



March 12, 2019

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir/Madam:

Congress first allowed the use of nutrient content claims in food labeling in 1990 “in order to help consumers make appropriate dietary choices.”¹ FDA established requirements for the use of nutrient content claims shortly thereafter, based entirely on prevailing dietary recommendations at that time – in particular, that consumers should focus on reducing the fat, saturated fat, cholesterol, and sodium in their diets. This regulatory framework is now significantly outdated as a result of scientific progress in the nutrition space, because it does not reflect key principles of today’s evidence-based dietary guidance. This regulatory framework is also demonstrably not effective in actually helping consumers make appropriate dietary choices, but instead allows the use of nutrient content claims that mislead consumers to believe that the products bearing such claims provide useful evidence-based dietary value, when they do not.

Food labeling claims, including nutrient content claims, play a critical role in informing consumer’s dietary choices. FDA has a fundamental duty to ensure that food labeling claims are truthful and non-misleading, and that food products only bear nutrient content claims that can help consumers maintain healthy dietary practices. As currently structured, FDA’s nutrient content claim regulatory framework allows the use of claims based solely on the *quantity* of particular nutrients, without any consideration for the *quality* of the food bearing the claim; this does not assist consumers in making dietary choices consistent with current recommendations and science, and encourages the widespread fortification of foods that are *not* good dietary choices.

I. Action Requested

Through this petition, and for the reasons explained in more detail below, KIND respectfully requests that FDA take the following actions to update the framework for regulating nutrient content claims:

- Revise its nutrient content claim regulations to only allow a food to bear a nutrient content claim highlighting the presence or absence of a nutrient if the food contains a meaningful amount of at least one health-promoting food, such as: vegetables, fruits (especially whole fruits), whole grains, legumes, nuts, and seeds, which are recommended in the most recent Dietary Guidelines for Americans.

Specifically, KIND requests that FDA amend 21 C.F.R. 101.13(g) to provide as follows:

(g) General nutrient content claim requirements.

(1) Any food that bears a nutrient content claim must contain a meaningful amount of at least one health-promoting food, such as: vegetables, fruits (especially whole fruits),

¹ 58 Fed. Reg. 2,302, 2,375 (Jan. 6, 1993) (citing 136 Cong. Rec. 33,428 (1990)).

whole grains, legumes, nuts, and seeds, which are recommended in the most recent Dietary Guidelines for Americans.

- Amend 21 C.F.R. 101.13(h) to include disclosure levels for added sugar and *trans* fat² and to remove disclosure levels for total fat and cholesterol.

Specifically, 21 C.F.R. 101.13(h) currently provides as follows:

(h)(1) If a food, except a meal product as defined in § 101.13(l), a main dish product as defined in § 101.13(m), or food intended specifically for use by infants and children less than 2 years of age, contains more than 13.0 g of fat, 4.0 g of saturated fat, 60 milligrams (mg) of cholesterol, or 480 mg of sodium per reference amount customarily consumed, per labeled serving, or, for a food with a reference amount customarily consumed of 30 g or less or 2 tablespoons or less, per 50 g (for dehydrated foods that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 101.9(f)(1), of all nutrients per reference amount customarily consumed, the per 50 g criterion refers to the “as prepared” form), then that food must bear a statement disclosing that the nutrient exceeding the specified level is present in the food as follows: “See nutrition information for ___ content” with the blank filled in with the identity of the nutrient exceeding the specified level, e.g., “See nutrition information for fat content.”

(2) If a food is a meal product as defined in § 101.13(l), and contains more than 26 g of fat, 8.0 g of saturated fat, 120 mg of cholesterol, or 960 mg of sodium per labeled serving, then that food must disclose, in accordance with the requirements as provided in paragraph (h)(1) of this section, that the nutrient exceeding the specified level is present in the food.

(3) If a food is a main dish product as defined in § 101.13(m), and contains more than 19.5 g of fat, 6.0 g of saturated fat, 90 mg of cholesterol, or 720 mg of sodium per labeled serving, then that food must disclose, in accordance with the requirements as provided in paragraph (h)(1) of this section, that the nutrient exceeding the specified level is present in the food.

