for mozzarella cheese (§ 133.155) or with new § 130.10(d)(2) and, therefore, must be labeled as 'imitation mozzarella

More specifically, new section 101.3(e)(6)(iii) would apply to non-dairy substitute foods that are nutritionally inferior to the reference standardized dairy food they substitute for and resemble. The provision is designed to align generally with the imitation labeling requirements for nutritionally inferior substitute foods that currently apply under section 101.3(e)(1), with one key difference. Under the new provision, imitation labeling under FDCA section 403(c) would not be required for a nutritionally inferior non-dairy substitute food that adheres to certain labeling practices designed to prevent consumer deception, including prominent and conspicuous disclosure of the nutritional inferiority and any performance limitations (*e.g.*, "not suitable for frying") of the nutritionally inferior non-dairy substitute food as compared to the reference standardized dairy food. Ultimately, under the new provision, nutritionally inferior non-dairy substitute foods could either be identified with the legally defined term, "imitation" *(e.g.*, "imitation milk"), to disclose the nutritional inferiority of the non-dairy substitute as compared to the reference standardized dairy food, or alternatively, the substitute food could be labeled to disclose the material facts that are represented by the "imitation" disclosure – that is, the facts that the non-dairy substitute is nutritionally inferior and materially different from the standardized food (*i.e.*, is likely to have material performance limitations) that must be disclosed to consumers (*e.g.*, "not suitable for frying") – in accordance with existing FDA policies.[122]

In addition, to avoid "imitation" labeling requirements under FDCA section 403(c), the nutritionally inferior non-dairy substitute food would be required to be labeled in a manner that makes no express or implied representation that suggests that the non-dairy food is a form of milk, cheese, ice cream, butter or any other dairy food that is governed by a standard of identity, except as expressly permitted. In this regard, representations that are made in the name of a nutritionally inferior non-dairy substitute food would be considered, specifically including the use of a standardized dairy term (*e.g.*, "milk") in the statement of identity for the substitute food. Under new section 101.3(e)(6)(v), a nutritionally inferior substitute food would be permitted to use a standardized dairy term in its statement of identity provided the material fact that the food is a substitute or alternative to the reference standardized dairy food, and not the standardized dairy food itself, is disclosed (*e.g.*, "Milk Substitute;" "Milk Alternative"). In addition, to avoid imitation labeling requirements, the labeling for the nutritionally inferior non-dairy substitute food would not be permitted to make any express or implied representation (falsely) suggesting that the substitute food is nutritionally equivalent or superior to the reference standardized dairy food, or (falsely) suggesting that consuming the nutritionally inferior substitute in lieu of the reference standardized dairy food would either have positive or insignificant nutritional consequences for consumers.

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cheese' if nutritionally inferior to mozzarella cheese or as 'mozzarella cheese alternative' or 'mozzarella cheese substitute' if it is not nutritionally inferior.").

[122] *See, e.g.*, 21 C.F.R. § 101.67(b) ("If there is a significant difference in performance characteristics (that materially limits the uses of the product compared to butter) the label shall include a statement informing the consumer of such difference (*e.g.*, if appropriate, "not recommended for baking purposes"); 21 C.F.R. § 130.10 ("The performance characteristics (*e.g.*, physical properties, flavor characteristics, functional properties, shelf life) of the food shall be similar to those of the standardized food as produced under parts 131 through 169 of this chapter, except that if there is a significant difference in performance characteristics that materially limits the uses of the food compared to the uses of the standardized food, the label shall include a statement informing the consumer of such difference (*e.g.*, if appropriate, "not recommended for cooking"). Such statement shall comply with the requirements of 101.13(d) of this chapter.").

Similarly, new section 101.3(e)(6)(iv) would apply to non-dairy substitute foods that are not nutritionally inferior to the reference standardized dairy food they substitute for and resemble. The provision aligns generally with the requirements that already apply to nutritionally equivalent substitute foods under section 101.3(e)(2) and related provisions, for which compliance is essential to qualify for the exemption from "imitation" status and related labeling requirements.

Under new section 101.3(e)(6)(iv), to avoid triggering imitation requirements under FDCA section 403(c), non-dairy substitute foods that are not nutritionally inferior would not only be required to comply with existing section 101.3(e)(2), but would also be required to be labeled and advertised in a manner that makes no express or implied representation (falsely) suggesting that the non-dairy food is a form of milk, cheese, ice cream, butter or any other standardized dairy food. In this regard, representations that are made in the name of the non-dairy substitute food would be considered, including the use of a standardized dairy term (*e.g.*, "milk") in the statement of identity of the non-dairy substitute food. Under new section 101.3(e)(6)(v), non-dairy substitutes for standardized dairy foods would be permitted to use a standardized dairy term to identify the food as a substitute or alternative to the reference standardized dairy food (*e.g.*, "Milk Substitute;" "Milk Alternative"). In addition, any material performance limitations of the non-dairy substitute as compared to the reference standardized dairy food would be required to be disclosed prominently and conspicuously on labels and in labeling, consistent with existing FDA requirements.[123] These requirements are consistent with the requirements of the Act, and FDA policies and precedents, including those reflected in sections 130.10 and 101.67.[124]

In sum, the Actions Requested ask FDA to adopt new section 101.3(e)(6) to codify existing requirements that prohibit false and misleading representations that already apply to non-dairy substitutes under the Act, and to make explicit the disclosure requirements that already apply to these substitute foods – specifically the disclosure of material facts to prevent consumer deception and requiring non-dairy substitutes to be identified in a manner that adequately distinguishes them from standardized dairy foods (*i.e.*, "Imitation [SOI Dairy Food]," ["Substitute [SOI Dairy Food]," "Alternative [SOI Dairy Food]"). The Actions Requested are carefully tailored to ensure that these disclosure requirements apply in limited contexts where the manufacturer of a non-dairy substitute food has affirmatively chosen to manufacture and label a food that substitutes for and resembles a reference standardized dairy food, *and* has chosen to employ the standardized dairy term in the name of the non-dairy substitute. Under the Actions Requested, "Imitation" and "Alternative" or "Substitute" disclosure statements would not be required for non-dairy foods that do not substitute for and resemble standardized dairy foods, *or* that are identified using distinctive names that do not reference or incorporate standardized dairy terms and otherwise comply with sections 101.3 and 102.5 of FDA regulations. For example, a non-dairy beverage that is made from soy and other non-dairy ingredients that is identified as a "Natural Soy Beverage" would not be required to comply with the disclosure requirements under either current section 101.3(e) or section 101.3(e) as amended by the Actions Requested in this petition, even if the food otherwise resembles and substitutes for a standardized dairy food.

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123 21 U.S.C. §§ 321(n), 343(a); *see also* 21 C.F.R. §§ 101.67, 130.10.

124 *See supra* Sections I.C.3-5.

Notably, under new section 101.3(e)(6), the conditions under which "imitation" labeling would be legally required for non-dairy substitutes for standardized dairy foods would continue to be highly limited, and would potentially be more limited than under existing regulations. As under current FDA regulations and policies, there would be no unavoidable requirement to use of the terms "imitation," "alternative," or "substitute" to identify a non-dairy substitute for a standardized dairy food in view of the substantial freedom FDA policies give manufacturers in naming new foods under sections 101.3 and 102.5 of existing FDA regulations. In this regard, NMPF has observed that there are some non-dairy substitutes on the market that already are labeled in a manner that avoids any reference to the standardized dairy food that they substitute for and resemble (*e.g.*, "Rice Beverage") in accordance with FDA labeling policies under sections 101.3 and 102.5,[125] and thus are not subject to "imitation," "substitute," and "alternative" disclosure requirements under existing law, or under the amendments proposed by the Actions Requested.

For the reasons discussed further below, the "imitation" labeling requirements that the petition asks FDA to enforce would target misbranded products that fail to bear the mandatory "imitation" disclosure statement and that are labeled in a false and misleading manner. In the absence of compliance with the mandatory imitation labeling requirements, such non-dairy substitute foods are being identified in a manner that implies a false equivalence between the non-dairy substitute and its reference standardized dairy food, and potentially also, a broader false equivalence across all non-dairy products that substitute for and resemble a reference standardized dairy food (*e.g.*, milk) and are identified using a standardized dairy term that refers to that reference standardized dairy food (*e.g.*, across all non-dairy "milk" products). In short, the Actions Requested ask FDA to undertake enforcement actions against non-dairy substitutes that are labeled in a false and misleading manner as a result of their lack of compliance with FDCA sections 201(n), 403(a), and 403(c). There is no question that such enforcement actions targeting false and misleading labeling are permitted on both statutory and First Amendment grounds.

The Actions Requested also ask FDA to adopt amendments to section 101.3(e), including new section 101.3(e)(6), which would provide that nutritionally inferior non-dairy substitute foods would not be subject to "imitation" labeling requirements, provided that the non-dairy substitute food is named in a manner that does not represent it as being a form of a standardized dairy food (*e.g.*, by using a standardized dairy term in the name of the non-dairy substitute food without also disclosing that the product is a "substitute" or "alternative" to the standardized food), and the material differences between the non-dairy substitute and the reference standardized dairy food are disclosed in product labeling (*e.g.*, nutritional inferiority, performance limitations). In addition, the proposed amendments would make clear that non-dairy substitutes that are not nutritionally inferior would not be subject to "imitation" labeling requirements when they comply with existing regulations that require the food to be named in compliance with sections 101.3 and 102.5 of FDA regulations, and in addition, disclose any material limitations of the non-dairy substitute. Additionally, new section 101.3(e) would expressly permit non-dairy substitutes to use a reference standardized dairy term as part of the statement of identity provided the material fact that the food is a substitute or alternative to the reference standardized dairy

[125] See Attachment C.

food, and not the standardized dairy food itself, is disclosed (*e.g.*, "Milk Substitute;" "Milk Alternative").

There is no question that such factual and uncontroversial disclosure requirements designed to prevent consumer deception and protect consumer health and public health can be adopted and enforced in view of the First Amendment standards that govern the regulation of commercial speech such as food labeling. Section A provides an overview of relevant case law from the Supreme Court's recognition of First Amendment protection in *Central Hudson*[126] to the D.C. Circuit's recent important en banc decision in *American Meat Institute*.[127] Section B explains how the effects on commercial speech contemplated by the Actions Requested fall well within established First Amendment confines.

A. Overview of Central First Amendment Precedent

1. The Foundational Supreme Court Cases – *Central Hudson* & *Zauderer*

The Supreme Court articulated the framework that has served as the touchstone for evaluating the constitutionality of content-based restrictions imposed on commercial speech in *Central Hudson Gas & Electric Corp. v. Public Service Commission*.[128] In *Central Hudson*, the Court made clear that, while the government has authority to ban speech that is misleading or related to an unlawful activity entirely, the government's authority to restrict commercial speech otherwise is more circumscribed.[129] The Court explained:

> The state must assert a substantial interest to be achieved by restrictions on commercial speech. Moreover, the regulatory technique must be in proportion to that interest. The limitation on expression must be designed carefully to achieve the State's goal. Compliance with this requirement may be measured by two criteria. First, the restriction must directly advance the state interest involved; the regulation may not be sustained if it provides only ineffective or remote support for the government's purpose. Second, if the governmental interest could be served as well by a more limited restriction on commercial speech, the excessive restrictions cannot survive.[130]

The Court ultimately concluded that the Commission's "complete suppression of speech" violated the First Amendment because the state attempted to justify it through an "energy conservation rationale" that the speech ban was not shown to affect whatsoever.

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126 *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 564 (1980).

127 *Am. Meat Inst. v. USDA*, 760 F.3d 18 (D.C. Cir. 2014) (en banc).

128 *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 564 (1980) (striking down regulation of New York Public Service Commission which completely banned an electric utility from advertising to promote the use of electricity because the state's interconnected utility system did not have sufficient fuel stocks or sources of supply to meet all customer demands for the winter).

129 *Id.*

130 *Cent. Hudson* 447 U.S. at 564.

In another foundational commercial speech case, *Zauderer v. Office of Disciplinary Counsel*,[131] the Court considered the First Amendment framework for evaluating content-based restrictions imposed on commercial speech in the context of a mandatory disclosure requirement that applied to an advertisement run by a lawyer for contingent fee representation.[132] The advertisement included the claims, "the cases are handled on a contingent fee basis of the amount recovered. If there is no recovery, no legal fees are owed by our clients."[133] The state's enforcement action against the attorney alleged that the advertisement ran afoul of the state's Disciplinary Code for reasons including the advertisement's failure to disclose that clients in contingent fee cases would be liable for costs (as opposed to legal fees) even if their claims were unsuccessful, rendering the advertisement "deceptive" and unlawful.[134]

In *Zauderer*, the Court first addressed the applicable standard of review:

> There is no longer any room to doubt that what has come to be known as "commercial speech" is entitled to the protection of the First Amendment, albeit to protection somewhat less extensive than that afforded "noncommercial speech."[135] . . . Our general approach to restrictions on commercial speech is also by now well settled. The States and the Federal Government are free to prevent the dissemination of commercial speech that is false, deceptive, or misleading,[136] or that proposes an illegal transaction.[137] Commercial speech that is not false or deceptive and does not concern unlawful activities, however, may be restricted only in the service of a substantial government interest, and only through means that directly advance that interest.[138] Our application of these principles to the commercial speech of attorneys has led us to conclude that blanket bans on price advertising by attorneys and rules preventing attorneys from using nondeceptive

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131 *Zauderer v. Office of Disciplinary Counsel of Supreme Court*, 471 U.S. 626 (1985).

