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

CITIZEN PETITION

Dear Sir/Madam:

When the Scientific Report from the 2015 Dietary Guidelines Advisory Committee (DGAC) was released early this year, it reiterated an important shift in U.S. dietary guidance that was the basis of the 2010 *Dietary Guidelines for Americans*. These documents shined attention on the importance of eating certain *foods*, including vegetables, fruits, whole grains, low- or non-fat dairy, seafood, lean meats and poultry, eggs, legumes, and nuts and seeds, in achieving better health and wellness. This is in contrast to prior federal dietary guidance, which placed greater emphasis on the specific *nutrient levels* in the diet rather than the overall contribution of recommended foods to a healthy diet. Many current federal labeling regulations are based upon this past thinking, preventing foods that contain beneficial whole ingredients and are recommended for consumption—like nuts, avocados, olives, and salmon—from bearing the word “healthy” in their labeling.

KIND respectfully submits this citizen petition requesting the Commissioner of Food and Drugs to update the Food and Drug Administration’s (FDA’s) existing requirements related to food labeling to become consistent with current federal dietary guidance as set forth in the 2010 *Dietary Guidelines for Americans* and with the latest scientific evidence discussed in the *Scientific Report of the 2015 Dietary Guidelines Advisory Committee (2015 DGAC Report)*. The requested changes outlined in this petition are also in line with the DGAC’s decision against recommending a limit on total fat intake as well as its decision to emphasize *whole foods* and dietary patterns rather than *specific nutrients* like fat. The 2015 *DGAC Report* will form the scientific basis for the 2015 *Dietary Guidelines for Americans*, which is anticipated later this year.

Under FDA’s current application of food labeling regulations, whether or not a food can be labeled “healthy” is based on specific nutrient levels in the food rather than its overall nutrition quality. FDA formulated those regulations more than 20 years ago, when available science *and* federal dietary recommendations focused on limiting total fat intake. Today, these regulations still require that the majority of foods featuring a “healthy” nutrient content claim meet “low fat” and “low saturated fat” standards regardless of their nutrient density. This is despite the fact that current science no longer supports those standards.

The requests in this petition, which are outlined in the following section, are supported by a broad base of signatories that include nationally-recognized health and wellness experts and organizations, identified in Appendix 2.

I. Actions Requested

For the reasons explained in more detail below, KIND respectfully requests that FDA take the following actions:

- Fully reevaluate its nutrient content claim regulations and amend those requirements as necessary to ensure consistency with current federal dietary recommendations. In particular, KIND requests that FDA amend the regulation for general nutritional claims in 21 C.F.R. 101.65(d)(2) to revise the conditions for total fat and saturated fat content to convey that, in calculating the total fat or saturated fat levels of a food to determine compliance with the requirements in subsection (i), producers may exclude the total fat or saturated fat content contributed to the food product by the following foods, provided that such foods are used in their whole form or have been processed in such a way that did not materially degrade their nutritional value: fruits, vegetables, nuts, seeds, legumes, whole grains, and seafood.

Specifically, 21 C.F.R. 101.65(d)(2) currently provides as follows:

(d) General nutritional claims.

(2) You may use the term “healthy” or related terms (e.g., “health,” “healthful,” “healthfully,” “healthfulness,” “healthier,” “healthiest,” “healthily,” and “healthiness”) as an implied nutrient content claim on the label or in labeling of a food that is useful in creating a diet that is consistent with dietary recommendations if:

(i) The food meets the following conditions for fat, saturated fat, cholesterol, and other nutrients

KIND requests that FDA amend 21 C.F.R. 101.65(d)(2) to provide as follows:

(d) General nutritional claims.

(2) You may use the term “healthy” or related terms (e.g., “health,” “healthful,” “healthfully,” “healthfulness,” “healthier,” “healthiest,” “healthily,” and “healthiness”) as an implied nutrient content claim on the label or in labeling of a

food that is useful in creating a diet that is consistent with dietary recommendations if:

(i) The food meets the following conditions for fat, saturated fat, and cholesterol exclusive of the fat and saturated fat contributed to the food product by the following foods, provided that such foods are used in their whole form or have been processed in such a way that did not materially degrade their nutritional value: fruits, vegetables, nuts, seeds, legumes, whole grains, and seafood; and the food meets the following conditions for other nutrients

- Undertake rulemaking to define a “dietary guidance statement” as a statement in food labeling about the usefulness of a food, or a category of foods, in maintaining healthy dietary practices. This definition of “dietary guidance statement” would include a statement that focuses on general dietary patterns, practices, and recommendations that promote health (e.g., “Nuts are part of a healthy diet”). This definition of “dietary guidance statement” would also include a statement that highlights the presence or amount of a food or category of foods in relation to a general health benefit or healthful diet (e.g., “Contains healthy whole grains”) or recommends the substitution of a food or food category that is consistent with current dietary recommendations for a food or food category that is less beneficial to health (e.g., “Eat foods made from healthy whole grains instead of refined grains”). Specifically, KIND requests that this rulemaking explicitly allow for the use of claims in food labeling to communicate that certain foods are useful in creating a diet that is consistent with current dietary recommendations, and also that this rulemaking establish certain requirements, such as a meaningful amount requirement, to ensure that dietary guidance statements are not misleading.
- Amend its regulation for “general nutritional claims,” found at 21 C.F.R. 101.65(d), to clarify that a labeling claim that a food is useful in maintaining healthy dietary practices is an implied nutrient content claim only if the claim is immediately adjacent to an implicit claim or statement about a nutrient. Specifically, 21 C.F.R. 101.65(d)(1) currently provides as follows:

(d) General nutritional claims.

(1) This paragraph covers labeling claims that are implied nutrient content claims because they:

- (i) Suggest that a food because of its nutrient content may help consumers maintain healthy dietary practices; and
- (ii) Are made in connection with an explicit or implicit claim or statement about a nutrient (e.g., “healthy, contains 3 grams of fat”).