KIND requests that FDA amend 21 C.F.R. 101.13(h) to provide as follows:

(h)(1) If a food, except a meal product as defined in § 101.13(l), a main dish product as defined in § 101.13(m), or food intended specifically for use by infants and children less than 2 years of age, contains more than 10.0 g of added sugars, 0.5 g of *trans* fat, 4.0 g of saturated fat, or 460 mg of sodium per reference amount customarily consumed, per labeled serving, or, for a food with a reference amount customarily consumed of 30 g or less or 2 tablespoons or less, per 50 g (for dehydrated foods that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount,

² While we applaud FDA for the steps that it has already taken to decrease the consumption of *trans* fats, including revoking the “generally recognized as safe” (“GRAS”) status for partially hydrogenated oils, which are the primary dietary source of synthetic *trans* fats, we request that FDA include *trans* fat in the disclosure requirement because *trans* fats have not been fully eliminated from the food supply, primarily due to *trans* fats that are still present in certain foods and ingredients derived from animals.

as defined in § 101.9(f)(1), of all nutrients per reference amount customarily consumed, the per 50 g criterion refers to the “as prepared” form), then that food must bear a statement disclosing that the nutrient exceeding the specified level is present in the food as follows: “See nutrition information for ___ content” with the blank filled in with the identity of the nutrient exceeding the specified level, e.g., “See nutrition information for fat content.”

(2) If a food is a meal product as defined in § 101.13(l), and contains more than 20.0 g of added sugars, 8.0 g of saturated fat, 0.5 g of *trans* fat, or 920 mg of sodium per labeled serving, then that food must disclose, in accordance with the requirements as provided in paragraph (h)(1) of this section, that the nutrient exceeding the specified level is present in the food.

(3) If a food is a main dish product as defined in § 101.13(m), and contains more than 15.0 g of added sugars, 0.5 g of *trans* fat, 6.0 g of saturated fat, or 690 mg of sodium per labeled serving, then that food must disclose, in accordance with the requirements as provided in paragraph (h)(1) of this section, that the nutrient exceeding the specified level is present in the food.

- Revise its nutrient content claim regulations to disqualify foods, other than meal products or main dish products,³ that contribute more than 25 percent of the daily value for saturated fat, sodium, or added sugar or more than 1.0 gram of *trans* fat from bearing nutrient content claims.

KIND requests that FDA amend 21 C.F.R. 101.13(g) to provide as follows:

(g) General nutrient content claim requirements.

(2) Any food that bears a nutrient content claim must contain 25 percent or less of the daily reference value of saturated fat, sodium, or added sugar, or 1.0 g *trans* fat or less, per reference amount customarily consumed, per labeled serving, or, for a food with a reference amount customarily consumed of 30 g or less or 2 tablespoons or less, per 50 g (for dehydrated foods that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 101.9(f)(1), of all nutrients per reference amount customarily consumed, the per 50 g criterion refers to the “as prepared” form).

- Revise its nutrient content claim regulations to require that, where a nutrient content claim is based on a nutrient that has been added to a food, such fortification is in accordance with FDA’s policy on fortification of foods in 21 C.F.R. 104.20.

KIND requests that FDA amend 21 C.F.R. 101.13(g) to provide as follows:

(g) General nutrient content claim requirements.

³ We request that FDA also establish disqualifying levels for meal products and main dish products at thresholds the agency deems appropriate based on current information about the types of foods marketed in these categories and their nutritional profiles.

(3) Where the nutrient content claim is based on a nutrient that has been added to the food, that fortification must be in accordance with the policy on fortification of foods in § 104.20 of this chapter.

II. Statement of Grounds

FDA has long recognized the importance of food labeling claims, including nutrient content claims, in informing consumer dietary choices, and nutrition experts globally agree that informing healthy, nutritionally sound dietary choices is more critical now than ever before. The 2015-2020 *Dietary Guidelines for Americans* emphasizes the urgent need to improve dietary patterns of the American public in order to slow the increasing rates of chronic, diet-related diseases,⁴ and aims to do so by focusing on healthy eating patterns and food and nutrient characteristics, rather than individual dietary components.⁵ As the Secretaries of HHS and USDA stated when releasing the 2015-2020 *Dietary Guidelines*, “Now more than ever, we recognize the importance of focusing not on individual nutrients or foods in isolation, but on everything we eat and drink—healthy eating patterns as a whole—to bring about lasting improvements in individual and population health.”⁶ Nutrient content claims play a key role in helping consumers construct a healthy eating pattern by choosing foods that are part of that pattern. Because the *Dietary Guidelines* is intended to serve as the cornerstone for all federal nutrition education and program activities, and because federal law requires that the most current *Dietary Guidelines* “be promoted by each [f]ederal agency in carrying out any [f]ederal food, nutrition, or health program,”⁷ FDA must update its nutrient content claim regulations to ensure that claims are consistent with current dietary recommendations.