132 *Id.* at 630-31.

133 *Id.*

134 *Id*. at 633-634.

135 *Id.* at 637 (citing *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60 (1983) (holding that law prohibiting mailing of unsolicited advertisements for contraceptives violates First Amendment); *In re R.M.J.*, 455 U.S. 191 (1982) (holding that state rule that completely banned advertising of certain types of attorney specializations in attorney advertising violates First Amendment); *Central Hudson Gas & Electric Corp. v. Public Service Comm'n,* 447 U.S. 557 (1980)).

136 *Id.* at 638 (citing *Friedman v. Rogers*, 440 U.S. 1 (1979)) (regulation prohibiting the practice of optometry under a trade name was permissible because it prevented misleading advertising and trade names "convey[] no information about the price and nature of the servicers offered" and because "there is a significant possibility that trade names will be used to mislead the public").

137 *Zauderer*, 471 U.S. at 638 (citing *Pittsburgh Press Co. v. Human Relations Comm'n,* 413 U.S. 376 (1973) (advertising jobs in local newspaper based on desired sex of employee was illegal and thus not entitled to First Amendment protection).

138 *Zauderer*, 471 U.S. at 638 (citing *Central Hudson*, 447 U.S. at 566) (finding that speech restrictions must directly advance a government interest but may still violate the First Amendment if there are speech neutral options).

> terminology to describe their fields of practice are impermissible,. . . .[139] To resolve this appeal, we must apply the teachings of these cases to three separate forms of regulation Ohio has imposed on advertising by its attorneys: [including] . . . disclosure requirements relating to the terms of contingent fees."[140]

In its review of the validity of the Ohio Supreme Court's decision to discipline the appellant (lawyer) for his failure to include in his advertisement the information that clients in contingent fee cases might be liable for significant costs even if their lawsuits were unsuccessful, the Court rejected the appellant's contention that the evaluation of the disclosure requirement under the First Amendment entails precisely the same inquiry as would be involved in the evaluation of a speech ban.[141] The Court observed that the appellant's argument in this regard "overlooks material differences between disclosure requirements and outright prohibitions on speech. In requiring attorneys who advertise their willingness to represent clients on a contingent fee basis to state that the client may have to bear certain expenses even if he loses, Ohio has not attempted to prevent attorneys from conveying information to the public; it has only required them to provide somewhat more information than they might otherwise be inclined to present."[142]

The Court recognized that, in some instances, the Court has found that the compulsion of speech may be as violative of the First Amendment as prohibitions on speech.[143] The Court distinguished Ohio's disclosure requirement – which was designed to prevent consumer deception presented by the contingent fee claim appellant had chosen to make in his attorney advertisement – finding that Ohio had not attempted to "prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion or force citizens to confess by word or act their faith therein"[144] but rather had "attempted only to prescribe what shall be orthodox in commercial advertising, and its prescription has taken the form of a requirement that appellant

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139 *Id.* (citing *Bates v. State Bar of Arizona*, 433 U.S. 350 (striking down complete ban on attorney advertising); *In re R.M.J.*, 455 U.S. at 191 (1982).

140 *Id.*

141 *Zauderer*, 471 U.S. at 647 (holding that an attorney may not be disciplined for soliciting legal business through printed advertising if it contains truthful and non-deceptive information and advice regarding the legal rights of potential clients in reliance on *Central Hudson* and related cases); *see also Zauderer*, 471 U.S. at 649 (holding that the appellant could not be disciplined for his use of an accurate and non-deceptive illustration in reliance on *Central Hudson* and related cases).

142 *Zauderer*, 471 U.S. at 650.

143 *Id.* (citing *Wooley v. Maynard*, 430 U.S. 705 (1977) (New Hampshire law criminalizing individuals from covering over portion of license plate with motto "Live Free or Die" violated First Amendment because it commands communication of "an idea they find morally objectionable"); *Miami Herald Publishing Co. v. Tornillo*, 418 U.S. 241 (1974) (holding Florida right of reply statute unconstitutional because newspaper could not be compelled to print all perspectives without expression of editorial judgment consistent with First Amendment); *West Virginia State Bd. of Ed. v. Barnette*, 319 U.S. 624, 633 (1943) (stating that "involuntary affirmation could be commanded only on even more immediate and urgent grounds than silence" and holding that regulation requiring children in public schools to salute the American flag was unconstitutional)).

144 *Zauderer*, 471 U.S. at 651 (quoting *Barnette*, 319 U.S. at 642).

include in his advertising purely factual and uncontroversial information about the terms under which his services will be available."[145] The Court reasoned that:

> Because the extension of First Amendment protection to commercial speech is justified principally be the value to consumers of the information such speech provides,[146] appellant's constitutionally protected interest in *not* providing any particular factual information is minimal. Thus, in virtually all our commercial speech decisions to date, we have emphasized that because disclosure requirements trench much more narrowly on an advertiser's interests than do flat prohibitions on speech, "warning[s] or disclaimer[s] might be appropriately required . . . in order to dissipate the possibility of consumer confusion or deception."[147] We do not suggest that disclosure requirements do not implicate the advertiser's First Amendment rights at all. We recognize that unjustified or unduly burdensome disclosure requirements might offend the First Amendment by chilling protected commercial speech. But we hold that an advertiser's rights are adequately protected as long as disclosure requirements are reasonably related to the State's interest in preventing deception of consumers.[148]

The Court explicitly rejected the appellant's argument that disclosure requirements are subject to a "least restrictive means" analysis under which they must be struck down if there are other means by which the State's purposes may be serve. The Court explained that:

> Although we have subjected outright prohibitions on speech to such analysis, all our discussions of restraints on commercial speech have recommended disclosure requirements as one of the acceptable less restrictive alternatives to actual suppression of speech. Because the First Amendment interests implicated by disclosure are substantially weaker than those at stake when speech is actually suppressed, we do not think it appropriate to strike down such requirements merely because other possible means by which the State might achieve its purposes can be hypothesized. Similarly, we are unpersuaded by appellant's argument that a disclosure requirement is subject to attack if it is "under-inclusive" – that is, if it does not get at all facets of the problem it is designed to ameliorate. As a general matter, governments are entitled to attack problems piecemeal, save where their policies implicate rights so fundamental that strict

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145 *Id.*

146 *Id.* (citing *Virginia Pharmacy Board v. Virginia Citizens Consumer Council, Inc.*, 425 U.S 748 (1976) (ban on advertising prescription drug prices could not be justified by State's interest in promoting professionalism in pharmacists and noting that "[t]he First Amendment protects the advertisement because of the information of potential interest and value conveyed").

147 *Id.* (*citing In re R.M.J.*, 455 at 201. *Accord Central Hudson*, 447 U.S. at 565; *Bates*, 433 U.S. at 384; *Virginia Pharmacy Bd*, 425 U.S. at 772, n.24).

148 *Id.*

> scrutiny must be applied. The right of a commercial speaker not to divulge accurate information regarding his services is not such a fundamental right.[149]

2. A Recent Elaboration by the Supreme Court on *Central Hudson* and *Zauderer – Milavetz, Gallop & Milavetz, P.A. v. United States*

In *Milavetz, Gallop & Milavetz, P.A. v. United St*ates,[150] the Court relied on *Zauderer* in upholding a disclosure requirement that was enacted "to correct perceived abuses" that applied to the advertising of "debt relief agen[cies]," an identity term established by the statute and defined to encompass "any person who provides any bankruptcy assistance to an assisted person [i.e., consumer] in return for . . . payment . . . , or who is a bankruptcy petition preparer."[151]

The mandatory disclosure at issue required professionals that meet the statutory definition of a "debt relief agency" to disclose in advertisements promoting the bankruptcy services offered to the general public, the following or a "substantially similar statement": "We are a debt relief agency. We help people file for bankruptcy relief under the Bankruptcy Code."[152] The Court rejected the argument advanced by the regulated parties challenging the requirement that the disclosure requirement should be struck down under *Central Hudson,* agreeing with the government's argument that since the disclosure requirement is directed at misleading commercial speech, the disclosure requirement must be upheld under the "less exacting scrutiny described in *Zauderer*."[153] The effectively unanimous[154] Court offered the following further explanation:

> Noting that First Amendment protection for commercial speech is justified in large part by the information's value to consumers, the Court [in *Zauderer*] concluded that an attorney's constitutionally protected interest in *not* providing the required factual information is justified in large part by the information's value to consumers, [and] . . . concluded that an attorney's constitutionally protected interest in *not* providing the required factual information is 'minimal.' . . . Unjustified or unduly burdensome disclosure requirements offend the First Amendment by chilling protected speech, but 'an advertiser's rights are adequately protected as long as disclosure requirements are reasonably related to the State's interest in preventing deception of consumers.'[155]

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149 *Zauderer*, 471 U.S. at 673 n.14.

150 *Milavetz, Gallop & Milavetz, P.A. v. United St*ates, 559 U.S. 229 (2010)

151 *Id*. at 229 (citing section 101(12A) of the Bankruptcy Abuse Prevention and Consumer Protection Act of 2005 ("BAPCPA)).

152 *Id.* at 233.

153 *Id.* at 249.

154 Justice Sotomayor delivered the opinion of the court, in which Chief Justice Roberts, and Justices Stevens, Kennedy, Ginsburg, Breyer and Alito joined, and which Scalia and Thomas joined for certain parts.

155 *Milavetz* 559 U.S. at 249-50.

In upholding the disclosure requirements the statute imposed on "debt relief agenc[ies]" as they would be applied to the regulated parties in the case, the Court explained that the disclosure requirements shared "essential features" with those that were upheld in *Zauderer*.[156] Additionally, while recognizing that the regulated parties objected to using the statutorily defined term "debt relief agency," and would prefer to use the terms "attorney" or "law firm" to refer to themselves instead, the Court concluded that this nomenclature preference lacks any constitutional basis.[157] The Court found that the disclosures in *Milavetz* entail only an accurate statement identifying the advertiser's legal status and the character of the assistance provided, and they do not prevent [the regulated parties] . . . from conveying any additional information."[158]

3. Key Federal Circuit Court Decisions Related to Disclosure of Factual and Non-Controversial Information

As in *Zauderer* and *Milavetz*, restrictions on commercial speech involving the disclosure of factual and noncontroversial information concerning a product or service that is marketed to the public have also been upheld by lower courts. In *American Meat Institute v. USDA*, the Court of Appeals for the District of Columbia Circuit in an en banc decision upheld detailed country-of-origin labeling requirements for meat products on First Amendment grounds.[159] In doing so, the court held that the principles articulated in *Zauderer* for evaluating mandatory disclosure requirements apply not only when disclosures are designed to prevent deception, but apply more broadly to factual and uncontroversial disclosures intended to serve other government interests.[160] The regulations at issue in the case require the country-of-origin disclosure statement to specify not only the countr(ies) origin, but also the production step occurring in each country – that is, where the animal was born, raised and slaughtered (*e.g.*, "Born in Canada, Raised and Slaughtered in the United States").[161]

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156 *Id.* at 250. Specifically, in both cases, the challenged disclosures "are intended to combat the problem of inherently misleading commercial advertisements." *Id.*

157 *Id.* at 251-52 ("Milavetz offers no evidence to support its claim that the label [disclosure] is confusing. Because sec. 528 [of the statute] by its terms applies only to debt relief agencies, the disclosures are necessarily accurate to that extent: Only debt relief agencies must identify themselves as such in their advertisements. This statement provides interested observers with pertinent information about the advertiser's services and client obligations.").

158 *Id.* at. 250. The Court distinguished the disclosure requirements applied to debt relief agencies from the speech restrictions in *R.M.J.* that "prohibited attorneys from advertising their practice areas in terms other than those prescribed by the State Supreme Court and from announcing the courts in which they were admitted to practice." The Court noted that the *R.M.J.* decision emphasized that States retain authority to regulate inherently misleading advertisements, particularly through disclosure requirements. *Id.* at. 250-51.

159 *Am. Meat Inst. v. USDA*, 760 F.3d 18 (D.C. Cir. 2014) (en banc).

160 *Id.* at 22 ("All told, *Zauderer's* characterization of the speaker's interest in opposing forced disclosure of such information as 'minimal' seems inherently applicable beyond the problem of deception, as other circuits have found. To the extent that other cases in this circuit may be read as holding to the contrary and limiting *Zauderer* to cases in which the government points to an inherent interest in correcting deception, we now overrule them.") (citations omitted).

161 *Id.* at 21.