KIND requests that FDA amend 21 C.F.R. 101.65(d)(1) to provide as follows:

(d) General nutritional claims.

(1) This paragraph covers labeling claims that are implied nutrient content claims because they:

(i) Suggest that a food because of its nutrient content may help consumers maintain healthy dietary practices; and

(ii) Are immediately adjacent to an explicit or implicit claim or statement about a nutrient (e.g., “healthy, contains 3 grams of fat”).

- Amend its regulation for “label statements that are not implied claims,” found at 21 C.F.R. 101.65(b), to clarify that a statement that claims that a food is useful in maintaining healthy dietary practices and that does not appear immediately adjacent to an explicit or implicit claim or statement about a nutrient is generally not an implied nutrient content claim, but is instead a dietary guidance statement. Specifically, 21 C.F.R. 101.65(b) currently provides as follows:

Certain label statements about the nature of a product are not nutrient content claims unless such statements are made in a context that would make them an implied claim under § 101.13(b)(2). The following types of label statements are generally not implied nutrient content claims and, as such, are not subject to the requirements of § 101.13 and this section

KIND requests that FDA amend 21 C.F.R. 101.65(b) to add new subsection (7), which, together with the first paragraph of 21 C.F.R. 101.65(b), would read as follows:

Certain label statements about the nature of a product are not nutrient content claims unless such statements are made in a context that would make them an implied claim under § 101.13(b)(2). The following types of label statements are generally not implied nutrient content claims and, as such, are not subject to the requirements of § 101.13 and this section

(7) A dietary guidance statement about the usefulness of a food, or a category of foods, in maintaining healthy dietary practices, unless such claim is an implied nutrient content claim because it is

immediately adjacent to an explicit or implicit claim or statement about a nutrient, as described in subsection (d)(1) of this section.

- In the interim, while FDA is undertaking rulemaking to amend 21 C.F.R. 101.65 and to define “dietary guidance statement,” issue a guidance document for industry to clarify that a statement about the usefulness of a food, or a category of foods, in maintaining healthy dietary practices is a dietary guidance statement that is not subject to the requirements in FDA’s nutrient content claim regulations unless it is an implied nutrient content claim because it is immediately adjacent to an explicit or implicit claim or statement about a nutrient.

II. Statement of Grounds

Educating consumers about the key components of a healthful diet has become increasingly important for the public health. This year, the DGAC, which is comprised of nationally recognized experts in the field of nutrition and health, emphasized the urgent need to improve the dietary patterns of the American public. Unfortunately, FDA’s current regulatory approach for food labeling claims limits the ability of food producers to tell consumers that products containing certain foods—such as nuts, whole grains, seafood, fruits, and vegetables—are healthy, even though they are currently recommended as key components of a healthful diet. KIND is asking FDA to make certain changes in order to facilitate such communication, which would help the American public better understand how to improve its dietary patterns. As discussed in more detail below, this request would make FDA’s regulatory regime consistent with current federal dietary recommendations (as is required by law), consistent with current scientific evidence about the health benefits of certain foods, and would significantly benefit the public health by ensuring that consumers fully understand the dietary value of foods available for purchase.

A. Regulatory Background

1. Nutrient Content Claim Regulations

The Nutrition Labeling and Education Act of 1990 (NLEA)¹ 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

¹ Pub. L. 101-535, 104 Stat. 2353 (1990).

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.

FDA implemented this statutory authority more than twenty years ago through a number of rulemakings that were finalized in 1993 and 1994. These rulemakings relied heavily on federal dietary recommendations in place at that time, including the 1990 *Dietary Guidelines for Americans* and various U.S. Department of Health and Human Services (HHS) and National Academy of Sciences (NAS) publications.² Of relevance to this petition, FDA determined that “implied nutrient content claims” include claims that suggest that a food, “*because of its nutrient content*, may be useful in maintaining healthy dietary practices and [are] made in association with an explicit claim or statement about a nutrient.”³ FDA based this determination in part on the intent of Congress in providing FDA with the authority to regulate nutrient content claims through NLEA. Specifically, FDA noted that Senate proceedings during NLEA’s development “show that 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.”⁴ FDA concluded that a claim that a food is healthy or nutritious, specifically *because of its nutrient content*, clearly characterizes the level of a nutrient in that food because the claim is “essentially saying that the level of nutrients in the food is such that the food will contribute to good health.”⁵ However, FDA acknowledged that terms such as “healthy,” “wholesome,” and “nutritious” could appear in food labeling in a context that would not render the terms implied nutrient content claims, and in those circumstances FDA’s nutrient content claim regulations would not apply to the use of such terms.⁶

Specifically with regard to the use of the term “healthy” as a nutrient content claim, FDA established a definition of the term “healthy” and specific requirements for when the term “healthy” can be used as a nutrient content claim in the labeling of food.⁷ In doing so, FDA

² See, e.g., Committee on Diet and Health, National Research Council, DIET AND HEALTH: IMPLICATIONS FOR REDUCING CHRONIC DISEASE RISK (1989); Surgeon General, U.S. Public Health Service, THE SURGEON GENERAL’S REPORT ON NUTRITION AND HEALTH (1988).

³ 21 C.F.R. 101.13(b)(2)(ii) (emphasis added).

⁴ 58 Fed. Reg. 2302, 2375 (Jan. 6, 1993), citing 101 Cong. Rec. S16610 (Oct. 24, 1990) (136 Cong. Rec. 33428 (1990)).