Moreover, in the Nutrition Action Plan that is part of FDA’s 2018 Strategic Policy Roadmap, FDA emphasized its goal to “[r]educe preventable death and disease caused by poor nutrition by ensuring that consumers have access to accurate, useful information to make healthy food choices.”⁸ To accomplish that goal, FDA explained that it aims “to advance policies that better leverage nutrition and diet as ways to reduce morbidity and mortality from disease,” including steps such as “revising requirements for certain existing food claims such as ‘healthy’”

⁴ Of note, a study released earlier this year estimated that eating a diet lacking in healthy foods and/or high in unhealthy foods contributed to more than 400,000 deaths from heart and blood vessel diseases in the U.S. in 2015, and also that eating more nuts and seeds, vegetables, and whole grains, and less sodium, could save tens of thousands of lives in the U.S. each year. See Ashkan Afshin & Patrick Sur, “The Impact of Suboptimal Diet on Cardiovascular Disease Mortality in the United States,” *CIRCULATION*, 2018;135:A15, Mar. 27, 2018.

⁵ See, e.g., U.S. DEPT. OF HEALTH & HUMAN SERVS. & U.S. DEPT. OF AGRIC., 2015–2020 DIETARY GUIDELINES FOR AMERICANS xi-xvii (8th ed. Dec. 2015), available at https://health.gov/dietaryguidelines/2015/resources/2015-2020_Dietary_Guidelines.pdf [Hereinafter “2015-2020 Dietary Guidelines”].

⁶ “Message from the Secretaries,” available at: <https://health.gov/dietaryguidelines/2015/guidelines/message/#subnav-0>.

⁷ 7 U.S.C. 5341(a)(1).

⁸ See FDA, *Healthy Innovation, Safer Families: FDA’s 2018 Strategic Policy Roadmap*, at 15 (Jan. 2018), available at <https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM592001.pdf>.

and “providing new opportunities to make ingredient information more helpful to consumers.”⁹ As discussed in more detail below, the actions requested by this petition are necessary to further the goals identified in FDA’s Nutrition Action Plan and to ensure that nutrient content claims serve the purpose that Congress intended – assist consumers in maintaining healthy dietary practices – by including information that promotes healthful eating and without misleading consumers regarding the nutritional value of foods they purchase..

A. Background

The Nutrition Labeling and Education Act of 1990 (NLEA)¹⁰ amended the Federal Food, Drug, and Cosmetic Act (FDCA) to, in part, give FDA the authority to regulate the use of certain claims in the labeling of food. Specifically, NLEA added section 403(r) to the FDCA. Section 403(r)(1)(A) of the FDCA provides that a food is misbranded if it bears a claim in its label or labeling that either expressly or implicitly characterizes the level of any nutrient of the type required to be declared as part of the nutrition labeling (a “nutrient content claim”), unless such claim is made in accordance with section 403(r)(2) of the FDCA, which provides that such a claim may be made only if it has been defined by FDA by regulation.

As FDA has explained previously, one purpose of NLEA was to regulate the use of nutrient content claims that appear on food labels and labeling “in order to help consumers make appropriate dietary choices.”¹¹ In addition, as FDA noted in its rulemaking implementing NLEA, “section 403(r) of the [FDCA] itself, repeatedly uses the phrase “. . . will assist consumers in maintaining healthy dietary practices” to describe the information for which provision is being made.”¹² Consumer research, including research conducted and evaluated by FDA, demonstrates that nutrient content claims have significant influence in dietary choices, and in particular that the presence of a nutrient content claim can increase consumers’ perceptions of a food’s overall healthfulness.

In particular, a study published by researchers from FDA and the University of Maryland found nutrient content claims associated with fortified snack foods had a significant influence on the associated product’s perceived healthfulness.¹³ That study assessed the effects of ten nutrient content claims on consumers’ perception and nutrition decisions in the context of fortified snack foods. Across all ten examples, the study found that nutrient content claims significantly increased the associated product’s perceived healthfulness compared to the same product with no nutrient content claim, leading to substitution of foods of less nutritional quality for those of high nutritional quality. Moreover, the reported results were comparable for both adults and children, demonstrating that the influence of nutrient content claims is not limited to adults.

⁹ *Id.*

¹⁰ Pub. L. No. 101-535, 104 Stat. 2353 (1990).

¹¹ 58 Fed. Reg. at 2,375 (citing 136 Cong. Rec. 33,428 (1990)).

¹² See, e.g., section 403(r)(2)(A)(ii)(II) and (r)(2)(A)(iii)(I) of the FDCA.