The court's First Amendment analysis began with an assessment of the adequacy of the government's interest motivating the country-of-origin labeling scheme. Based on the context and long-history of country-of-origin disclosure requirements to enable consumers to choose American-made products, the demonstrated consumer interest in extending the requirements through the challenged rule, and the individual health concerns and market impacts that can arise in the event of a foodborne outbreak in the absence of such labeling, the court concluded that the government interest motivating the detailed country-of-origin labeling rule for meat was a "substantial one."[162] The court's First Amendment analysis proceeded to assess the relationship between the government's substantial interest and the regulatory "means" for serving the "chosen ends."[163] In this regard, some courts in other circuits have characterized the standard for assessing disclosure requirements under *Zauderer* as constituting a more lenient rational basis standard than the standard that governs the assessment of other types of restrictions (*e.g.*, speech bans) under *Central Hudson.*[164] In contrast, in *American Meat Institute,* the court explained the alignment of the standards to be applied under *Zauderer* and *Central Hudson* as follows:

> Under *Central Hudson*, we would determine whether 'the regulatory technique [is] in proportion to [the] interest,' an inquiry comprised of assessing whether the chosen means 'directly advance[s] the state interest involved' and whether it is narrowly tailored to serve that end. *Central Hudson,* 447 U.S. at 564; *Fox,* U.S. at 480. *Zauderer's method of evaluating fit differs in wording, though perhaps not significantly in substance, at least on these facts.*
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> When the Supreme Court has analyzed Central Hudson's 'directly advance' requirement, it has commonly required evidence of a measure's effectiveness. *See Edenfield,* 507 U.S. at 770-71. But as the Court recognized in *Zauderer,* such evidentiary parsing is hardly necessary when the government uses a disclosure mandate to achieve a goal of informing consumers about a particular product trait, assuming of course that the reason for informing consumers qualifies as an adequate interest. 471 U.S. at 650; *see also Milavetz,* 559 U.S. at 249 (referring to *Zauderer* as providing for 'less exacting scrutiny'). *Zauderer,* like the doctrine of *res ipsa loquitur,* identifies specific circumstances where a party carries part of its evidentiary burden in a way different from the customary one. (Citations omitted). There, a plaintiff proves negligence by meeting the specified criteria (such as by proving the defendant's exclusive control over the agency causing the injury); here, by acting through a reasonably crafted disclosure mandate, the government meets its burden of showing that the mandate advances its interest in making the 'purely factual and uncontroversial information' accessible to the recipients. Of course, to match *Zauderer* logically, the disclosure mandated must relate to the good or service offered by the regulated party, a link that in *Zauderer* itself was inherent in the facts, as the disclosure mandate necessarily related to such goods or services. *See Zauderer,* 471 U.S. at 651 . . . . For purposes of this case, we need not decide on the precise scope or character of that relationship.

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162 *Id.* at 23.

163 *Id.* at 25.

164 *See, e.g., Nat'l Elec. Mfrs. Ass'n v. Sorrell,* 272 F.3d 104 (2d Cir. 2001).

> The self-evident tendency of a disclosure mandate to assure that recipients get the mandated information may in part explain why, where that is the goal, many such mandates have persisted for decades without anyone questioning their constitutionality. . . .[165]
>
> To the extent that the government's interest is in assuring that consumers receive particular information (as it plainly is when mandating disclosures that correct deception), the means-end fit is self-evidently satisfied when the government acts only through a reasonably crafted mandate to disclose 'purely factual and uncontroversial information' about attributes of the product or service being offered. In other words, this particular method of achieving a government interest will almost always demonstrate a reasonable means-ends relationship, absent a showing that the disclosure is 'unduly burdensome' in a way that 'chill[s] protected commercial speech,' *id.* at 651.
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> *Thus, to the extent that the preconditions to application of Zauderer warrant inferences that the mandate will 'directly advance' the government's interest and show a 'reasonable fit' between means and ends, one could think of Zauderer largely as 'an application of Central Hudson, where several of Central Hudson's elements have already been established*.[166]

In *American Meat Institute*, the court upheld the country-of-origin labeling requirements on First Amendment grounds under *Zauderer*, and in doing so found that the labeling requirements were neither "controversial" nor unduly burdensome. The court recognized that the mandatory disclosure requirements had evoked some objection from the regulated industry (*i.e.*, the term "slaughtered" apparently is less attractive to some members of the regulated industry than the term, "harvested," which the court found is also permitted by the rule). At the same time, the court suggested that such concerns about the innuendo that may be attached to particular terms do not rise to the level of "controversy" for First Amendment purposes where *the message* conveyed by the mandatory disclosure is itself factual and uncontroversial. The court explained:

> We . . . do not understand country-of-origin labeling to be controversial in the sense that it communicates a message that is controversial for some reason other than dispute about simple factual accuracy. *Cf. Nat'l Ass'n of Mfrs. v. SEC,* 748

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165 *Am. Meat Inst.*, 760 F.3d at 26 (citing other "routine disclosure mandates about product attributes, including, for instance, disclosures of fiber content, 16 C.F.R. pt. 303, care instructions for clothing items, 16 C.F.R. pt. 423, and listing of ingredients, 21 C.F.R. § 101.4").

166 *Id.* at 26-27 (emphasis added) (citing the Supplemental Brief filed by the American Meat Institute at 9). *See also id.* at 34 (Kavanaugh, concurring) ("The majority opinion properly does not equate *Zauderer* to mere rational basis review and properly insists that the mandatory disclosure here must meet all of the various *Zauderer* requirements. And the majority opinion and I agree on the following: To justify a compelled commercial disclosure, assuming the Government articulates a substantial governmental interest, the Government must show that the disclosure is purely factual, uncontroversial, not unduly burdensome and reasonably related to the Government's interest. In this case, as the majority opinion properly concludes, those stringent *Zauderer* fit requirements are met. The country-of-origin labeling requirement at issue here is purely factual, is not unduly burdensome, and as explained above is reasonably related to the Government's longstanding interest in supporting American farmers and ranchers.").

> F.3d at 371 (questioning but not deciding whether the information mandated was factual and uncontroversial). Leaving aside the possibility that some required factual disclosures could be so one-sided or incomplete that they would not qualify as 'factual and uncontroversial,' cf. *Nat'l Ass'n of Mfrs. v. NLRB,* 717 F.3d at 958 (describing one party's argument that disclosures were 'one-sided . . . favoring unionization'), country-of-origin facts are not of that type. AMI does not suggest anything controversial about *the message* that its members are required to express.[167]

The court further distinguished the country-of-origin labeling requirements from unconstitutional disclosure mandates that "require corporations to carry the messages of third parties, *where the messages themselves are biased against or expressly contrary to the corporation's views,"*[168] and from unduly detailed disclosure mandates that are so burdensome as to essentially operate as a restriction on constitutionally protected commercial speech.[169]

In *National Electrical Manufacturers Association v. Sorrell,*[170] in the face of a First Amendment challenge brought on behalf of the regulated industry, the Court of Appeals for the Second Circuit upheld a Vermont statute requiring manufacturers of some mercury-containing products, including fluorescent light bulbs, to label their products and packaging to inform consumers that their products contain mercury and, on disposal, should be recycled or disposed of as hazardous waste. In reliance on *Zauderer*[171], the court justified the distinction between the method for

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[167] *Id.* at 27 (emphasis added) ("Though [slaughter] seems a plain, blunt word for a plain, blunt action, we can understand a claim that 'slaughter,' used on a product of any origin, might convey a certain innuendo. But we need not address such a claim because the . . . rule allows retailers to use the term 'harvested' instead . . . and AMI has posed no objection to that."). *See also id.* at 34-35 (Kavanaugh, concurring) ("[R]egardless of how the 'uncontroversial' requirement might play out in other cases, the issue poses little difficulty here. Unlike the mandated disclosures at issue in *R.J. Reynolds* and *National Association of Manufacturers*, for example, a country-of-origin label cannot be considered controversial' given the factually straightforward, evenhanded, and readily understood nature of the information, as well as the historical pedigree of this specific kind of disclosure requirement. *Cf. National Association of Manufacturers,* 748 F.3d at 71 (disclosure requirement that in essence compelled 'an issuer to confess blood on its hands'); *R.J. Reynolds,* 696 F.3d at 1216-17 (disclosure requirements that compelled the display of 'inflammatory images' and constituted 'unabashed attempts to evoke emotion' and 'browbeat customers').

[168] *Id.* at 12 (citing *Pacific Gas & Electric Co. v. Public Utilities Comm'n,* 475 U.S. 1, 15-16 n.12 (1986) (order requiring utility to publish in billing envelopes any message from a particular group in effort to apportion "extra space" impermissibly required utility to espouse ideas of others)).

[169] *Id.* at 27 (citing *Ibanez v. Florida Department of Business and Professional Regulation,* 512 U.S. 136, 146-47 (1994) ("where a required disclaimer was so detailed that it 'effectively rule[d] out notation of the 'specialist' designation on a business card or letterhead, or in a yellow pages listing'").

[170] *Nat'l Elec. Mfrs. Ass'n v. Sorrell,* 272 F.3d 104 (2d Cir. 2001).

[171] *Id.* at page 114 n.6 ("Although we applied the *Central Hudson* test in *IDFA* [*v. Amestoy,* 92 F.3d 67 (2d Cir. 1996)] – which addressed a Vermont regulation requiring dairy producers to label dairy products derived from cows treated with recombinant Bovine Somatotropin (rBST) – our decision was expressly limited to cases in which a state disclosure requirement is supported by no interest other than the gratification of 'consumer curiosity.'… The disclosure statute at issue here, however, is based on Vermont's substantial interest in protecting human health and the environment from mercury poisoning. Moreover, because our decision in IDFA was predicated on the state's inability to identify a sufficient legitimate state interest, we did not reach the proper relationship between a disclosure regulation's means and its ends, the issue we face here."). *See also IDFA,* 92 F.3d at 72-73 ("We need

evaluating purely factual and uncontroversial disclosure requirements and outright prohibitions on commercial speech as follows:

> Commercial disclosure requirements are treated differently from restrictions on commercial speech because mandated disclosure of accurate, factual, commercial information does not offend the core First Amendment values of promoting efficient exchange of information or protecting individual liberty interests. Such disclosure furthers, rather than hinders, the First Amendment goal of the discovery of truth and contributes to the efficiency of the "marketplace of ideas."[172]

In contrast to the disclosure requirement at issue in *Zauderer*, the disclosures of mercury content and product disposal information required by the Vermont statute in *Sorrell* was not intended to prevent consumer confusion or deception, but rather to better inform consumers about the products they purchase. The court explained, "[a]lthough the overall goal of the statute is plainly to reduce the amount of mercury released into the environment, it is inextricably intertwined with the goal of increasing consumer awareness of the presence of mercury in a variety of products. Accordingly, we cannot say that the statute's goal is inconsistent with the policies underlying First Amendment protection of commercial speech . . . and the reasons supporting the distinction between compelled and restricted commercial speech."[173]

In upholding the Vermont disclosure requirements, the court found that Vermont's interest in protecting human health and the environment from mercury poisoning is a legitimate and significant public goal and the relationship between the regulatory means adopted to serve these government interests was sufficient to meet First Amendment standards. "The prescribed labeling would likely contribute directly to the reduction of mercury pollution, whether or not it makes the greatest possible contribution. It is probable that some mercury lamp purchasers, newly informed by the Vermont label, will properly dispose of them and thereby reduce mercury

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not address the controversy concerning the nature of the speech in question—commercial or political—because we find that Vermont fails to meet the less stringent constitutional requirements applicable to compelled commercial speech [under *Central Hudson*]. . . . As the district court made clear, Vermont 'does not claim that health or safety concerns prompted the passage of the Vermont Labeling Law,' but instead defense the statute on the basis of 'strong consumer interest and the public's 'right to know' . . . These interests are insufficient to justify compromising protected constitutional rights."); *id.* at 73 n.1 ("Vermont's sole expressed interest was, indeed, 'consumer curiosity.' The district court plainly stated that, 'Vermont takes no position on whether rBST is beneficial or detrimental. However, the district court explained, 'Vermon has determined that its consumers want to know whether rBST has been used in the production of their milk and milk products.' It is clear from the opinion below that the state itself has not adopted the concerns of the consumers; it has only adopted that the consumers are concerned. Unfortunately, mere consumer concern is not, in itself, a substantial interest."); *id.* at 73 ("We do not doubt that Vermont's asserted interest, the demand of its citizenry for such information, is genuine; reluctantly, however, we conclude that it is inadequate. We are aware of no case in which consumer interest alone was sufficient to justify requiring a product's manufacturers to publish the functional equivalent of a warning about a production method that has no discernable impact on the final product.").

[172] *Id.* at 113-14 (citing *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 501 (1996); *Zauderer*, 471 U.S. at 650-51)).