⁵ *Id.*

⁶ *Id.*

⁷ 21 C.F.R. 101.65; see also 59 Fed. Reg. 24232 (May 10, 1994).

concluded that the term “healthy” is a “unique nutrient content claim” that “not only characterizes the level of the nutrients in a food but implies a judgment about the food itself.”⁸ Additionally, FDA rejected comments that asserted that FDA should regulate the term “healthy” as an implied nutrient content claim regardless of whether it is used in a specific nutritional context.⁹ In doing so, FDA concluded that the term “healthy” does *not* inherently imply that a food has a particular nutrient profile or contains a nutrient in a particular amount, but that “such inferences are likely to be drawn only if the term ‘healthy’ is accompanied by additional language or graphic material or is otherwise presented in a context that explicitly or implicitly suggests that the food has a particular nutrient profile.”¹⁰

Based on these conclusions, FDA determined that it was necessary to set limits for total fat, saturated fat, cholesterol, and sodium for various categories of food, and also set minimum levels of certain nutrients (vitamin A, vitamin C, calcium, iron, protein, or fiber) for some of those categories of food in order to bear a “healthy” nutrient content claim.¹¹ In particular, FDA concluded that foods that bear a “healthy” nutrient content claim should generally be “low fat” and “low saturated fat” as defined in FDA regulations, because “these restrictions recognize the need to reduce dietary intake of fat and saturated fat as recognized by the Surgeon General and the Food and Nutrition Board” *at that time* and would therefore “assist consumers in constructing a total diet that is consistent with dietary recommendations.”¹² FDA further concluded that “the ‘low’ criteria are sufficient to assist consumers in restricting their fat and saturated fat intake, without being so restrictive that it would preclude a sufficient number and variety of foods from bearing the claim,”¹³ and that the criteria would “permit a sufficient number and variety of foods *in all food categories* to bear the term to help consumers achieve a total diet that is consistent with current dietary recommendations.”¹⁴ However, FDA noted that it would be “*inappropriate if the definition of ‘healthy’ were to exclude an entire category of foods that is recommended in the dietary guidelines.*”¹⁵ Nonetheless, FDA’s current regulatory approach for the use of a “healthy” nutrient content claim *does, in fact, exclude an entire category of foods that is*

⁸ 59 Fed. Reg. at 24232.

⁹ *Id.* at 24234-35.

¹⁰ *Id.* at 24235.

¹¹ 21 C.F.R. 101.65(d)(2).

¹² 59 Fed. Reg. at 24238.

¹³ *Id.*

¹⁴ *Id.* at 24233 (emphasis added).

¹⁵ *Id.* (emphasis added).

recommended in the dietary guidelines—nuts—from bearing such a claim because nuts are not low in fat.

2. Dietary Guidance Statements

In December 2002, FDA announced the Consumer Health Information for Better Nutrition Initiative (CHIBNI), with the goal of making available more and better information about conventional foods and dietary supplements to help consumers improve their health and decrease the risk of contracting diseases by making sound dietary decisions.¹⁶ Under this initiative, the agency established the Task Force on Consumer Health Information for Better Nutrition (the Task Force). The Task Force was charged with, among other things, reporting on how the agency can improve consumer understanding of the health consequences of dietary choices and increase competition by product developers in support of healthier diets.¹⁷ The Task Force concluded that “significant public health benefits will result when consumers *have access to, and use, more and better information to aid them in their purchases*, information that goes beyond just price, convenience, and taste, but extends to include science-based health factors,” and that “[p]ublic health priorities dictate a need for federal agencies and other stakeholders to partner to find useful and understandable health messages about general food choices and dietary patterns.”¹⁸

In particular, the Task Force considered data from the most recent, at the time, Food Marketing Institute Trends in the United States Survey, which indicated that while the percentage of consumers who recognize the importance of eating healthfully and who are interested in trying foods that may improve their health is increasing (86% agreed or strongly agreed that “in most cases, eating healthfully is a better way to manage illness than medications”), the percentage of consumers who acknowledge unhealthy eating behaviors is also increasing (72% of shoppers agreed or strongly agreed with the statement, “I eat foods I enjoy, even if they’re not good for me”).¹⁹ The Task Force report included considerations related to the goal of increasing the quantity and improving the impact of health messages on conventional human foods and human dietary supplements, and concluded that finding more effective ways to improve consumer understanding and behavior is an urgent public health priority. In response to this report, in November, 2003, FDA issued an advance notice of proposed rulemaking (2003

¹⁶ See, e.g., FDA, *Consumer Health Information for Better Nutrition Initiative: Task Force Final Report* (July 2003), <http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm096010.htm>.

¹⁷ *Id.*

¹⁸ *Id.* at Overview and Executive Summary (emphasis added).

¹⁹ *Id.*

ANPRM) to, in part, request comments on the appropriateness and nature of dietary guidance statements in food labeling.²⁰

In the 2003 ANPRM, FDA explained that the “purpose of such dietary guidance statements is to assist and encourage individuals in making better food choices and establishing healthier eating patterns.”²¹ FDA also recognized the value of dietary guidance in “assisting and encouraging the U.S. population to make better food choices and establish healthier eating patterns,” specifically those based on major Federal documents such as the *Dietary Guidelines for Americans*.²² FDA has included a proposed rule about dietary guidance statements in a number of its Unified Agenda entries (beginning in Spring 2010). Through those entries, FDA has communicated its intent to issue a proposed rule that would define a dietary guidance statement as “statements in food labeling about the usefulness of a food or a category of foods in maintaining healthy dietary practices . . . [that] focus on general dietary patterns, practices, and recommendations that promote health, [and that] . . . may highlight the presence or amount of a food or category of foods in relation to a general health benefit or health-related condition, or recommend the substitution of a food or food category that is consistent with current dietary recommendations for a food or food category that is less beneficial to health.”²³ FDA’s website currently provides the following example of a dietary guidance statement: “Carrots are good for your health.”²⁴ Food producers can currently use dietary guidance statements in food labeling so long as such statements are truthful and nonmisleading. However, because FDA has not undertaken rulemaking related to dietary guidance statements, as contemplated by recent Unified Agenda entries, there remains significant uncertainty regarding what a dietary guidance statement is and how such statements can be used in food labeling.