¹³ Irina A. Iles et al., *Nutrient Content Claims: How They Impact Perceived Healthfulness of Fortified Snack Foods and the Moderating Effects of Nutrition Fact Labels*, HEALTH COMMUN. 2018 Oct; 33(10):1308-1316.

Similarly, a separate study found that consumers would consider increasing their consumption of nutritionally poor foods if they were marketed with fortification claims.¹⁴ That study involved an online survey of 1200 adults and teens in Canada to assess interest in fortified foods such as energy bars, frozen desserts, fruit drinks, and soda pop. The majority of respondents expressed interest in consuming these fortified foods and indicated that they would increase their consumption of such foods if they were fortified.

KIND further confirmed these findings with its own consumer research.¹⁵ On KIND's behalf, a third-party vendor surveyed over 2,200 consumers regarding their perception of nutrient content claims and FDA's regulation of these claims. The results of this research demonstrate the influence of nutrient content claims on consumer purchasing decisions and the need for change to the related regulatory regime to ensure that such claims are not misleading. Notably, more than 2/3 (68 percent) of respondents stated that nutrient content claims are important when deciding which products to purchase at a grocery store. Notably, a majority of respondents (56 percent) also expressed that FDA should revise its nutrient content claim regulations to make these claims clearer and less misleading. Relatedly, KIND also surveyed registered dietitians that are members of KIND's Nutrition Collective.¹⁶ Seventy-five percent of these dietitians responded that their patients believe food products bearing nutrient content claims are healthy items, and 85 percent responded that they often encounter products with nutrient content claims that they would not recommend as part of a healthy diet.

These studies are a limited sampling of the much broader research supporting that nutrient content claims have significant influence in dietary choices, even where the products associated with these claims are of poor nutritional quality. The consumer data indicates that the current nutrient content claim framework is not serving the purpose that Congress intended, and supports a clear need for reform to FDA's nutrient content claim requirements to prevent consumer deception regarding the nutritional quality of their dietary choices.

- B. FDA Must Update its Nutrient Content Claim Regulations to Ensure that such Claims are not Misleading
 - 1. FDA's Existing Nutrient Content Claim Framework Allows Claims that Mislead Consumers Regarding Quality of Foods

FDA's general framework for nutrient content claims focuses solely on the quantity of nutrients in a food product rather than also requiring consideration of the quality of the food in the overall diet. This framework reflects federal dietary recommendations in the early 1990s, when FDA implemented NLEA – recommendations that emphasized specific nutrients instead of food groups or broader dietary patterns. However, as explained above, federal dietary

¹⁴ Maria Kalergis, & Andrew MacDonald, *A Discretionary Food Fortification: Implications of Consumer Attitudes*, CAN J DIET PRACT RES. 2009 Winter; 70(4):e26-31.

¹⁵ This survey was funded by KIND and conducted by Morning Consult from February 19-21, 2019, among a national sample of 2202 adults.

¹⁶ This survey was conducted from February 18-March 4, 2019, among a national sample of 595 Registered Dietitians. All respondents were part of KIND's Nutrition Collective; however, none are employed by KIND and the views expressed are their own.

recommendations have shifted significantly over the nearly three decades since that time. The 2015-2020 *Dietary Guidelines* now emphasizes:

Individuals should aim to meet their nutrient needs through healthy eating patterns that include nutrient-dense foods. Foods in nutrient-dense forms contain essential vitamins and minerals and also dietary fiber and other naturally occurring substances that may have positive health effects. In some cases, fortified foods and dietary supplements may be useful in providing one or more nutrients that otherwise may be consumed in less than recommended amounts.¹⁷

FDA's nutrient content claim regulations do not reflect this current thinking. Further, as explained above, consumer research consistently demonstrates that the use of a nutrient content claim alone causes consumers to believe that a food is more healthful or provides greater nutritional value than a comparable product marketed without a claim. Without appropriate considerations for the overall quality of a food that bears a nutrient content claim, there is material risk that nutrient content claims will encourage consumption of foods that are not recommended by current dietary recommendations and mislead consumers.

For example, for most nutrients, a food can bear a "good source" or "excellent source" claim, regardless of whether the highlighted nutrient is naturally-occurring or was added through fortification, and regardless of whether the food is otherwise nutrient-dense. This means that a pack of gummy bears, fortified with inulin (a dietary fiber), could be labeled as a "good source of fiber" so long as the gummy bears contain about 3 grams of fiber – i.e., 10 percent of the daily value for fiber – per reference amount customarily consumed (RACC).¹⁸ FDA's nutrient content claim regulations do not currently require any disclosures about the amount of added sugars in the gummy bears, nor do they require that the gummy bears contain *any* other nutrients of value. However, based on consumer research, we know that a the "good source of fiber" claim is likely to mislead consumers to believe that the gummy bears are healthful and are an "appropriate dietary choice," even though that is not the case.