[173] *Id.* at 115.

pollution. By encouraging such changes in consumer behavior, the labeling requirement is rationally related to the state's goal of reducing mercury contamination."[174]

The court further observed the potentially wide-ranging implications of NEMA's First Amendment complaint challenging the mercury-related disclosure requirements. The court noted that "[i]nnumerable federal and state regulatory programs require the disclosure of product and other commercial information," citing examples including FDA regulation of nutrition labeling under FDCA section 403(q) among others.[175] The court's opinion concluded with this statement: "To hold that the Vermont statute is insufficiently related to the state's interest in reducing mercury pollution would expose these long-established programs to searching scrutiny by unelected courts. Such a result is neither wise nor constitutionally required."[176]

In *New York State Restaurant Ass'n v. New York City Board of Health,*[177] the Court of Appeals for the Second Circuit upheld a city law requiring certain restaurants to disclose the calorie content information on menus and menu boards on First Amendment grounds in a case brought on behalf of the regulated restaurants by the New York State Restaurant Association ("NYSRA"). The court evaluated the city law under *Zauderer,* which the court has construed as subjecting disclosure requirements in commercial speech to evaluation under a "rational basis test."[178] The court's evaluation of the disclosure requirements established by the city law observed that New York City had adopted the requirements in response to the "obesity epidemic" to (1) reduce consumer confusion and deception; and (2) to promote informed consumer decision-making so as to reduce obesity and the diseases associated with it."[179] The court proceeded to review the findings the city had made in adopting the requirements, including findings with respect to the increasing obesity rates in New York City, the links between obesity and excess caloric intakes including from restaurant foods, the links between distorted consumer perceptions concerning the calorie content of foods and unhealthy food choices, and the City's finding that by providing calorie information at the point-of-purchase, similar to that provided through FDA nutrition labeling requirements for packaged foods, the calorie information would help consumers make informed, healthier food choices.[180]

The court found that New York City was not alone in making these observations, and that the recent "Keystone Report" report commissioned by FDA had also concluded that obesity rates has risen to epidemic proportions, and obesity has been linked to eating out.[181] In addition, the

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174 *Id.*

175 *Id. Nat'l Elec. Mfrs. Ass'n,* 272 F.3d at 116.

176 *Id.*

177 *New York State Restaurant Ass'n v. New York City Board of Health,* 556 F.3d 114 (2d Cir. 2009).

178 *Id.* at 132 ("In light of *Zauderer,* this Circuit thus held that rules 'mandating that commercial actors disclose commercial information' are subject to the rational basis test." (citing *Nat'l Elec. Mfrs. Ass'n v. Sorrell,* 272 F.3d at 114-15)).

179 *Id.* at 134.

180 *Id.* at 134-36.

181 *Id.* at 135 (citing Keystone Ctr., *The Keystone Forum on Away-from-Home Foods: Opportunities for Preventing Weight Gain and Obesity* (2006)).

Keystone Report had found that "calorie information is most relevant to obesity prevention," and "restaurants should provide consumers with calorie information in a standard format that is easily accessible and easy to use" allowing consumers to view the information "when standing at a counter, while reviewing a menu board, in a car when reading a drive-through menu, or when sitting down at a table reviewing a menu."[182] The Keystone Report further stated that "[w]ithout nutrition information, consumers typically are unable to assess the caloric content of foods."[183] In response to this finding of the Keystone Report, the court said "we do not doubt [this statement] upon being informed, counter-intuitively, that a smoked turkey sandwich . . . contains 930 calories, more than a sirloin steak, which contains 540, or that 2 jelly-filled doughnuts . . . have fewer calories than a sesame bagel with cream cheese," citing evidence suggesting that "calories in restaurant items were almost two times more than what consumers expected."[184]

On these facts, the court held that, the calorie disclosure requirements satisfied the applicable constitutional standards and "do[] not violate . . . the First Amendment rights" of the regulated industry.[185] In addition, the court observed that NYSRA had not contended that the calorie information that must be disclosed is not "factual," they had claimed that the regulated industry members objected to communicating to their customers that calorie amounts should be prioritized among other nutrient amounts (*e.g.*, as opposed to Nutrition Facts, which placed calories into a different context). The court responded, "[h]owever, the First Amendment does not bar the City from compelling such 'under-inclusive' factual disclosures [where] . . . the City's decision to focus its attention on calorie amounts is rational.[186]

In *Pharmaceutical Care Management Ass'n v. Rowe,*[187] the Court of Appeals for the First Circuit upheld disclosure requirements that were imposed on pharmacy benefit managers (PBMs) under the Maine Unfair Prescription Drug Practices Act ("UPDPA"). The UPDPA law was enacted with the aim of placing the Maine health benefit providers (*e.g.*, health insurance providers) that rely on PBMs in a better position to determine whether their PBMs are acting against their interests, and correspondingly to help control prescription drug costs and increase access to prescription drugs.

The UPDPA imposes a number of requirements on those PBM's that choose to enter into contracts in Maine with health benefit providers, including with health insurance companies, the state Medicaid program, and employer health plans in the state. Under the UPDPA PBMs are required to act as fiduciaries for their clients (health benefit providers) and adhere to specific duties. Among these duties is the disgorgement of profits from self-dealing, and the disclosure to client-health benefit providers of conflicts of interest and certain of their financial arrangements with third parties. On behalf of PBMs, the Pharmaceutical Care Management Association ("PCMA") challenged the UPDPA disclosure requirements on First Amendment

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182 *Id*. at 136 (citing Keystone Report at pages 76, 77 and 80).

183 *Id*. (citing Keystone Report at page 68).

184 *Id*.

185 *Id*.

186 *Id*. at 134.

187 *Pharm. Care Mgmt. Ass'n v. Rowe,* 429 F.3d 294 (1st Cir. 2005) (per curiam).

grounds, arguing that they violate the First Amendment by compelling commercial speech as a condition of doing business in Maine. In upholding the UPDPA disclosure requirements, the court relied on *Zauderer*, emphasizing that the Supreme Court's holding had recognized that the "First Amendment protection [of] commercial speech is justified principally by the value to consumers of the information such speech provides," and a party faced with a disclosure requirement had only a minimal interest in withholding the information requested of him by law.[188] The court characterized the holding as providing that the regulated "party's rights are adequately protected 'as long as disclosure requirements are reasonably related to the State's interest in preventing deception of consumers."[189] Applying these principles, the court held that the UPDPA disclosure requirements did not run afoul of the First Amendment:

> PCMA's member PBMs only have a minimal interest in withholding the information the UPDPA requires from them, especially given Maine's interest in ensuring that its citizens receive the best and most cost effective health care possible. The information disclosed under the UPDPA will help the [covered health benefit providers] . . . that are responsible for paying for medications in Maine ensure that they and their customers are not adversely affected by the abuses and self-dealing of certain PBMs. Furthermore, we think it obvious that the UPDPA's disclosure requirements are "reasonably related" to Maine's interest in preventing deception of consumers and increasing public access to prescription drugs. As the district court noted, these disclosure requirements are "designed to create incentives within the market for the abandonment of certain practices that are likely to unnecessarily increase cost without providing any corresponding benefit to the individual whose prescription is being filled and that appear to be designed merely to improve a drug manufacturer's market share."[190]

The joint concurring opinion of Chief Judge Boudin and Judge Dyk on the First Amendment issues in *Rowe* offer an expanded statement of rationale supporting the court's holding in the case and constitutes the opinion of the court.[191] The opinion distinguishes the "routine" UPDPA disclosure requirements from the disclosure requirements of the kind that raise serious First Amendment concerns.

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188 *Id.* at 310 (citing *Zauderer*, 471 U.S. at 651).

189 *Id.*

190 *Id.* at 310. In upholding the UPDPA disclosure requirements on First Amendment grounds, the court rejected PCMA's argument that the PBM's interest in not disclosing the mandatory information was "acute" and not "minimal" in the context of the standard articulated in *Zauderer*, because the required disclosures "take their valuable property." *Id.* The court pointed out that the court had already rejected PCMA's separate claim that the UPDPA effects a "taking" of the PBM's property under the Fourth Amendment, and stated that "[w]e do not see how the situation is any different in the First Amendment context." *Id.*

191 *Id.* at 297 ("The panel unanimously affirms the district court's grant of summary judgment for defendant [the state] on all claims. On the ERISA preemption, due process, and Commerce Clause issues, the panel unanimously adopts Judge Torruella's reasoning [in the majority opinion he wrote]. As to the association standing, Takings Clause, and First Amendment issues, the joint concurring opinion of Chief Judge Boudin and Judge Dyk represents the opinion of the court.").

> PCMA's First Amendment claim is completely without merit. So-called 'compelled speech' may under modern Supreme Court jurisprudence raise a serious First Amendment concern where it effects a forced association between the speaker and a particular viewpoint. *See*, *e.g.*, *Wooley v. Maynard*, 430 U.S. 705 (1977) (requiring all New Hampshire drivers to display 'Liver Free or Die' on their license plates); *Miami Herald Publ'g Co. v. Tornillo,* 418 U.S. 241 (1974) (requiring newspapers to afford political candidates a right to reply to editorial critiques).
>
> What is at stake here, by contrast, is simply routine disclosure of economically significant information designed to forward ordinary regulatory purposes-in this case, protecting covered entities [health benefit providers (*e.g.*, health insurance providers)] from questionable business practices. *There are literally thousands of similar regulations on the books-such as product-labeling laws*, environmental spill reporting, accident reports by common carriers, SEC reporting as to corporate losses and (most obviously) the requirement to file tax returns to government units who use the information to the obvious disadvantage of the taxpayer.
>
> The idea that these thousands of routine regulations require an extensive First Amendment analysis is mistaken. *Zauderer* . . . makes clear "that an advertiser's rights are adequately protected as long as disclosure requirements are reasonably related to the State's interest in preventing deception of consumers…This test is so obviously met in this case as to make elaboration pointless."[192]While laws and regulations that mandate the disclosure of information that relates to a product or service and is factual and noncontroversial in nature have been upheld by the courts, disclosure requirements that reach beyond such facts compels a commercial speaker to associate with a particular viewpoint that is objectionable are subjected to searching First Amendment scrutiny.

4. Key Federal Circuit Court Decisions Related to Controversial and Non-Factual Disclosure Requirements

In *R.J. Reynolds Tobacco Company v. Food and Drug Administration,*[193] the U.S. Court of Appeals for the District of Columbia Circuit struck down FDA regulations implementing the Family Smoking Prevention and Tobacco Control Act which required cigarette packages to bear one of nine textual warnings, as well as color graphics depicting the negative consequences of smoking. The FDA regulations specified the nine images that would accompany the statutorily prescribed warnings and required the display of the National Cancer Institute's "Network of Tobacco Cessation Quitlines," which uses the telephone portal "1-800-QUIT-NOW." The statute required that the following textual warnings, accompanied by color graphics depicting the negative health consequences of smoking (to be selected by FDA) appear on product labels on a rotating basis:

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192 *Id.* at 316 (joint concurring opinion of J. Boudin and J. Dyk).

193 *R.J. Reynolds Tobacco Co. v. FDA*, 402 U.S. App. D.C. 438 (2012).

WARNING: Cigarettes are addictive;

WARNING: Tobacco smoke can harm your children

WARNING: Cigarettes cause fatal lung disease

WARNING: Cigarettes cause cancer

WARNING: Cigarettes cause strokes and heart disease

WARNING: Smoking during pregnancy can harm your baby

WARNING: Smoking can kill you

WARNING: Tobacco smoke causes fatal lung disease in nonsmokers[194]

FDA based its selection of the final set of nine images – one for each warning statement – on an 18,000-person internet-based consumer study it commissioned. The court explained that the FDA study divided respondents into two groups: a control group that was shown the new text in the format of the already established warnings (located on the side of the cigarette packages), and a separate treatment group that was shown the proposed graphic warnings, which included the new text, the accompanying graphic image, and the 1-800-QUIT-NOW number. Each group then answered questions designed to assess, among other things, whether the graphic warnings, as comparted to the text-only control, (1) increased viewers' intention to quit or refrain from smoking; (2) increased viewers' knowledge of the health risks of smoking or secondhand smoke; and (3) were "salient," which FDA defined to include effects as causing viewers to feel "depressed," "discouraged," or "afraid."[195]

During the rulemaking process, FDA received over a thousand comments relating to the evidence upon which FDA relied in selecting the nine graphic images to accompany the text warning statements. The court detailed the concerns that were raised concerning the limitations of the FDA study, and FDA's responses to these concerns.[196] In evaluating the cigarette

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194 *Id.* at 458 n.2 *(*citing Tobacco Control Act § 201, 15 U.S.C. § 1333 Note).

195 *Id.* at 442.