²⁰ 68 Fed. Reg. 66040 (Nov. 25, 2003).

²¹ *Id.* at 66046.

²² *Id.* at 66047.

²³ See, e.g., Office of Information and Regulatory Affairs, Office of Management and Budget, *Unified Agenda: Food Labeling; Dietary Guidance Statements*, RIN 0910-AG50 (Spring 2010), <http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201004&RIN=0910-AG50>.

²⁴ Center for Food Safety and Applied Nutrition (CFSAN), FDA, *Guidance for Industry and FDA: Dear Manufacturer Letter Regarding Food Labeling* (Jan. 2007), <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm053425.htm>.

B. Current Federal Dietary Recommendations, Supported by Current Scientific Evidence, Encourage Dietary Patterns that Are Rich in Nuts, Whole Grains, Legumes, Seeds, Fruits, Vegetables, and Seafood

1. The Dietary Guidelines for Americans

The *Dietary Guidelines for Americans* (*Dietary Guidelines*) is a federal policy document that the Secretaries of HHS and the U.S. Department of Agriculture (USDA) release every five years. The primary goal of the *Dietary Guidelines* is to provide Americans with recommendations for making dietary and physical activity choices that promote good health and a healthy weight and that help prevent disease.²⁵ The recommendations are based on a rigorous review of relevant scientific evidence. The *Dietary Guidelines* is intended to serve as the cornerstone for all federal nutrition education and program activities. Under federal law, the most current *Dietary Guidelines* must “be promoted by each [f]ederal agency in carrying out any [f]ederal food, nutrition, or health program.”²⁶

The 2010 *Dietary Guidelines* is the current federal nutrition policy document. The 2010 *Dietary Guidelines* focuses on the overall nutritional quality of the diet and types of foods that people should eat, with less consideration given to specific nutrient levels in each individual food that people consume. Its key recommendations encompass two overarching concepts: (1) maintenance of calorie balance over time to achieve and sustain a healthy weight; and (2) consumption of nutrient-dense foods and beverages.²⁷ Specifically, the 2010 *Dietary Guidelines* states that a “healthy eating pattern . . . emphasizes nutrient-dense foods and beverages—vegetables, fruits, whole grains, fat-free or low-fat milk and milk products, seafood, lean meats

²⁵ The *Dietary Guidelines* is congressionally mandated under the 1990 National Nutrition Monitoring and Related Research Act (Pub. L. No. 101-445, § 301, 7 U.S.C. 5341). This law requires the *Dietary Guidelines* to be based on the preponderance of current scientific and medical knowledge. 7 U.S.C. 5341(a)(1).

²⁶ 7 U.S.C. 5341(a)(1).

²⁷ By contrast, the key recommendations of the 1990 *Dietary Guidelines*, which was in effect when FDA promulgated 21 C.F.R. 101.65, recommended that Americans “[c]hoose a diet low in fat, saturated fat, and cholesterol” and “[c]hoose a diet with plenty of vegetables, fruits, and grain products,” but did not specifically recommend that Americans consume whole grains, nuts, seeds, legumes, or seafood, which are recognized today as key components of a healthful diet. Further, the 1990 *Dietary Guidelines* recommended that Americans consume more breads, cereals, rice, and pasta than *any other category of foods* on a daily basis, a recommendation that is inconsistent with current dietary guidance. USDA & HHS, *Nutrition and Your Health: Dietary Guidelines for Americans* 1, 7, 13-17 (Nov. 1990), available at <http://www.health.gov/dietaryguidelines/1990thin.pdf> (emphasis added).

and poultry, eggs, beans and peas, and nuts and seeds.”²⁸ The 2010 *Dietary Guidelines* sets forth a number of “Key Recommendations,” which it characterizes as the “most important in terms of their implications for improving the public health.” These recommendations include the following:

- “Increase vegetable and fruit intake”;
- “Consume at least half of all grains as whole grains”;
- “Choose a variety of protein foods, which include seafood, lean meat and poultry, eggs, beans and peas, soy products, and unsalted nuts and seeds”;
- “Increase the amount and variety of seafood consumed by choosing seafood in place of some meat and poultry”;
- “Use oils to replace solid fats where possible”; and
- “Select an eating pattern that meets nutrient needs over time at an appropriate calorie level.”²⁹

The 2010 *Dietary Guidelines* explains that an important underlying principle in constructing a healthy diet is to focus on nutrient-dense foods, because these “foods provide vitamins, minerals, and other substances that may have positive health effects, with relatively few calories.”³⁰ While a healthy eating pattern focuses on nutrient-dense foods, the 2010 *Dietary Guidelines* emphasizes that this does not mean that a healthy eating pattern requires a rigid focus on the nutrient composition of each food that is consumed. Instead, it communicates that Americans have significant flexibility in constructing a healthy eating pattern that adapts to individual circumstances, and consuming a variety of nutrient-dense foods (vegetables, fruits, whole grains, seafood, eggs, legumes, nuts and seeds) in a range of patterns will allow Americans to meet current dietary recommendations.³¹ The 2010 *Dietary Guidelines* also notes that “average American eating patterns currently bear little resemblance to these dietary recommendations,” finding that Americans eat too much solid fat and refined grains, and

²⁸ USDA & HHS, *Dietary Guidelines for Americans*, 2010 (Dec. 2010), at ix (footnote omitted) (2010 *Dietary Guidelines*).

²⁹ *Id.* at ix, xi.

³⁰ *Id.* at 35.