Similarly, FDA's nutrient content claim regulations allow a food to bear a "good source" or "excellent source" of protein claim so long as the food contains at least ten percent or twenty percent, respectively, of the daily value for protein per RACC. This provision poses the same issued described above, where a cookie or brownie could be fortified with protein and marketed as a "good source of protein," even though the cookie or brownie is not otherwise nutrient-dense and does not contain any health-promoting foods.

Further, FDA's regulations also require the daily value calculation for protein to be adjusted to reflect the protein digestibility-corrected amino acid score (PDCAAS).¹⁹ This calculation is intended to account for the "quality" of the protein ingredient, where animal sources of protein are generally scored "higher quality" than plant sources of protein because of a greater distribution of the 9 essential amino acids and higher digestibility scores. Nutrition experts have expressed concern that "food sources of 'high quality' protein, as defined by existing [FDA] metrics, do not reliably improve the quality of the diet, or health," and that this

¹⁷ 2015-2020 *Dietary Guidelines*, Chapter 1, Key Elements of Healthy Eating Patterns.

¹⁸ See 21 C.F.R. 101.54(c).

¹⁹ See *id.* § 101.9(c)(7).

scoring system “is directly opposed to current Dietary Guidelines for Americans, which encourage consumption of more plant foods and less meat.”²⁰

Particularly, experts conclude that “[m]easures of protein quality that consider only content and distribution of essential amino acids can be misleading because they represent the biological value of a single nutrient in isolation, not the net effects of consuming the source of that nutrient,” including the environmental and health effects that accompany the consumption of certain protein sources.²¹ It is therefore more challenging for a plant-based protein product to meet the threshold for a protein nutrient content claim than an animal-based protein product, even though experts agree that consumers should be seeking to consume more protein from plants.²² Although PDCAAS may carry some value as a metric for digestibility, the PDCAAS metric alone is insufficient to adequately capture the protein quality of all protein sources, nor does it ensure that foods bearing protein nutrient content claims are foods that consumers should be selecting as part of a healthy dietary pattern.

FDA expressed concerns about examples such as those described above in establishing its “fortification policy,” which is a nonbinding policy that “discourages indiscriminate addition of nutrients to foods.”²³ Specifically, FDA explains:

Under our fortification policy, it is not appropriate to fortify certain foods, such as . . . sugars; or snack foods such as candies and carbonated beverages. In the fortification policy, snack foods refer to foods that are not naturally nutrient dense; examples include cookies, candies, cakes, chips, and carbonated beverages (both sweetened and unsweetened). **Fortification of these types of snack foods could mislead consumers to believe that substitution of naturally nutrient dense foods with fortified snack foods would ensure a nutritionally adequate diet.** Moreover, the fortification of such snack foods would disrupt public understanding about the nutritional value of individual foods and **thereby promote confusion among consumers, making it more difficult for them to construct diets that are nutritionally adequate.**²⁴

²⁰ David L. Katz et al., *The Public Health Case for Modernizing the Definition of Protein Quality*, at 3, 6-7 ADV NUTR. (forthcoming 2019) [hereinafter Katz, *Modernizing Protein Quality Definition*]; see also EAT-Lancet Commission, *Food in the Anthropocene: the Eat-Lancet Commission on Healthy Diets from Sustainable Foods Systems* (Jan. 16, 2019), https://eatforum.org/content/uploads/2019/01/EAT-Lancet_Commission_Summary_Report.pdf.

²¹ Katz, *Modernizing Protein Quality Definition*, at 8.

²² See *id.* at 7 (“[T]he . . . 2015-2020 [Dietary Guidelines] include a recommendation that Americans consume ‘a variety of protein foods, including seafood, lean meats and poultry, eggs, legumes (beans and peas), and nuts, seeds, and soy products[.]’ but legumes, nuts, and seeds have lower PDCAAS values compared with animal sources of protein.”).

²³ FDA, *Guidance for Industry: Questions and Answers on FDA’s Fortification Policy* (Nov. 2015); see also 21 C.F.R. 104.20.

²⁴ FDA, *Guidance for Industry: Questions and Answers on FDA’s Fortification Policy* (Nov. 2015) (emphasis added).