196 *Id.* at 443-44 ("Several comments – including comments from cancer researchers, nonprofits, and academics – criticized the single exposure study design, noting it prevented the government from assessing the long-term or actual effects of the proposed warnings. Two of these comments recommended that FDA conduct longitudinal research or post-market surveillance to assess actual long-term effects. . . . FDA conceded the study did not permit it to reach 'firm' conclusions about the 'long-term, real-world effects' of the proposed warnings, but claimed the existing scientific literature 'provides a substantial basis for our conclusion that the required warnings will effectively communicate the health risks of smoking, thereby encouraging smoking cessation and discouraging smoking initiation.' . . . Still other comments asserted that FDA's research study failed to provide evidence that the proposed warnings would actually affect smoking rates, significantly affect consumers' knowledge of the risks of smoking, or bring about actual behavior change. . . . But FDA disagreed, again relying on the 'substantial research' showing the effectiveness of similar graphic health warnings in other countries . . . Another comment asserted that the study's selection bias constituted a serious methodological flaw. Namely, participants were recruited from an internet panel and offered the opportunity to participate in an FDA-sponsored research study. . . . FDA avoided the substance of this argument by conceding that its study 'provides insight on the relative effectiveness of the various

disclosure requirements under the First Amendment, the court relied on the more searching standard articulated in *Central Hudson*, rather than the test that has been applied to uphold factual and noncontroversial disclosure requirements under *Zauderer* in the D.C. Circuit and other circuits, as discussed above. The court distinguished the cigarette disclosure requirements by explaining,

> [T]he graphic warnings do not constitute the type of 'purely factual and uncontroversial' information . . . to which the *Zauderer* standard may be applied. The disclosures approved in *Zauderer* and *Milavetz* were clear statements that were both indisputably accurate and not subject to misinterpretation by consumers. . . .
>
> FDA's images are a much different animal. FDA concedes that the images are not meant to be interpreted literally, but rather they symbolize the textual warning statements, which provide 'additional context for what is shown.' . . . Moreover, the graphic warnings are not 'purely' factual because – as FDA tacitly admits – they are primarily intended to evoke an emotional response, or at most, shock the viewer into retaining the information in the text warning. . . .
>
> In fact, many of the images do not convey any warning information at all, much less make a 'accurate statement' about cigarettes. For example, the images of a woman crying, a small child, and the man wearing a T-shirt emblazoned with the words 'I QUIT' do not offer any information about the health effects of smoking. And the '1-800-QUIT-NOW' number, when presented without any explanation about the services provided on the hotline, hardly sounds like an unbiased source of information. These inflammatory images and the provocatively-named hotline cannot rationally be viewed as pure attempts to convey information to consumers. They are unabashed attempts to evoke emotion (and perhaps embarrassment) and browbeat consumers into quitting . . . While none of these images are patently false, they certainly do not impart purely factual, accurate, or uncontroversial information to consumers. Consequently, the images fall outside the ambit of *Zauderer*.[197]

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warnings under consideration,' not on the 'absolute effects of the warnings in general.'. . . Some comments also criticized the lack of statistical evidence supporting FDA's belief that requiring cigarette packages to bear the graphic warnings would reduce smoking rates. . . . For example, the [regulated companies] . . . noted that the Canadian data revealed no statistically significant decline in smoking rates for adolescents and adults after the introduction of similar graphic warnings, which implied that the warnings were ineffective and that FDA's warnings would be ineffective as well . . . FDA summarily disagreed, stating that the images it selected would satisfy its 'primary goal,' which is to effectively convey the negative health consequences of smoking on cigarette packages and in advertisements,' which can help 'both to discourage nonsmokers from initiating cigarette use and to encourage current smokers to consider cessation.' . . . FDA also explained that the data from Canada did not indicate that the warnings had been ineffective, because other studies showed that the warnings had been 'effective at providing smokers with health information, making consumers think about the health effects of smoking, and increasing smokers' motivations to quit smoking.' . . .").

197 *Id.* at 450 (citations omitted).

In applying the *Central Hudson* test, the court relied on FDA's statements in the administrative record indicating that the primary objective of the regulation was to discourage nonsmokers from initiating cigarette use and to encourage current smokers to consider quitting, concluding that these interests were "substantial."[198] The court next considered whether the FDA had offered "substantial evidence" showing that the graphic warning requirements "directly advance[] the governmental interest asserted," to a "material degree."[199] The court emphasized that "[t]he requirement that a restriction directly advance the asserted interest is 'critical,' because without it, the government 'could [interfere with] commercial speech in the service of other objectives that could not themselves justify a burden on commercial expression."[200] The court found that "FDA ha[d] not provided a shred of evidence—much less the 'substantial evidence' required by the [Administrative Procedure Act] – showing that the graphic warnings will 'directly advance' its interest in reducing the number of Americans who smoke," and that the agency's Regulatory Impact Analysis itself "essentially concede[d] the agency lacks any evidence showing that the graphic warnings are likely to reduce smoking rates."[201]

In striking down the graphic cigarette warnings on First Amendment grounds, the court concluded,

> The graphic warnings represent FDA's attempt to level the playing field, not only by limiting the [regulated companies'] . . . ability to advertise, but also by forcing the [regulated companies] . . . to bear the cost of disseminating an anti-smoking message. . . . The First Amendment requires the government not only to state a substantial interest justifying a regulation on commercial speech, but also to show that its regulation directly advances that goal. FDA failed to present any data—much less the substantial evidence required under the [Administrative Procedure Act] – showing that enacting their proposed graphic warnings will accomplish the agency's stated objective of reducing smoking rates. The Rule thus cannot pass muster under *Central Hudson.*[202]

In *National Association of Manufacturers v. Securities and Exchange Commission,*[203] the U.S. Court of Appeals for the District of Columbia Circuit struck down a Securities and Exchange Commission ("SEC") rule that required companies that use gold, tantalum, tin, and tungsten originating in and around the Democratic Republic of the Congo ("DRC") to state on their websites that their products are "DRC conflict free" under certain conditions. The court explained that for many years, the DRC has experienced war and related humanitarian catastrophe, and the armed groups fighting the war have financed their operations by exploiting

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198 *Id*. at 450-51.

199 *Id*. at 451-52 (*citing Cent. Hudson, 447 U.S. at 566 and F. Bar. V. Went for It, Inc.,* 515 U.S. 618, 626 (1995)).

200 *Id*. at 452 (*citing Rubin v. Coors Brewing Co.,* 514 U.S. 476, 487 (1995)).

201 *Id*. at 452-53.

202 *Id*. at 455.

203 *Nat'l Ass'n of Mfrs. v. SEC,* 748 F.3d 359 (D.C. Cir. 2014), *aff'd, Nat'l Ass'n of Mfrs. v. SEC,* 800 F.3d 518 (D.C. Cir. 2015).

the regional trade in the above listed minerals, including extortion and direct management of the DRC mining operations, which are minimally regulated.[204]

In response to the Congo war, Congress devised certain provisions of the Dodd-Frank Wall Street Reform and Consumer Protection Act to require the SEC to issue regulations requiring firms using "conflict minerals" to investigate and disclose the origin of those minerals. These "conflict mineral" provisions require regulated companies to "disclose annually, whether [it's necessary] conflict minerals . . . did originate in the [Congo] or an adjoining country."[205] If the conflict minerals did originate in these countries, then the regulated company must submit a report to the SEC describing the "due diligence" measures undertaken to establish "the source and chain of custody" of the minerals and list "the products manufactured or contracted to be manufactured that [contain gold, tantalum, tin, or tungsten that] are not DRC conflict free."[206] For a product to qualify as "DRC conflict free," its necessary conflict minerals must not have "directly or indirectly finance[d] or benefit[ted] armed groups" in the DRC or an adjoining country.[207] The Act provides no *de minimis* exception from these requirements. The SEC implementing regulation elaborates upon these requirements, and specifies that if, after performing due diligence, a regulated company has reason to believe that its conflict minerals may have originated in the DRC or an adjoining country, then it must file a conflict minerals report with the SEC describing both its due diligence efforts, and listing the products that have "not been found to be 'DRC conflict free.'"[208]

In evaluating the "not been found to be DRC conflict free" disclosure requirement under the First Amendment, the court applied the *Central Hudson* standard, finding that *Zauderer* was inapplicable to this kind of disclosure requirement.

> [I]t is far from clear that the description at issue – whether a product is 'conflict free'—is factual and non-ideological. Products and minerals do not fight conflicts. The label 'conflict free' is a metaphor that conveys moral responsibility for the Congo war. It requires an issuer to tell consumers that its products are ethically tainted, even if they only indirectly finance armed groups. [A regulated company], including [one] who condemns the atrocities of the Congo war in the strongest terms, may disagree with that assessment of its moral responsibility. And it may convey that 'message' through 'silence.' . . . By compelling an issuer to confess blood on its hands, the statute interferes with that exercise of the freedom of speech under the First Amendment.[209]

The court contemplated the possibility that the strict scrutiny standards applicable to political speech may apply, but declined to decide that issue based on the court's conclusion that the

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204 *Id.* at 362.

205 *Id.* at 363.

206 *Id.* at 364.

207 *Id.* at 363.

208 *Id.* at 364.

209 *Id.* at 371 (citations omitted).

disclosure requirement did not survive First Amendment scrutiny under the less stringent *Central Hudson* test. The court's evaluation of the conflict minerals disclosure requirement under *Central Hudson* concluded that the SEC had failed to establish that there is a reasonable fit between the regulatory means and ends to be served by the regulation, having offered no evidence that less restrictive means would not work.[210] "The government cannot satisfy that standard if it presents no evidence that less restrictive means would fail."[211]

The court observed that the Association had suggested alternatives, such as having the SEC compile its own list of products that it believes are affiliated with the Congo War, based on information the regulated companies submit to the SEC. While the SEC rejected this concept as less effective than the disclosure requirement, the court noted that a centralized list compiled by the SEC in one place may be more convenient or trustworthy to investors and consumers and "[t]he commission has failed to explain why (much less provide evidence that) [such] . . . alternatives to regulating speech would be any less effective."[212]

In view of the court's subsequent decision in *American Meat Institute (*discussed above), the court revisited its 2014 decision in a rehearing en banc.*[213]* In upholding its prior decision, the court explained:

> By compelling [a regulated company] to confess blood on his hands, the statute interferes with [the] exercise of the freedom of speech under the First Amendment. . . . We see no reason to change our analysis in this respect. And we continue to agree with [the Association] that '[r]equiring a company to publicly condemn itself is undoubtedly a more 'effective' way for the government to stigmatize and shape behavior than for the government to have to convey its views itself, but that makes the requirement more constitutionally offensive, not less so.'"[214]

In *Entertainment Software Association v. Blagojevich,*[215] the U.S. Court of Appeals for the Seventh Circuit held that video game labeling and in-store brochure and signage placement requirements imposed on video game retailers under an Illinois statute violated the First Amendment, applying a strict scrutiny standard of review. The Illinois statute includes provisions known as the "Sexually Explicit Video Game Law" ("SEVGL"), which require video game retailers to place a four square-inch label with the numerals "18" on any "sexually explicit" video game, and to place brochures and a sign in their stores explaining the video game rating system.[216] The statute defines "sexually explicit"

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210 *Id.* at 372 (citing *Bd. Of Trs. v. Fox,* 492 U.S. 469, 480 (1989)).

211 *Id.* (citing *Sable Commc'ns v. FCC,* 492 U.S. 115, 128-32 (1989)).

212 *Id.* at 373.

213 *Nat'l Ass'n of Mfrs. v. SEC*, 800 F.3d 518 (D.C. Cir. 2015) (en banc).

214 *Id.* at 530.

215 *Entm't Software Ass'n v. Blagojevich*, 469 F.3d 641 (7th Cir. 2006).

216 *Id.* at 643.

video games in a manner that does not align with the industry standards.[217] The Entertainment Software Association challenged the law on behalf of video game manufacturers and retailers, who also are participants in the video game industry's ratings system (the Entertainment Software Rating Board) ("ESRB"), which rates games on the basis of the maturity/age for which the game is considered appropriate.[218]

In striking down the SEVGL disclosure requirements, the court rejected the State's argument that all of these disclosure requirements are like the mercury disclosure requirements that were upheld in *Sorrell* under the *Zauderer* standard.[219] With respect to the "18" sticker to be placed on the labels of "sexually explicit" video games, the court explained that the "State's definition of th[e] term [sexually explicit,] is far more opinion-based than the question of whether a particular chemical is within any given product."[220] The court further explained,

> Even if one assumes that the State's definition of 'sexually explicit' is precise, it is the State's definition – the video game manufacturer or retailer may have an entirely different definition of this term. Yet the requirement that the '18' sticker be attached to all games meeting the State's definition forces the game-seller to include this non-factual information in its message that is the game's packaging. The sticker ultimately communicates a subjective and highly controversial message – that the game's content is sexually explicit. This is unlike a surgeon general's warning of the carcinogenic properties of cigarettes, the analogy the State attempts to draw. For these reasons, we must apply strict scrutiny to the SEVGL's requirement that the '18' sticker be placed on all covered video games.[221]

In applying the "strict scrutiny" standard, the court concluded that the "18" sticker requirement was not "narrowly tailored" to the State's goal of ensuring that parents are informed of the

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217 *Id.* ("[T]hose that the average person, applying contemporary community standards would find, with respect to minors, is designed to appeal or pander to the prurient interest and depict or represent in a manner patently offensive with respect to minors, an actual or simulated sexual act or sexual contact, an actual or simulated normal or perverted sexual act or a lewd exhibition of the genitals or post-pubescent female breast.").

218 *Id.* at 643 n.2 ("[T]he [ESRB] ratings include EC (early child), E (everyone), E10+ (for those over age ten), T (teen), M (mature – for those over 17), and AO (adults only). Under the ESRB video games are also labeled with content descriptors such as 'strong sexual content.'").