³¹ *Id.* at 44-46.

consume too little dietary fiber, unsaturated fatty acids from oils, nuts, and seafood, and other important nutrients that are typically found in vegetables, fruits, and whole grains.³²

The federal government is in the process of developing the 2015 *Dietary Guidelines*. The first stage of this process, in which an external scientific DGAC is tasked with analyzing new scientific evidence related to diet and health and preparing a report summarizing its findings, was completed when the DGAC submitted its 2015 *DGAC Report* to the Secretaries of HHS and USDA in January 2015.³³ HHS and USDA requested public comments on the 2015 *DGAC Report*. During the second stage, currently underway, HHS and USDA will consider the recommendations in the 2015 *DGAC Report*, public comments, and any other relevant scientific information, and will develop the final policy document, the 2015 *Dietary Guidelines*.

The 2015 DGAC communicated its intent that the 2015 *DGAC Report* “aid in developing public policies that aim to establish a ‘culture of health’ at individual and population levels, and, in so doing, make healthy lifestyle choices easy, accessible, affordable, and normative.”³⁴ The 2015 *DGAC Report* has a particular focus on dietary patterns, based on the premise that “the *totality of diet*—the combinations and quantities in which foods and nutrients are consumed—may have synergistic and cumulative effects on health and disease.”³⁵ Specifically, the 2015 *DGAC Report* concludes that the overall body of evidence indicates that a “healthy dietary pattern is *higher in* vegetables, fruits, whole grains, low- or non-fat dairy, seafood, legumes, and nuts; moderate in alcohol (among adults); lower in red and processed meat; and low in sugar-sweetened foods and drinks and refined grains,” and communicates that these dietary patterns can be achieved in a variety of ways.³⁶ The 2015 *DGAC Report* also encourages consumption of healthy dietary patterns that are low in saturated fat, added sugars, and sodium, but emphasizes that these nutrients are *not* intended to be reduced in isolation, but instead as a part of a balanced healthy dietary pattern. These recommendations align closely with the recommendations in the 2010 *Dietary Guidelines*, discussed above. Moreover, for the first time in recent history, the 2015 *DGAC Report* does not recommend an upper limit on total fat.³⁷ Americans should not

³² *Id.* at 45.

³³ See 2015 Dietary Guidelines Advisory Committee, USDA & FDA, *Scientific Report of the 2015 Dietary Guidelines Advisory Committee* (Feb. 2015), available at <http://www.health.gov/dietaryguidelines/2015-scientific-report/PDFs/Scientific-Report-of-the-2015-Dietary-Guidelines-Advisory-Committee.pdf> (2015 *DGAC Report*).

³⁴ *Id.*, Letter to the Secretaries at 2.

³⁵ *Id.*, Executive Summary at 3 (emphasis added).

³⁶ *Id.* at 4 (emphasis added) (footnote omitted).

³⁷ *Id.*, Part D, Chapter 1, at 17.

focus on reducing these nutrients, the report says, but instead should focus on constructing healthy eating patterns that are rich in recommended food groups containing nutrient-dense foods.³⁸

2. Current Scientific Evidence Supports the Health Benefits of Recommended Dietary Patterns

a. There is a large, growing, global consensus among experts in public health nutrition that dietary recommendations should emphasize foods, not specific nutrients

Formal dietary guidance in the U.S. originated with the Recommended Daily Allowances, now the Dietary Reference Intakes, which focused efforts on helping Americans to construct a diet in a way that would ensure nutritional adequacy and avoid nutrient deficiencies.³⁹ When the federal government first issued the *Dietary Guidelines*, this precedent informed its recommendations, and thus the first *Dietary Guidelines* placed a certain emphasis on nutrients, as well as the food sources of nutrients.⁴⁰ However, the peer-reviewed literature, scientific consensus, and global dietary guidance increasingly reflect the need to emphasize foods and dietary patterns, rather than nutrients.⁴¹ For example, a 2003 World Health Organization (WHO) report concluded that “national governments should aim to produce dietary guidelines that are simple, realistic and food-based.”⁴²

The 2015 DGAC agreed, explaining that the dietary patterns approach “considers the inherent interactions between foods and nutrients in promoting health or increasing disease

³⁸ *Id.* at 9.

³⁹ See Institute of Medicine, NAS, DIETARY REFERENCE INTAKES: THE ESSENTIAL GUIDE TO NUTRIENT REQUIREMENTS vii, 1, 5-6 (2006), available at http://www.nal.usda.gov/fnic/DRI/Essential_Guide/DRIEssentialGuideNutReq.pdf.

⁴⁰ See USDA & HHS, *Nutrition and Your Health: Dietary Guidelines for Americans* (Feb. 1980), available at <http://health.gov/dietaryguidelines/1980thin.pdf> (1980 *Dietary Guidelines*).

⁴¹ See, e.g., National Agricultural Library, USDA, *Dietary guidelines from around the world*, <http://fnic.nal.usda.gov/professional-and-career-resources/ethnic-and-cultural-resources/dietary-guidelines-around-world> (last visited Nov. 30, 2015); NZ Nutrition Foundation, *Food not nutrients symposium*, <http://www.nutritionfoundation.org.nz/Symposium> (last visited Nov. 30, 2015); EAT, *Stockholm Food Forum 2015*, <http://www.eatforum.org/event/stockholm-food-forum-2015/> (last visited Nov. 30, 2015).