In two specific instances, FDA's fortification policy does prevent manufacturers from adding a nutrient to a food of poor nutritional quality for the purpose of making nutrient content claims: "healthy" nutrient content claims, and "enhanced" or "more" nutrient content claims regulated by 21 C.F.R. 101.54(e).²⁵ However, the fortification policy is not otherwise binding, and FDA cannot take enforcement action based solely on non-conformance with the policy; therefore, the fortification policy does not generally prevent the potential confusion and deception that FDA has conceded would stem from fortification simply to support a nutrient content claim.

2. FDA Should Amend its Nutrient Content Claim Regulations to Ensure that Claims Help Consumers Make Appropriate Dietary Choices

As discussed above, nutrient content claims are not currently regulated in a way that ensures that such claims are actually helping consumers choose healthful and appropriate foods. FDA could address this issue by making two critical changes to its nutrient content claim regulatory framework: (1) only allow a food to bear a nutrient content claim highlighting the presence or absence of a nutrient if the food contains a meaningful amount of at least one health-promoting food, such as: vegetables, fruits (especially whole fruits), whole grains, legumes, nuts, and seeds, which are recommended in the most recent *Dietary Guidelines for Americans*; and (2) require that, where a nutrient content claim is based on a nutrient that has been added to a food, such fortification is in accordance with FDA's policy on fortification of foods in 21 C.F.R. 104.20.

Limiting nutrient content claims highlighting the presence or absence of a nutrient to foods containing a meaningful amount of at least one of the health-promoting foods identified in the 2015-2020 *Dietary Guidelines* is necessary to accomplish FDA's goal of reducing "preventable death and disease caused by poor nutrition by ensuring that consumers have access to accurate, useful information to make healthy food choices."²⁶ Currently *many* foods bearing nutrient content claims are *not* foods that nutrition experts, including through the 2015-2020 *Dietary Guidelines*, consider to be part of a healthy dietary pattern. In many circumstances, foods bearing nutrient content claims have high levels of added sugars or other nutrients of concern and/or are not nutrient-dense, and are thus foods that consumers should generally seek to avoid; however, the presence of nutrient content claims mislead consumers to believe that such foods are a strong dietary choice.

In making these changes, FDA will also have to define when a food has a "meaningful amount" of one of the identified health-promoting foods. While we ultimately defer to FDA and its scientific expertise regarding when a food has a "meaningful amount" of a health-promoting food, we request that FDA consider two potential definitions that we believe would ensure that

²⁵ A food cannot bear "[a] relative claim using the terms 'more,' 'fortified,' 'enriched,' 'added,' 'extra,' and 'plus'" to describe "the level of protein, vitamin, minerals, dietary fiber, or potassium" if that claim "is based on a nutrient that has been added to the food" and such "fortification is in accordance with the policy on fortification of foods" described in 21 C.F.R. 104.20. *Id.* § 101.54(e). With respect to "healthy" claims, as defined in 21 C.F.R. 101.65(d), certain types of foods, including meats and foods not specifically listed in the regulation, cannot bear a "healthy" claim unless, *inter alia*, they contain a minimum amount of vitamin A, vitamin C, calcium, iron, protein, or fiber. *Id.* § 101.65(d)(2)(i). However, if a food is fortified with one of these nutrients to meet the applicable minimum requirement, "that addition must be in accordance with" FDA's fortification policy. *Id.* § 101.65(d)(2)(iv).

²⁶ See FDA, *Healthy Innovation, Safer Families: FDA's 2018 Strategic Policy Roadmap*, at 15.

nutrient content claims promote dietary patterns consistent with the 2015-2020 *Dietary Guidelines*.

First, FDA could define “meaningful amount” in a way that requires food making a nutrient content claim to contain at least 51% of ingredients by weight to be sourced from a health-promoting food. By requiring foods that are marketed with nutrient content claims to include more than half of their ingredients by weight from health-promoting foods, FDA would ensure that foods bearing these claims include, at a minimum, more health-promoting ingredients than not, and are therefore nutrient-dense and part of a healthy dietary pattern. Alternatively, FDA could define “meaningful amount” to require that a food marketed with a nutrient content claim contain at least one serving size or ounce-equivalent of a health-promoting food, as reflected in the *Dietary Guidelines* for weekly recommendations to building a healthy eating pattern and USDA’s MyPlate. This definition would prevent the use of nutrient content claims to misleadingly promote foods that do not provide any material contribution to a healthy diet.