219 *Id.* at 650-51 ("As the Supreme Court recently observed, some of its 'leading First Amendment precedents have established the principle that freedom of speech prohibits the government from telling people what they must say.' The Court has stated that where a statute '[m]andat[es] speech that a speaker would not otherwise make,' that statute 'necessarily alters the content of the speech.' Moreover, 'speech does not lose its protection because of the corporate identity of the speaker.' However, the First Amendment's guarantee of freedom from 'compelled speech' is not absolute. Particularly in the commercial arena, the Constitution permits the State to require speakers to express certain messages without their consent, the most prominent examples being warning and nutritional information labels. The Court has allowed states to require the inclusion of 'purely factual and uncontroversial information . . . as long as disclosure requirements are reasonably related to the State's interest in preventing deception of consumers.'").

220 *Id.* at 652.

221 *Id.*

sexually explicit content in games for reasons including the size of the sticker,[222] and the fact that the State had not demonstrated that it could not accomplish its goal through a broader educational campaign about the ESRB rating system that already was established.[223]

The court applied the strict scrutiny standard to the in-store brochure and signage requirements also, finding that the information required to be disclosed about the ESRB video game rating system was neither purely factual nor uncontroversial:

> The signs and the brochures are intended to communicate that any video games in the store can be properly judged pursuant to the standards described in the ESRB ratings. Moreover, the signs communicate endorsement of ESRB, a non-governmental third party whose message may be in conflict with that of any particular retailer. . . . [R]etailers affected by the SEVGL [disclosure requirements] have salespeople and their own information that communicate messages about the relative value of various games for buyers of different age groups. The State cannot force them to potentially compromise this message by inclusion of the ESRB ratings. The State is certainly entitled to communicate the good news about the ESRB to the public. Indeed, the [Association's] proposed alternative to the SEVGL [requirements] . . . would involve a broad educational campaign directed at the public about the ESRB system.[224]

5. Supreme Court Cases Addressing Limited Speech Bans

Finally, the Supreme Court has also considered government regulations that impose limited speech bans by prohibiting the use of certain claims or language unless accompanied by a disclosure that provides more information to modify the claim or language to remedy potential consumer deception. Many of these cases therefore address government regulations that impose both compelled speech requirements and partial speech bans, although they may decline to use such language. For example, in *Zauderer*, the requirement to disclose that potential clients might be liable for significant litigation costs even if their contingency fee lawsuits were unsuccessful operates as a limited speech ban as applied to advertisements for contingency fee cases that fail to include the required disclosure.[225] Notably, the Court in *Zauderer* distinguishes the disclosure requirement (and the related limited speech ban as it relates to contingency fee ads without the required disclosure) from the outright bans from soliciting business and from using accurate and non-deceptive illustrations in advertising.[226] Similarly, in *Milavetz*, the regulation upheld by the Court functions to ban advertisements for debt relief unless accompanied by a disclosure that the

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222 *Id.* ("Indeed, at four square inches, the '18' sticker *literally* fails to be narrowly tailored – the sticker covers a substantial portion of the box. The State has failed to even explain why a smaller sticker would not suffice. Certainly we would not condone a health department's requirement that half of the space on a restaurant menu be consumed by the raw shellfish warning. Nor will we condone the State's unjustified requirement of the four square-inch '18' sticker.").

223 *Id.* at 650-51.

224 *Id.* at 653.

225 *Zauderer*, 471 U.S. at 651.

226 *Id.*

entity creating the advertisement is a debt relief agency, and that there may be costs associated with any possible bankruptcy filing.[227] While simultaneously functioning as a compelled speech requirement and limited speech ban, the requirement passed First Amendment scrutiny because the government "retain[s] authority to regulate inherently misleading advertisements, particularly through disclosure requirements."[228]

The Supreme Court has also upheld limited speech bans outside of regulations requiring disclosures. For example, in *Friedman v. Rogers*, the Supreme Court upheld a law that prohibited optometrists from practicing under a trade name because, unlike more substantive commercial messages that are "self-contained and self-explanatory," the use of trade names by themselves had "no intrinsic meaning."[229] The Court acknowledged that trade names could eventually take on meaning after being "in use for some time," but rejected the argument that this use over time entitled them to First Amendment protection, holding that the names – by themselves – "convey[] no information about the price and nature of the services offered."[230]

B. The Actions Requested Comport with Well-Established First Amendment Principles

As discussed in detail above, while the Supreme Court has struck down bans of constitutionally protected commercial speech and other restrictions that fundamentally undermine free speech rights, the Court has distinguished more limited regulatory schemes that require the disclosure of factual and uncontroversial information concerning a product or service because such disclosure requirements "trench much more narrowly on an advertiser's interests than do flat prohibitions on speech."[231] Importantly, the disclosure requirements addressed in the Actions Requested would apply only to those manufacturers of non-dairy foods that have chosen to take a number of affirmative steps to manufacture and label a non-dairy food in such a manner that it substitutes for and resembles a reference standardized dairy food (*e.g.*, milk) and identifies the non-dairy substitute through the use of a standardized dairy term reserved for the reference standardized dairy food substituted for and resembled. Moreover, for the reasons discussed above, when the "imitation" labeling would be required, it would function to explicitly distinguish the non-dairy substitute from the reference standardized dairy food in a manner that is factually accurate and uncontroversial.

In addition, under both current section 101.3(e) and related FDA policies, and section 101.3(e) as amended by the Actions Requested, "Imitation" and "Substitute"/"Alternative" labeling disclosures can be readily avoided. Specifically, under current regulations, the "Imitation" disclosure is not required for non-dairy substitutes that are nutritionally equivalent to the reference standardized dairy food when they are identified using a distinctive name that complies with sections 101.3 and 102.5 and makes no use of a standardized dairy term (*e.g.*, "milk") in the

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227 *Milavetz*, 559 U.S. at 249-50.

228 *Id.* at 250.

229 *Friedman v. Rogers*, 440 U.S. 1, 11-13 (1979).

230 *Id.* at 12.

231 *Zauderer*, 471 U.S. at 651.

statement of identity of the non-dairy substitute (*e.g.*, "Rice Beverage"). Similarly, under related FDA policies, the use of the "Substitute"/"Alternative" labeling disclosure can be readily avoided for a nutritionally equivalent non-dairy substitute that complies with sections 101.3 and 102.5, and makes no use of a standardized dairy term (*e.g.*, "milk") in the statement of identity of the non-dairy substitute (*e.g.*, "Soy Beverage"). It is only when a manufacturer formulates and labels its non-dairy substitute food in a manner that causes the non-dairy food not only to substitute for and resemble a reference standardized dairy food (*e.g.*, milk) – but also to be identified in a manner that misappropriates the name of the reference standardized food (*e.g.*, "Hempmilk") that the "imitation" disclosure is required for nutritionally inferior substitutes, and the "substitute" or "alternative" disclosure is required for substitutes that are not nutritionally inferior. Examples of permissible approaches under current law include:

- "Hempmilk – Imitation Milk";
- "Hempmilk Fortified with [X nutrients (*i.e.*, nutrients added to achieve nutritional equivalence to milk)] – Milk Alternative" or "Milk Substitute"); and
- "Hemp Beverage" (no imitation, substitute, or alternative labeling disclosure required, regardless of nutritional inferiority compared to a dairy alternative).

Under essentially the same conditions, "imitation" and "substitute"/"alternative" disclosures would also be avoided under new section 101.3(e)(6), which places existing requirements under section 101.3(e) into the specific context of non-dairy substitutes for standardized dairy foods, and explicitly specifies requirements that already apply under FDCA sections 403(a) and 201(n) to prevent consumer deception and applies them in such a way that would permit "substitute"/"alternative" labeling for nutritionally inferior products in lieu of current shorthand "imitation" labeling under certain circumstances.

Specifically, new section 101.3(e)(6)(iii)-(vi) would specify that the "imitation" disclosure requirement would not apply to either nutritionally inferior or nutritionally equivalent non-dairy substitutes for standardized dairy foods that do not represent in the labeling of the non-dairy substitute that they are a form of "milk," "yogurt," "cheese," "ice cream," or another standardized dairy food, including through the use of a standardized dairy term in the statement of identity (*e.g.*, "Oat Beverage" rather than "Oat Milk"). In addition, for nutritionally inferior non-dairy substitutes, no representation could be made in labeling that suggests that the nutritionally inferior non-dairy substitute is nutritionally equivalent or superior to the reference standardized dairy food, or that suggests that using the nutritionally inferior non-dairy substitute food rather than the standardized dairy food would have insignificant or beneficial nutritional consequences for consumers.[232] (Notably, both of these representations would be false.)

For both nutritionally inferior and nutritionally equivalent non-dairy substitutes, the product labeling would be required to disclose material differences in the performance characteristics of the non-dairy substitute as compared to the reference standardized dairy food (*e.g.*, not suitable for frying) – a disclosure requirement that already is specified under FDCA sections 403(a) and

[232] Proposed 21 C.F.R. § 101.3(e)(6)(iii)(c).

201(n).[233] For nutritionally inferior non-dairy substitutes for standardized dairy foods that are not labeled with the "imitation" disclosure statement, the "nutritional inferiority" of the substitute would be required to be disclosed on product labels and in labeling in a prominent and conspicuous manner, in accordance with the requirements of FDCA sections 403(a) and 201(n), which prohibit false and misleading labeling and require the disclosure of material facts.[234]

In addition to the use of reference standardized foods when appropriately qualified through "imitation," substitute," or "alternative" disclosures, under new section 101.3(e)(6)(v), use of a standardized dairy term (*e.g.*, "milk") would be authorized for non-dairy substitutes that satisfy the requirements necessary to avoid the imitation labeling disclosure in the context of an *optional* "substitute"/"alternative" disclosure statement.[235] Examples:

- "Rice Beverage" or "Rice Beverage – Milk Substitute"; and
- "Coconut-Hemp Drink" or "Coconut-Hemp Drink – Milk Alternative."

The enforcement and regulatory Actions Requested by this petition are carefully tailored to advance FDA's indisputably substantial and longstanding interests in preventing consumer deception, protecting consumer health, and in the aggregate, thereby also protecting public health.[236] The enforcement initiative requested by this Petition does not ask the Agency to enforce a ban on constitutionally protected truthful and non-misleading speech. This Petition instead asks FDA to undertake enforcement actions against misbranded products that by their very nature violate no less than three core misbranding provisions of the Act – FDCA sections 201(n), 403(a) and 403(c)[237] – and are labeled in a false and misleading manner. False and misleading commercial speech is not entitled to protection under the First Amendment, and where the misleading nature of the targeted non-dairy substitute food can be remedied through factual disclosures that are already mandatory under the Act (*e.g.*, "Imitation [Milk]," "not suitable for frying"), such disclosure requirements easily satisfy the requirements of *Central Hudson*, *Zauderer*, and progeny.

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233 Proposed 21 C.F.R. §§ 101.3(e)(6)(iii)(d), 101.3(e)(6)(iv)(c).

234 Proposed 21 C.F.R. §§ 101.3(e)(6)(iii)(d).

235 The use of the "substitute" or "alternative" language here is optional because, unlike the examples highlighted above where a non-dairy substitute's statement of identity references a standardized dairy food the product is intended to substitute for and resemble , the statement of identity here does not reference a standardized dairy food (*e.g.*, "Rice Beverage" versus "Rice Milk").

236 21 C.F.R. 101.3(e)(4) (defining nutritional inferiority); *see also* FDA Fortification Policy, 21 C.F.R. § 104.20 ("The fundamental objective of this subpart is to establish a uniform set of principles that will serve as a model for the rational addition of nutrients to foods. The achievement and maintenance of a desirable level of nutritional quality in the nation's food supply is an important public health objective. The addition of nutrients to specific foods can be an effective way of maintaining and improving the overall nutritional quality of the food supply.").

237 *See also* 21 U.S.C. §§ 343(b) (providing that a food is misbranded if it is "offered for sale under the name of another food") and 343(g) (providing 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 by regulation under [FDCA section 401]" and fails to comply with such standard of identity).

Similarly, the adoption of the amendments to section 101.3(e), including the adoption of new section 101.3(e)(6), function to require "imitation" labeling in highly limited circumstances in which the term functions to qualify the use of a standardized dairy term that is being used to identify a non-dairy food which does not qualify for the use of the term under the applicable dairy standard of identity,[238] and yet has been formulated and labeled to substitute for and resemble the reference standardized dairy food. In this context, requiring the standardized term (*e.g.*, "milk") to be accompanied by the "imitation" disclosure (*e.g.*, "Hempmilk – Imitation Milk") functions to inform consumers that, despite appearances, the non-dairy substitute is fundamentally different from the reference standardized food, notwithstanding that its legally defined name has been borrowed for labeling and marketing purposes. Thus, like existing section 101.3(e)(1), the new provision does not ban the use of standardized terms as part of the statement of identity of non-dairy substitutes, but rather allows such use only under conditions in which the term is qualified to meet the requirements of FDCA section 403(c), consistent with the requirements of FDCA sections 403(a) and 201(n).[239]

In addition, as discussed above, under new section 101.3(e)(6), the "imitation" disclosure can be readily avoided through labeling practices that refrain from use of standardized dairy terms to identify non-dairy substitute foods (except as part of an optional "Substitute"/"Alternative" disclosure), disclose the nutritional inferiority and performance limitations of the substitute as compared to the reference standardized dairy food (to the extent applicable), and through the avoidance of false representations concerning the relative nutritional value and nutritional consequences of consuming the non-dairy substitute food. The proposed amendments to section 101.3(e) are carefully designed to provide factual and uncontroversial information to consumers

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238 Courts have held that the government can develop and enforce a legal definition for a particular term consistent with the First Amendment. *See, e.g.*, *Ass'n of Nat'l Advertisers v. Lungren*, 44 F.3d 726, 736 (9th Cir. 1994) (upholding California law defining permissible uses of environmental marketing claims such as "recycled" and biodegradable"); *Am. Food Inst. v. Matthews*, 413 F. Supp. 548, 555 (D.D.C 1976), *aff'd*, 555 F.2d 1059 (D.C. Cir. 1977) (rejecting argument that FDA lacks authority to create common or usual names for frozen heat and serve dinners and for seafood cocktails under the FDCA and the First Amendment).