⁴² WHO, *Joint WHO/FAO Expert Consultation on Diet, Nutrition and the Prevention of Chronic Diseases* 45 (2003), available at http://whqlibdoc.who.int/trs/WHO_TRS_916.pdf.

risk.”⁴³ This has been reinforced by a body of research that has explored the relationships between diet and disease by studying dietary patterns rather than focusing on single nutrients or foods. This includes the PREDIMED (PREvencion con DIeta MEDiterranea) trial, the Portfolio Eat Plan (PEP), and Dietary Approaches to Stop Hypertension. PREDIMED is a multicenter, randomized, controlled, parallel group, primary prevention trial conducted in Spain to assess the effects of a Mediterranean diet on major cardiovascular events. The long-term trial has resulted in a volume of published papers demonstrating significant health benefits for the Mediterranean dietary pattern (MDP) versus a Western dietary pattern. In one analysis, for example, results showed that adherence to the MDP—defined as a diet loaded with vegetables, extra virgin olive oil, nuts, oily fish and canned fish, fruits, whole-wheat bread, white fish and low-fat dairy products, and low in refined grains—was associated with a 47% reduction in all-cause mortality and an inverse association of similar magnitude between the MDP and cardiovascular events.⁴⁴

As the 2010 *Dietary Guidelines* and the 2015 DGAC acknowledge, when wholesome foods are consumed in sensible combinations, people are generally likely to obtain nutrients at the levels recommended for health.⁴⁵ Conversely, focusing solely on nutrient recommendations rather than dietary patterns may result in nutrient thresholds being met by foods and dietary patterns that do not remotely approximate current scientific recommendations. While there is no absolute need to choose between food-based and nutrient-based dietary guidance, there is a clear need to ensure that the two are compatible. When nutrient-based guidance (e.g., a recommendation to limit intake of dietary fat) is at odds with food-based guidance (e.g., a recommendation to eat nuts and seeds routinely), the federal government must reconcile the two to avoid propagating consumer confusion, forestalling objectives of public health nutrition, and undermining public confidence in federal dietary recommendations such as the *Dietary Guidelines*.

b. A large and consistent body of scientific evidence recognizes the health benefits of nutrient-dense foods such as nuts, seeds, legumes, fruits and vegetables, and fatty fish

Recent scientific evidence supports the increased consumption of certain nutrient-dense foods, and has identified specific health benefits associated with a dietary pattern focused on

⁴³ 2015 *DGAC Report*, Part D, Chapter 2, at 2-3.

⁴⁴ Martinez-Gonzalez MA et al., *Empirically-derived food patterns and the risk of total mortality and cardiovascular events in the PREDIMED study*, CLIN NUTR. 2014 Sep 16. pii: S0261-5614(14)00233-7 (Epub ahead of print).

⁴⁵ See, e.g., Katz DL & Meller S, *Can we say what diet is best for health?*, ANNU REV PUBLIC HEALTH, 2014;35:83-103.

such foods. For example, a 2013 report by the American Heart Association (AHA) and American College of Cardiology (ACC), *Guideline on Lifestyle: Management to Reduce Cardiovascular Risk*, advised adults who would benefit from either LDL-cholesterol (LDL-C) reduction or blood pressure lowering to consume a dietary pattern that emphasizes intake of vegetables, fruits, and whole grains; includes nuts, non-tropical vegetable oils, low-fat dairy products, poultry, fish, and legumes; and limits intake of sweets, sugar-sweetened beverages, and red meats.⁴⁶ Refined carbohydrates and added sugars should be replaced by healthy sources of fats (e.g., nuts, seeds, legumes, and non-hydrogenated vegetable oils that are high in unsaturated fats) and healthy sources of carbohydrates (e.g., whole grains, legumes, vegetables, and fruits). Indeed, research indicates that daily consumption of almonds (1.5 oz.), substituted for a high-carbohydrate snack, “may be a simple dietary strategy to help prevent the onset of cardiometabolic diseases in healthy individuals.”⁴⁷

There is a consistent body of scientific evidence showing that plant-based dietary patterns that include nuts are associated with decreased risk of cardiovascular disease. Specifically, in healthy adults, increased adherence to dietary patterns scoring high in fruits, vegetables, whole grains, nuts, legumes, unsaturated oils, low-fat dairy, poultry, and fish is associated with decreased risk of both fatal and non-fatal cardiovascular diseases, including coronary heart disease and stroke.⁴⁸ Nut intake has been specifically associated with a reduction in all-cause mortality,⁴⁹ and nuts, in particular almonds and walnuts, score very high on an objective scale of overall nutritional quality validated against health outcomes.⁵⁰

⁴⁶ Eckel RH et al., *2013 AHA/ACC guideline on lifestyle management to reduce cardiovascular risk: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines*, J AM COLL CARDIOL. 2014;63(25 Pt B):2960-84.

⁴⁷ Berryman CE et al., *Effects of daily almond consumption on cardiometabolic risk and abdominal adiposity in healthy adults with elevated LDL-cholesterol: a randomized controlled trial*, J AM HEART ASSOC. 2015 Jan 5;4(1).

⁴⁸ See Evidence Analysis Library Division, USDA, *A series of systematic reviews on the relationship between dietary patterns and health outcomes 4* (March 2014), <http://www.nel.gov/vault/2440/web/files/DietaryPatterns/DPRptFullFinal.pdf>; 2015 DGAC Report, Part D, Ch. 2, at 8-9.

⁴⁹ See, e.g., Luo C et al., *Nut consumption and risk of type 2 diabetes, cardiovascular disease, and all-cause mortality: a systematic review and meta-analysis*, AM J CLIN NUTR. 2014 Jul;100(1):256-69; Bao Y et al., *Association of nut consumption with total and cause-specific mortality*, N ENGL J MED. 2013 Nov 21;369(21):2001-11.

⁵⁰ See, e.g., Chiuve SE et al., *The association between a nutritional quality index and risk of chronic disease*, AM J PREV MED. 2011 May;40(5):505-13.