Similarly, requiring foods bearing nutrient content claims to meet FDA’s fortification policy is consistent with past FDA conclusions that use of a nutrient content claim to market a fortified food has the potential to mislead consumers. Particularly, in requiring that foods bearing a “more” claim to describe the level of a particular nutrient comply with FDA’s fortification policy, FDA explained that foods making such claims without meeting the fortification policy would be deceptive or misleading.²⁷ Accordingly, the prohibition of “more” claims not meeting the fortification policy was within FDA’s authority to prevent the introduction into interstate commerce of any misbranded food, including food bearing labeling that is false or misleading in any particular.²⁸ As discussed above, recent evidence demonstrates a material risk of consumer deception concerning the nutrient value of a fortified food that is marketed with any type of nutrient content claim, not just “more” or “healthy” claims. Accordingly, FDA should use its authority under the FDCA to require that, where a nutrient content claim is based on a nutrient that has been added to a food, such fortification must be in accordance with FDA’s policy on fortification of foods in 21 C.F.R. 104.20.

3. FDA Should Amend its Nutrient Content Claim Regulations to Require a Disclosure Statement for *Trans* Fat and Added Sugar and to Remove Thresholds for Total Fat and Cholesterol

FDA’s nutrient content claim regulations require a “disclosure statement” for any product that bears a nutrient content claim but also exceeds established thresholds for total fat, saturated fat, cholesterol, and sodium.²⁹ This requirement is based on section 403(r)(2)(B) of the FDCA, which provides that if FDA determines that a nutrient at a given level “increases to persons in the general population the risk of a disease or health-related condition that is diet related,” the labeling of any food bearing a nutrient content claim and containing the discouraged nutrient above the established level must also contain, “prominently and in immediate proximity to such claim, the following statement: ‘See nutrition information for ____

²⁷ 56 Fed. Reg. at 60,453.

²⁸ See FDCA § 403(a).

²⁹ 21 C.F.R. 101.13(h).

content.” In its rulemaking implementing NLEA, FDA concluded that total fat, saturated fat, cholesterol, and sodium were all nutrients that posed this risk.

Since that time, dietary recommendations have evolved, and experts no longer recommend limiting overall fat intake or cholesterol, but instead encourage prioritizing increasing intakes of polyunsaturated and monounsaturated fats and decreasing intakes of saturated fat and *trans* fat.³⁰ The test in section 403(r)(2)(B) – that a nutrient increase the risk of a disease or health-related condition – is no longer met for total fat or cholesterol. FDA should therefore amend 21 C.F.R. 101.13(h) to remove the disclosure statement requirement for total fat and cholesterol. Similarly, FDA should require a disclosure statement for *trans* fat. Experts have concluded that “[i]ndividuals should limit intake of trans fats to as low as possible” because a “number of studies have observed an association between increased intake of trans fats and increased risk of” cardiovascular disease.³¹ As mentioned above, we applaud FDA for the steps that it has already taken to decrease the consumption of *trans* fats, including revoking the “generally recognized as safe” (“GRAS”) status for partially hydrogenated oils, which are the primary dietary source of synthetic *trans* fats.³² However, *trans* fats are still present in certain foods and ingredients derived from animals; given this, FDA should amend 21 C.F.R. 101.13(h) to require a disclosure statement for this nutrient.

Relatedly, experts now also strongly recommend limiting added sugar intake, and have concluded that added sugars contribute calories without contributing essential nutrients, which means that consuming added sugars can make it difficult for individuals to meet their nutrient needs while staying within calorie limits.³³ Reflecting this conclusion, FDA recently established a daily value for added sugars and began requiring an “added sugar” declaration on the Nutrition Facts Label based on its determination that “the declaration of added sugars on the nutrition label would assist consumers in maintaining healthy dietary practices by providing them with information necessary to meet the key recommendations to construct daily diets containing nutrient-dense foods and reduce calorie intake from added sugars.”³⁴ FDA should amend 21 C.F.R. 101.13(h) to require a disclosure statement when a food bearing a nutrient content claim contains more than twenty percent of the daily value of added sugar per RACC or per labeled serving.

4. FDA Should Amend its Nutrient Content Claim Regulations to Include a Disqualifying Level for Saturated Fat, *Trans* Fat, Sodium, and Added Sugar

In light of the breadth of consumer-based evidence discussed above establishing the significant influence of nutrient content claims on consumer dietary choices, the current disclosure statements required in 21 C.F.R. § 101.13(h) are inadequate to cure the misleading effect of nutrient content claims used to market food, such as snack foods, beverages, and side dishes, that contributes more than 25 percent of the daily value for saturated fat, sodium, or

³⁰ 2015-2020 *Dietary Guidelines*, Chapter 1, at 31-32.