239 See *Friedman v. Rogers*, 440 U.S. 1, 12-14 (1979)) (regulation prohibiting the practice of optometry under a trade name was permissible because it prevented misleading advertising and trade names "convey[] no information about the price and nature of the servicers offered"; because "there is a significant possibility that trade names will be used to mislead the public" and because "[t]he concerns of the Texas Legislature about the deceptive and misleading uses of optometrical trade names were not speculative or hypothetical, but were based on experience in Texas with which the legislature was familiar"). As in *Friedman*, the FDCA standard of identity authority was created specifically in response to deception and public health issues that emerged under the previous version of the Act, and are intended to address not only possible deception related to the identity of a food, but the nutritional profile, functional uses, and characterizing properties of the food. The FDCA goals, therefore, are more far-reaching than the issues considered by courts in false advertising challenges to product names for certain non-dairy, plant-based substitutes. *See, e.g.*, *Gitson v. Trader Joe's Co.*, No. 13-CV-01333-WHO, 2013 U.S. Dist. LEXIS 144917, at *2 (N.D. Cal. Oct. 4, 2013). In *Gitson*, the court found that the soy milk product's label "makes it impossible for a "reasonable consumer [to] believe that Organic Soy Milk is cow's milk," but declined to discuss the broader issues that form the basis for FDA's food standard authority (*i.e.*, the false equivalencies presented by use of a reference standardized food term as part of the statement of identity for a substitute product intended to substitute for and resemble that reference food).

in order to prevent consumer deception, protect consumer health through informed food choices, and in the aggregate, thereby also protect public health.[240]

The enforcement and regulatory Actions Requested by this petition are readily justified on First Amendment grounds, and are easily distinguishable from the commercial speech bans that have been invalidated by the Court, including those considered in *Central Hudson*,[241] *Bolger*,[242] *R.M.J.*,[243] *Bates*,[244] and *Western States*.[245] Instead, they resemble the many instances where courts have upheld disclosure requirements that seek to provide consumers with useful factual and uncontroversial information related to a product or service.[246] And to the extent that the Actions Requested may have the potential to be conceptualized as effectuating a speech ban with respect to the use of standardized dairy terms to name non-dairy substitutes, this would be at odds with the facts and applicable case law. The Actions Requested are more accurately cast as disclosure requirements – permitting the use of standardized dairy terms under conditions in

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[240] *Am. Meat Inst. v. USDA*, 760 F.3d 18 (D.C. Cir. 2014) (en banc) ("Leaving aside the possibility that some required factual disclosures could be so one-sided or incomplete that they would not qualify as "factual and uncontroversial," country-of-origin facts are not of that type. AMI does not suggest anything controversial about the message that its members are required to express."). The proposed regulation here can also be distinguished from the law invalidated in *Ocheesee Creamery LLC v. Putnam*, 851 F.3d 1228 (11th Cir. 2017), which addressed a creamery's challenge to Florida's restriction on use of the term "skim milk." That case involved natural milk products where fat had been removed from whole milk and therefore almost all Vitamin A – a fat soluble vitamin – was also removed. *Id.* Florida law prohibits use of the term "skim milk" unless the manufacturer restores vitamin A to the levels present in whole milk, so the manufacturer could not reference "skim milk" in the statement of identity in any capacity. *Ocheesee* offered language such as "PASTEURIZED SKIM MILK, NO VITAMIN A ADDED" or "PASTEURIZED SKIM MILK, MOST VITAMIN A REMOVED BY SKIMMING CREAM FRON MILK," but the state again refused to allow any reference to the term "skim milk" without fortification. That law and the state's related enforcement approach is easily distinguishable from the proposed regulation here, which rather than absolutely prohibit reference to standardized dairy terms, permits references when appropriately qualified to ensure that the use is not false or misleading. The regulation in *Ocheesee* also addressed a product that was, at one point, "milk," but that had been nutritionally modified to remove fat. Contrastingly, the regulations here only address foods that wish to use a standardized dairy food as part of the statement of identity for a non-dairy, plant-based substitute food that is intended to substitute for and resemble the reference food but that does not contain the reference food as a major ingredient in the food. Such a use has no "intrinsic meaning" and is thus inherently misleading under *Central Hudso*n and *Friedman*, unlike the use of "milk" to describe the product in *Ocheesee*.

[241] *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 564 (1980) (striking down regulation of New York Public Service Commission which completely banned an electric utility from advertising to promote the use of electricity because the state's interconnected utility system did not have sufficient fuel stocks or sources of supply to meet all customer demands for the winter).

[242] *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60 (1983) (holding that law prohibiting mailing of unsolicited advertisements for contraceptives violates First Amendment).

[243] *In re R.M.J.*, 455 U.S. 191 (1982) (holding that state rule that completely banned advertising of certain types of attorney specializations in attorney advertising violates First Amendment).

[244] *Bates*, 433 U.S. 384 (striking down complete ban on attorney advertising).

[245] *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 371 (2002) (striking down ban on advertising or promoting the compounding of drugs).

[246] *See, e.g., Zauderer v. Office of Disciplinary Counsel of Supreme Court*, 471 U.S. 626 (1985); *Milavetz, Gallop & Milavetz, P.A. v. United St*ates, 559 U.S. 229 (2010); *Am. Meat Instit. v. USDA*, 760 F.3d 18 (D.C. Cir. 2014) (en banc).

which they are qualified by descriptors (*e.g.*, "imitation," "substitute"/"alternative") that are factual and uncontroversial – conditions that have been found to easily pass First Amendment muster.[247] The Supreme Court's rationale in *Zauderer* applies equally here: the Actions Requested do not "attempt to prevent . . . conveying information to the public; [they] only require[] them to provide somewhat more information than they might otherwise be inclined to present."[248]

1. The Actions Requested require disclosures of factual and uncontroversial information in limited circumstances consistent with the First Amendment.

Importantly, rather than compel subjective and opinion-based statements,[249] or require images or words intended to shock and manipulate consumers,[250] the disclosure requirements sought to be enforced and codified by the Actions Requested are factual and uncontroversial and are intended to equip consumers with material information that can be used to inform consumer choice. Such disclosures have been consistently upheld under the First Amendment.[251]

Under both current FDA regulations and policies and those that would result from the Actions Requested by this petition, the "imitation" disclosure statement that is and would continue to be required when a manufacturer formulates and labels a nutritionally inferior non-dairy food in a manner that substitutes for and resembles a standardized dairy food – that is, imitates the standardized dairy food – and then borrows the name of the standardized food being imitated for labeling and marketing purposes. Under the conditions in which the "imitation" disclosure is required, it functions as an adjective to qualify the name of the food by conveying the factual and uncontroversial information that the non-dairy food is only an "imitation" of the referenced standardized food – not the food (*e.g.*, milk) that actually qualifies for the standardized term, (despite appearances and the misappropriation of the standardized name *(e.g.*, "milk")).

Indeed, the current Oxford Dictionary defines "imitation" to mean "[a] thing intended to simulate or copy something else."[252] When "imitation" is used as an adjective – as here – under the

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247 *See, e.g.*, *Milavetz* at 251-52; *Zauderer v. Office of Disciplinary Counsel of Supreme Court*, 471 U.S. 626 (1985); *Milavetz, Gallop & Milavetz, P.A. v. United St*ates, 559 U.S. 229 (2010); *Am. Meat Inst. v. USDA*, 760 F.3d 18 (D.C. Cir. 2014) (en banc); *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104 (2d Cir. 2001); *N.Y. State Rest. Ass'n v. N.Y.C. Bd. of Health*, 556 F.3d 114 (2d Cir. 2009).

248 *Zauderer*, 471 U.S. at 650.

249 *Entm't Software Ass'n v. Blagojevich*, 469 F.3d 641 (2006) ("The sticker ultimately communicates a subjective and highly controversial message – that the game's content is sexually explicit.")

250 *RJ Reynolds*, 402 U.S. App. D.C. at 450.

251 *See, e.g.*, *Zauderer v. Office of Disciplinary Counsel of Supreme Court*, 471 U.S. 626 (1985); *Milavetz, Gallop & Milavetz, P.A. v. United St*ates, 559 U.S. 229 (2010); *Am. Meat Instit. v. USDA*, 760 F.3d 18 (D.C. Cir. 2014) (en banc); *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104 (2d Cir. 2001); *N.Y. State Rest. Ass'n v. N.Y.C. Bd. of Health*, 556 F.3d 114 (2d Cir. 2009).

252 Merriam-Webster Dictionary (https://www.merriam-webster.com/dictionary/imitation) (last visited on December 20, 2018). At the time the imitation labeling requirements were established in FDCA section 403(c) through the enactment of the 1938 Act, the meaning of the term, "imitation," when used as an adjective (*e.g.*, "imitation milk"), had essentially the same meaning that it has today. *See* Webster's New International Dictionary

required conditions of use, the term means "resembling something else that is usually genuine and of better quality: not real."[253] For example, a nutritionally inferior hemp-based beverage that is identified using the term, "milk" (*e.g.*, "Hempmilk") would be required to include "Imitation Milk" in the statement of identity of the product (*e.g.*, "Hempmilk – Imitation"). As the "Hempmilk" example illustrates, the mandatory inclusion of the "imitation milk" disclosure in the statement of identity provides accurate, factual material information about the basic nature of the substitute food to consumers conveying that the food is imitation milk – a beverage that resembles milk but does not possess all of the qualities of milk (*e.g.*, the food is nutritionally inferior to standardized milk, at a minimum).

The "substitute"/"alternative" disclosure statement also would constitute factual and uncontroversial information that functions to distinguish a non-dairy substitute from the reference standardized dairy food it substitutes for and resembles under the conditions that a manufacturer would opt to use the disclosure. "Substitute" is defined as "a person or thing that takes the place or function of another" and can be used as either a noun or adjective.[254] "Alternative" is defined as "offering or expressing a choice" when used as an adjective or "a proposition or situation offering a choice between two or more things only one of which may be chosen" when used as a noun.[255] The "alternative" and "substitute" disclosure requirements constitute factual and uncontroversial descriptions of the labeled non-dairy substitute for a reference standardized dairy food. As discussed above, under section 101.3(e) as amended by the Actions Requested, a standardized dairy term would be permitted in the statement of identity for a non-dairy substitute when combined with the terms "substitute" and "alternative" to distinguish the non-dairy substitute from the reference food the substitute has been intentionally formulated and labeled to substitute for and resemble (*e.g.*, "Hempmilk Fortified with [X nutrients (*i.e.*, nutrients added to achieve nutritional equivalence to milk)] – Milk Alternative").

The amendments to Section 101.3(e) proposed by the Actions Requested would not only permit nutritionally equivalent non-dairy substitutes for standardized dairy foods to use the "substitute"/ "alternative" disclosure nomenclature, but would allow this nomenclature to be used for nutritionally inferior non-dairy substitutes when the product's nutritional inferiority and performance limitations (*e.g.*, "not suitable for frying") compared to the reference standardized dairy food are disclosed explicitly, prominently, and conspicuously on product labels and in labeling.[256] While current "imitation" labeling requirements are readily justified on First Amendment grounds for the same reasons discussed herein, the amendments to section 101.3(e) proposed by the Actions Requested would increase the flexibility of the disclosure requirements, providing two disclosure options: (1) continue to use the shorthand "imitation" disclosure to

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of the English Language (second ed. 1937) (defining "imitation" to mean "[s]imulating something superior, esp. something more costly; as *imitation* lace.").

253 Merriam-Webster Dictionary (https://www.merriam-webster.com/dictionary/imitation) (last visited on December 20, 2018).

254 Merriam-Webster Dictionary (https://www.merriam-webster.com/dictionary/substitute) (last visited on January 16, 2019).

255 Merriam-Webster Dictionary (https://www.merriam-webster.com/dictionary/alternative) (last visited on January 16, 2019).

256 See Proposed 21 C.F.R. § 101.3(e)(6)(iii)(b)-(d).

convey to consumers that the product substitutes for and resembles the reference standardized dairy food but is nutritionally inferior to that food; or (2) instead use the "substitute/"alternative" nomenclature combined with explicit disclosures of material distinctions between the substitute and standardized food, including the product's nutritional inferiority and performance limitations.