Nuts are nutrient-dense foods that are naturally rich in unsaturated fatty acids—including polyunsaturated fatty acids—fiber, vitamins, and minerals.⁵¹ Further, a strong evidence base from diverse intervention trials shows that nuts, in particular walnuts and almonds, exert favorable influences on a number of important biomarkers related to cardiometabolic health. For instance, almonds have been shown to reduce non-HDL-cholesterol (non-HDL-C), LDL-C, and central adiposity—important risk factors for cardiometabolic dysfunction—while maintaining HDL-cholesterol concentrations.⁵² In addition, a recently published systematic review and meta-analysis of randomized controlled clinical trials suggests that nut consumption reduces systolic blood pressure in individuals without type 2 diabetes.⁵³ The cardiovascular health benefits of nuts are further evidenced in the results of a meta-analysis that was recently published in the *American Journal of Clinical Nutrition*. That analysis indicated inverse associations between nut consumption and ischemic heart disease, overall cardiovascular disease, and all-cause mortality.⁵⁴

There is also growing evidence in support of the health benefits of other nutrient-dense foods that do not qualify as “healthy” under FDA’s current nutrient content claim regulations. For example, a recently-published clinical trial noted that inclusion of one avocado per day as part of a moderate-fat, cholesterol-lowering diet had LDL-C, LDL-particle and non-HDL-C lowering effects when compared to a low-fat diet in which 6 to 7% of the energy from saturated fats was replaced with carbohydrates from grains and to a moderate-fat diet where 6 to 7% of the energy from saturated fats was replaced with monounsaturated fats from high oleic acid oils (e.g., sunflower oil and canola oil). The results were not only consistent with existing research demonstrating the improvement in lipid profiles when saturated fats are replaced with monounsaturated fats, they may also point to functional effects of fruits and vegetables on lipid/lipoprotein risk factors that are independent of the substitution of macronutrients.⁵⁵

⁵¹ See, e.g., USDA, *National nutrient database for standard reference release 27*, <http://ndb.nal.usda.gov/ndb/search/list> (enter name of nut in search box) (last visited Nov. 30, 2015); Bao Y et al., *Association of nut consumption with total and cause-specific mortality*, N ENGL J MED. 2013 Nov 21;369(21):2001-11; 2015 *DGAC Report*, Part D, Ch. 1, at 34; *id.*, Appendix E-5, at 8.

⁵² Berryman CE et al., *Effects of daily almond consumption on cardiometabolic risk and abdominal adiposity in healthy adults with elevated LDL-cholesterol: a randomized controlled trial*, J AM HEART ASSOC. 2015 Jan 5;4(1).

⁵³ Mohammadifard N et al., *The effect of tree nut, peanut, and soy nut consumption on blood pressure: a systematic review and meta-analysis of randomized controlled clinical trials*, AM J CLIN NUTR. 2015 May;101(5):966-82.

⁵⁴ Luo C et al., *Nut consumption and risk of type 2 diabetes, cardiovascular disease, and all-cause mortality: a systematic review and meta-analysis*, AM J CLIN NUTR. 2014 Jul;100(1):256-69.

⁵⁵ Wang L et al., *Effect of a moderate fat diet with and without avocados on lipoprotein particle number*,

Additionally, an analysis of data from the National Health and Nutrition Examination Survey (NHANES) found that body weight, body mass index (BMI), and waist circumference were significantly lower and HDL-C was higher in avocado consumers. The odds ratio for metabolic syndrome was 50% lower in avocado consumers versus non-consumers.

Another group of foods associated with significant health benefits despite a high fat content is fatty fish. Fish consumption is specifically encouraged in the 2010 *Dietary Guidelines*, and in the 2015 *DGAC Report*. A recent meta-analysis identified a significant inverse association between fish consumption and incidence of metabolic syndrome.⁵⁶ Another meta-analysis identified a significant protective effect of oily fish intake on type 2 diabetes risk. A dose-response analysis suggested that every 80 g per day intake of oily fish may reduce type 2 diabetes risk by 20%.⁵⁷ Other studies have pointed to benefits for brain health, eye health, and infant development.⁵⁸

Collectively, these and related evidence suggest that a variety of foods that fail to meet the fat thresholds set forth in FDA's "healthy" nutrient content claim regulation are in fact "healthy" because they are (a) widely recognized as health-promoting; (b) encouraged by diverse expert sources; (c) staples in some of the world's healthiest diets; and (d) expressly recommended for consumption in the 2010 *Dietary Guidelines*. If FDA continues to prohibit the use of the word "healthy" to describe these foods solely because they are not "low fat" or "low saturated fat," its approach will conflict with the 2010 *Dietary Guidelines*, and there is significant potential for consumer confusion regarding whether a food is "healthy" and should be included in the diet. FDA should revise the conditions for total fat and saturated fat content in its "healthy" nutrient content claim regulation to convey that, in calculating the total fat or saturated fat levels of a food to determine compliance with the "healthy" claim requirements, producers may exclude the total fat or saturated fat content contributed to the food product by the following foods: fruits, vegetables, nuts, seeds, legumes, whole grains, and seafood. FDA should also

size and subclasses in overweight and obese adults: a randomized, controlled trial, J AM HEART ASSOC. 2015 Jan; 4(1): e001355.

⁵⁶ Kim Y et al., *Fish consumption, long-chain omega-3 polyunsaturated fatty acid intake and risk of metabolic syndrome: a meta-analysis*, NUTRIENTS. 2015 Apr; 7(4): 2085–2100.

⁵⁷ Zhang M et al., *Fish and marine omega-3 polyunsaturated fatty acid consumption and incidence of type 2 diabetes: a systematic review and meta-analysis*, INT J ENDOCRINOL. 2013; 2013: 501015.