³¹ *Id.* at 32.

³² 80 Fed. Reg. 34,650 (June 17, 2015).

³³ 2015-2010 *Dietary Guidelines*, Chapter 1, at 28-31.

³⁴ 81 Fed. Reg. 33742, 33763 (May 27, 2016).

added sugar, or more than one gram of *trans* fat, per RACC or per labeled serving. Foods that contain one of these nutrients to avoid at levels of more than 25 percent of the daily value, or that contain *trans* fat above trace levels (i.e., more than one gram³⁵) *cannot* be part of a healthy dietary pattern, and the use of a nutrient content claim to market such foods is inherently misleading and should be disqualified from making a nutrient content claims. Similarly, we request that FDA establish analogous disqualifying levels for meal products (as defined in § 101.13(l)) and main dish products (as defined in § 101.13(m)), as the agency deems appropriate based on current information about the types of foods marketed in these categories and their nutritional profiles.

C. The Requested Actions Are Not Precluded by the First Amendment

The requested actions are allowed under the First Amendment's protections against limitations on the dissemination of commercial speech. Consistent with FDA's longstanding position on the regulation of nutrient content claims,³⁶ FDA has the authority to prohibit the dissemination of misleading nutrient content claims. Moreover, the Agency's authority to limit the dissemination of misleading claims is apparent under the Supreme Court's *Central Hudson* test.³⁷ First, speech that is "inherently misleading" is not afforded any particular protection under the First Amendment.³⁸ Second, where speech is not "inherently misleading, but is instead "potentially misleading," the government can prohibit the dissemination of such speech where doing so directly advances a substantial government interest and does so in a manner that is a "reasonable fit" between the means of regulation and that interest.³⁹

As discussed above, nutrient content claims clearly influence consumer dietary decisions due to the widespread perception that foods bearing such claims contribute to a healthy diet. FDA's current regulatory regime for nutrient content claims allows many foods to bear such claims even where the food does not promote a healthy dietary pattern. The updates to FDA's nutrient content claim regulations proposed above are clearly tied to the recommendations in the 2015-2020 *Dietary Guidelines*, which are "grounded in the most current scientific evidence and [are] informed by the recommendations of the 2015 Dietary Guidelines Advisory Committee."⁴⁰ Accordingly, these requirements would prevent only those claims that are inherently misleading. Under *Central Hudson*, such claims are not protected by the First Amendment.

Even if these requirements would exclude some nutrient content claims that are only potentially misleading, the proposed limitations directly advance a substantial government

³⁵ The current *Dietary Guidelines* advises consumers to "limit intake of *trans* fats to as low as possible." 2015-2020 *Dietary Guidelines*, Chapter 1, "Saturated Fats, Trans Fats, and Cholesterol." Our requests here with regard to *trans* fat reflect this recommendation.

³⁶ See, e.g., 58 Fed. Reg. 2302, 2392, 2397 (Jan. 6, 1993).

³⁷ *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm. of N.Y. (Central Hudson)*, 447 U.S. 557, 564-65 (1980); see also *Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 368 (2002) (reaffirming *Central Hudson* as the appropriate test for gauging the constitutionality of commercial speech prohibitions).

³⁸ *Central Hudson*, 447 U.S. at 564.

³⁹ *Id.*

⁴⁰ 2015-2020 *Dietary Guidelines*, Message from the Secretaries, at vii.

interest and do so in a manner that is a reasonable fit between the means of regulation and that interest. FDA undisputedly has substantial government interests in both the promotion of the public health and the prevention of consumer fraud and confusion.⁴¹ By limiting nutrient content claims to only those foods that actually contribute to a healthy dietary pattern and doing so in a manner that is directly linked to the current dietary guidelines, FDA would be directly advancing that interest in a manner that is a “reasonable fit.” Accordingly, even if the proposed standards would preclude foods from bearing nutrient content claims that are potentially, but not inherently, misleading, the First Amendment does not preclude FDA from imposing these requirements.

III. Conclusion

For the reasons set forth above, KIND requests that FDA take the actions described in Section I.

IV. 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).

V. Economic Impact

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

VI. Certification

Pursuant to 21 C.F.R. 10.30(b), the undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petitioner relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully Submitted,



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Enclosures

⁴¹ See *Pearson v. Shalala (Pearson I)*, 164 F.3d 650, 655-56 (D.C. Cir. 1999).