Under either approach, the use of the "imitation," "alternative," or "substitute" language constitutes a factual and uncontroversial disclosure, as are the explicit disclosures of nutritional inferiority (based on essential nutrient content of the foods) and performance limitations (*e.g.*, "not suitable for frying"). These disclosures are of the same factual and uncontroversial nature as disclosure requirements that have been previously upheld by the courts.[257]

Moreover, in contrast to the factual and uncontroversial disclosures that have been upheld,[258] the disclosures at issue here can be readily avoided. Under the conditions provided by the Actions Requested, for manufacturers that adopt distinctive names for their non-dairy substitutes that comply with the requirements of sections 101.3 and 102.5 and avoid the misappropriation of standardized dairy terms in naming their non-dairy substitutes, there is no requirement that "imitation" or "substitute"/"alternative" disclosures appear in the labeling for their non-dairy substitutes. There are countless examples of non-dairy substitutes that have long adhered to this labeling practice, successfully avoiding "imitation," and "substitute/alternative" disclosure requirements under existing FDA policies (*e.g.*, rice beverages, non-dairy coffee creamers).

While the "imitation," and "substitute"/"alternative" disclosures, when applicable under the Actions Requested, may lack appeal for some manufacturers, these disclosures are necessary only when the name of the reference standardized food has been misappropriated to promote a non-dairy substitute, and any lack of marketing appeal does not cause these disclosures to become either non-factual or controversial for First Amendment purposes.[259] Unlike the compelled display of "inflammatory images" that constituted "unabashed attempts to evoke emotion" and "browbeat consumers" into quitting smoking,[260] or the compelled disclosure of whether a particular mineral had "not been found to be DRC conflict free" based on whether the mineral originated in the Democratic Republic of Congo or an adjoining country,[261] the

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257 *Zauderer* 471 U.S. at 626; *Milavetz*, 559 U.S. at 229; *Am. Meat Inst.*, 760 F.3d at 18; *Nat'l Elec. Mfrs. Ass'n*, 272 F.3d at 104; *N.Y. State Rest. Ass'n,* 556 F.3d at 114.

258 *See, e.g., Am. Meat Inst.*, 760 F.3d at 18 (requiring detailed country of origin labeling for all meat products); *Nat'l Elec. Mfrs. Ass'n*, 272 F.3d at 104 (requiring mercury warning);.*N.Y. State Rest. Ass'n,* 556 F.3d at 114 (requiring calorie information for restaurant menus).

259 *Am. Meat Inst.*, 760 F.3d at 18 ("AMI does not disagree with the truth of the facts required to be disclosed, so there is no claim that they are controversial in that sense").

260 *R.J. Reynolds*, 696 F.3d at 1216-17.

261 *Nat'l Ass'n of Mfrs. v. SEC*, 409 U.S. App. D.C. 210, 222, 748 F.3d 359, 371 (2014) ("At all events, it is far from clear that the description at issue—whether a product is 'conflict free'—is factual and non-ideological. Products and minerals do not fight conflicts. The label 'conflict free' is a metaphor that conveys moral responsibility for the Congo war. It requires an issuer to tell consumers that its products are ethically tainted, even if they only indirectly finance armed groups. An issuer, including an issuer who condemns the atrocities of the Congo war in the strongest terms, may disagree with that assessment of its moral responsibility. And it may convey that 'message'

"imitation" and "substitute"/"alternative" disclosures here are factual and do not convey a subjective view or assign "moral responsibility" to regulated companies based on subjective, ideological criteria.[262] The disclosure requirements at issue here closely align with the features of other factual disclosure requirements that have been contested but upheld under the First Amendment.[263]

Notably, courts have recognized that parties subject to a disclosure requirement may object to the particular nomenclature prescribed for disclosing the required factual information, but such objections do not render a disclosure requirement to be non-factual or controversial.[264] For example, in *American Meat Institute v. USDA*, the D.C. Circuit Court of Appeals sitting en banc recognized that mandatory country of origin disclosure requirements evoked some objection from the regulated industry based on the phrasing (*i.e.*, the term "slaughtered" apparently is less attractive to some members of the regulated industry than the term, "harvested," which the court found is also permitted by the rule). At the same time, the court suggested that such concerns about the innuendo that may be attached to particular terms do not rise to the level of "controversy" for First Amendment purposes where the message conveyed by the mandatory disclosure is itself factual and uncontroversial. The court explained:

> We . . . do not understand country-of-origin labeling to be controversial in the sense that it communicates a message that is controversial for some reason other than dispute about simple factual accuracy. Leaving aside the possibility that some required factual disclosures could be so one-sided or incomplete that they would not qualify as "factual and uncontroversial," country-of-origin facts are not of that type. AMI does not suggest anything controversial about the message that its members are required to express.[265]

Similarly, in *Milavetz*, the Court rejected plaintiff's argument that the term "debt relief agency" was "confusing and misleading" because "[t]his contention amounts to little more than a preference on Milavetz's part for referring to itself as something other than a 'debt relief agency'-*e.g.*, an attorney or a law firm" and "[f]or several reasons, [the court] conclude[d] that this preference lacks any constitutional basis."[266] And in *New York State Restaurant Association*, the court rejected an argument that calorie disclosure requirements violated the First Amendment because they were required in isolation, rather than as part of a broader Nutrition Facts style disclosure, instead holding that "the First Amendment does not bar the City from compelling

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through 'silence.' By compelling an issuer to confess blood on its hands, the statute interferes with that exercise of the freedom of speech under the First Amendment.") (citations omitted).

262 *Id.*

263 *Zauderer* 471 U.S. at 626; *Milavetz*, 559 U.S. at 229; *Am. Meat Inst.*, 760 F.3d at 18; *Nat'l Elec. Mfrs. Ass'n*, 272 F.3d at 104;.*N.Y. State Rest. Ass'n,* 556 F.3d at 114.

264 *Milavetz*, 559 U.S. at 251; *see also N.Y. State Rest. Ass'n,* 556 F.3d at 134 (rejecting argument that calorie disclosures could not be required in isolation rather than as part of broader Nutrition Facts disclosure because "the First Amendment does not bar the City from compelling such 'under-inclusive' factual disclosures").

265 *Am. Meat Inst.*, 760 F.3d at 27.

266 *Milavetz*, at 251-52.

such 'under-inclusive' factual disclosures."[267] Along the same lines, while some manufacturers of non-dairy substitutes for standardized dairy foods may wish to employ nomenclature other than "imitation" or "substitute"/"alternative," the mere objection to the prescribed nomenclature does not render the disclosure non-factual or controversial for First Amendment purposes.[268] As with "imitation" disclosure requirements, "substitute" and "alternative" disclosure requirements constitute factual and uncontroversial characterizations of products intended to substitute for and resemble dairy products that are referenced in the product's statement of identity.

2. The effects of the Actions Requested on commercial speech are carefully tailored to address important government interests

The Actions Requested are carefully tailored to only impose disclosure requirements in the limited instances discussed in Section IV.A where a manufacturer of a non-dairy substitute food that substitutes for and resembles a standardized dairy food references that standardized dairy food as part of its statement of identity. By carefully circumscribing the applicability of the disclosure requirements to these highly limited contexts, the Actions Requested align with First Amendment principles requiring a proportionate relationship between the impact on free speech rights and the governmental interests asserted.

As discussed above in Section I.B, FDA authority to establish and prescribe standards of identity is grounded in important consumer protection and public health goals. Indeed, the food standard provisions were adopted as part of the Act in 1938 in direct response to the consumer protection failures of the 1906 Act which stemmed from the absence of food standards that would provide benchmarks and a mechanism by which new food products made in the semblance of traditional foods were equivalent to the traditional foods, or were wholly distinct and different foods, or whether the new foods amounted to diluted or otherwise economically adulterated form of the traditional food.[269] The standards and related requirements were therefore necessary to address "the proliferation of cheap or debased foods" and establish compositional benchmarks for comparison to protect against detrimental public and consumer health consequences from consumption of cheap or debased foods.[270] The food standard provisions were later used in conjunction with the NLEA authority to authorize nutritionally modified standardized foods that protected standards of identity by limiting their use to clearly defined situations where the food

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267 *N.Y. State Rest. Ass'n,* 556 F.3d at 134.

268 *Milavetz*, at 251-52. It is also worth emphasizing that the requirements here simply require the manufacturer to identify the product as defined by regulation, and thus are by their very nature factual and uncontroversial. *Id*. ("Because sec. 528 [of the statute] by its terms applies only to debt relief agencies, the disclosures are necessarily accurate to that extent: Only debt relief agencies must identify themselves as such in their advertisements. This statement provides interested observers with pertinent information about the advertiser's services and client obligations.").

269 60 Fed. Reg. 67,493-67,494 (Dec. 29, 1995); *see also* Ruth deforest Lamb, AMERICAN CHAMBER OF HORRORS: THE TRUTH ABOUT FOOD AND DRUGS, 149-173,(1936) (describing the difficulties the Agency faced prior to the 1938 Act in targeting misleading, cheap and debased foods).

270 *Id.*

was fundamentally the same (*i.e.*, still comprised of the same major ingredients) but had been nutritionally modified to achieve public health benefits.[271]

FDA's establishment of nutritional benchmarks and standards of identity, along with its policies on fortification, have played a vital role in the reduction of serious nutritional deficiencies and related diseases and promoting public health, as discussed above.[272] By limiting use of standardized terms as part of the statement of identity for a substitute food that intended to substitute for and resemble a reference standardized food to defined circumstances, the Agency has prevented consumer deception, protected consumer health, and protected public health. At the same time, through use of its NLEA authority, FDA has continued to stimulate innovation in both standardized foods and non-standardized substitutes for standardized foods, provided they are named in such a manner that does not conceal the basic nature, nutritional profile, functional uses, and characterizing properties of the food.[273]

The disclosure requirements sought to be enforced and codified under the Actions Requested will advance these same goals by establishing and enforcing nutritional standards for dairy products and ensuring that material facts related to the nutritional density and quality of non-dairy substitute products are also disclosed. The disclosure requirements also address significant consumer deception risks that are presented when substitute food products are positioned as equivalent or superior to traditional food counterparts when they are not.[274] These consumer deception issues can in turn present risks to consumer health when consumers rely on misleading product labeling in making food choices that undermine the nutritional quality of their diets, and make it more difficult to achieve adequate intakes of essential nutrients.

In sum, while it is well-established that commercial speech is entitled to protection under the First Amendment, it is equally well-established that regulations that compel factual and uncontroversial information to help consumers make informed decisions comport with First Amendment requirements. The speech effects of the Actions Requested have been carefully

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271 *See supra* Section I.B.3.

272 *Guidelines on food fortification with micronutrients, World Health Organization, Food and Agricultural Organization of the United Nations* (2006), available at: https://www.who.int/nutrition/publications/guide_food_fortification_micronutrients.pdf.

273 *See supra* Section I.B.3.

274 *See, e.g.*, Food Standards: Requirements or Substitute Foods Named by Use of a Nutrient Content Claim and a Standardized Term, 56 Fed. Reg. at 60,520 (Nov. 27, 1991) ("FDA believes that replacing the milkfat in sour cream with vegetable oil to make a product labeled as 'cholesterol free sour cream' would be misleading because consumers expect sour cream to be a dairy product."); Substitutes for Milk, Cream, and Cheese; Withdrawal of Proposed Standards of Identity, 48 Fed. Reg. at 37,667 (Aug. 19, 1983) ("A food made in semblance of a milk, cream, or cheese product will be deemed to be an imitation and thus subject to the requirements of section 403(c) of the Federal Food, Drug, and Cosmetic Act if it is nutritionally inferior to the milk, cream, cheese, or cheese product simulated. If it is not nutritionally inferior, it must bear a common or usual name that complies with the provisions of 21 CFR 102.5 which is not false or misleading in any particular, or, in the absence of an existing common or usual name, an appropriately descriptive name which is not false or misleading. To ensure that the name of a substitute food is not misleading, the name should ordinarily not include the name of a product subject to a standard of identity unless (1) it complies with the standard of identity, or (2) it is nutritionally inferior to the food simulated and is labeled with the term 'imitation.'"); *see also supra* Section I.B-I.C.

tailored such that they apply in limited contexts where manufacturers of non-dairy substitutes have affirmatively elected both to formulate and label a product as a substitute for a standardized dairy food, and to explicitly reference the standardized dairy food that is substituted for and resembled as part of the statement of identity. For decades, and in response to well-documented consumer deception and public health risks, FDA has held that such misleading references do not align with its mission to protect consumers and thereby public health. The Actions Requested by this petition – to enforce these longstanding disclosure requirements in the narrow set of described circumstances to provide consumers with factual and uncontroversial information about a food – fall well within the permissible boundaries of First Amendment regulation. Any suggestion otherwise would raise fundamental questions about a host of other regulatory schemes requiring everyday disclosures like ingredients and nutrition facts.

PART C – ENVIRONMENTAL IMPACT

This petition is categorically excluded from the requirement for an environmental assessment or environmental impact statement under 21 C.F.R. § 25.30(k).

PART D – ECONOMIC IMPACT

Information on the economic impact of the petition will be provided upon request.

PART E – CERTIFICATION

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

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