⁵⁸ Raji CA et al., *Regular fish consumption and age-related brain gray matter loss*, AM J PREV MED. 2014 Oct;47(4):444-51.; Christen WG et al., *Dietary ω-3 Fatty Acid and Fish Intake and Incident Age-Related Macular Degeneration in Women*, ARCH OPHTHALMOL. 2011;129(7):921-929; FDA, Consumer Health Information, *New advice: pregnant women and young children should eat more fish* (June 2014), <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM400469.pdf>.

explicitly authorize the use of dietary guidance statements to communicate this information to consumers through claims other than nutrient content claims, to avoid such confusion.

c. Dietary recommendations and scientific evidence emphasize optimizing types of dietary fat rather than reducing total fat

In recent years, dietary recommendations worldwide have consistently emphasized that dietary patterns should optimize the types of dietary fat consumed rather than focusing on reducing total fat consumption. For example, the current Dietary Reference Intakes from NAS recognize that a wide range of total dietary fat intake is consistent with optimal health outcomes.⁵⁹ In addition, relevant authorities, ranging from the AHA, the Academy of Nutrition and Dietetics, and the ACC, have shifted their emphasis over time from dietary recommendations to restrict total fat intake to dietary recommendations to focus on the quality of fat consumed.⁶⁰ Specifically, experts still recommend that the public avoid *trans* fat and limit intake of saturated fat, but widely support liberalized intake of polyunsaturated and monounsaturated fat. Dietary patterns around the world associated with the greatest longevity and vitality vary widely in total fat intake. Those dietary patterns with higher fat levels associated with desired health outcomes are preferentially rich in unsaturated fats, with nuts and seeds an important source of such fats. FDA acknowledged this position in its recent proposed rule to amend requirements related to the Nutrition Facts Panel, where FDA proposed to remove the requirement for declaring “Calories from Fat” on food labels, concluding “current science supports a view that the type of fat is more relevant than overall total fat intake in increased risk of chronic diseases.”⁶¹

All naturally occurring sources of dietary fat contain a mix of fatty acids, including saturated fatty acids. For example, roughly 14% of the fat in olive oil is saturated fat. Like all

⁵⁹ Food and Nutrition Board, Institute of Medicine, DIETARY REFERENCE INTAKES FOR ENERGY, CARBOHYDRATE, FIBER, FAT, FATTY ACIDS, CHOLESTEROL, PROTEIN, AND AMINO ACIDS (MACRONUTRIENTS) 422-540 at 437 (2005), *available at* http://www.nal.usda.gov/fnic/DRI/DRI_Energy/422-541.pdf.

⁶⁰ AHA, *Know Your Fats*, http://www.heart.org/HEARTORG/Conditions/Cholesterol/PreventionTreatmentofHighCholesterol/Know-Your-Fats_UCM_305628_Article.jsp (April 21, 2014); Mayo Clinic, *Nutrition and healthy eating*, <http://www.mayoclinic.org/healthy-lifestyle/nutrition-and-healthy-eating/in-depth/fat/art-20045550> (last visited Nov. 30, 2015); Vannice G & Rasmussen H, *Position of the Academy of Nutrition and Dietetics: dietary fatty acids for healthy adults*, J ACAD NUTR DIET. 2014 Jan;114(1):136-53.

⁶¹ 79 Fed. Reg. 11880 at 11881 (March 3, 2014).

foods containing fats, nuts contain various mixes of fatty acids, including saturated fatty acids at differing levels.⁶² While advice to limit total saturated fat intake remains justifiable, that guidance should not be misconstrued as advice to restrict the intake of health promoting, nutrient-dense foods such as nuts and fish. More specifically, the reconciliation between guidance to limit total saturated fat intake and guidance to consume nuts routinely requires that the saturated fat content of nuts *not* be a concern. Rather, total saturated fat intake is appropriately moderated by limiting intake of foods that are preferential sources of saturated fat and that are not reliably associated with health benefit—not by avoiding foods such as nuts that may contain saturated fat, but that are reliably associated with health benefit.

Further, the health effects of saturated fat are not unitary. Whether or not any saturated fatty acids are actually health promoting, some are considered innocuous or nearly so. This conclusion, for instance, was reached about stearic acid by the 2010 DGAC, which advised that intake of saturated fat should be restricted, but that stearic acid should be exempted.⁶³ The 2010 *Dietary Guidelines* did not retain that recommendation, presumably not because of any concerns about the science, but rather concerns about translating that conclusion into something the public would understand. Similarly, evidence is accumulating that lauric acid, a predominant saturated fatty acid in coconut oil, may also be innocuous.⁶⁴ While further research in this area is needed, we note that recent meta-analyses concluded that the evidence did not clearly support cardiovascular guidelines recommending low consumption of total saturated fats.^{65,66}

⁶² See, e.g., Moncel B, *Nut Nutritional Comparison Chart: A side by side comparison of the major nutrients in common nuts*, AboutFood, http://foodreference.about.com/od/food_reference_charts/a/Nut-Nutritional-Comparison-Chart.htm (last visited Nov. 30, 2015).

⁶³ USDA & HHS, REPORT OF THE DIETARY GUIDELINES ADVISORY COMMITTEE ON THE DIETARY GUIDELINES FOR AMERICANS, 2010 at 229-230 (May 2010).

⁶⁴ Micha R & Mozaffarian D, *Saturated fat and cardiometabolic risk factors, coronary heart disease, stroke, and diabetes: a fresh look at the evidence*, LIPIDS. 2010 Oct;45(10):893-905.; Zelman KM, *The truth about coconut oil*, WebMD (March 10, 2011), <http://www.webmd.com/diet/coconut-oil-and-health>; de Roos N et al., *Consumption of a solid fat rich in lauric acid results in a more favorable serum lipid profile in healthy men and women than consumption of a solid fat rich in trans-fatty acids*, J NUTR. 2001 Feb;131(2):242-5..

⁶⁵ Chowdhury R et al., *Association of dietary, circulating, and supplement fatty acids with coronary risk: a systematic review and meta-analysis*, ANN INTERN MED. 2014;160(6): 398-406

⁶⁶ de Souza RJ et al., *Intake of saturated and trans unsaturated fatty acids and risk of all cause mortality, cardiovascular disease, and type 2 diabetes: systematic review and meta-analysis of observational studies*, BMJ, 2015;351:h3978.

C. FDA Should Allow Products Containing Certain Types of Foods that are Key Components of Healthful Diet, Including Nuts, Seafood, Fruits, and Vegetables, to Bear Claims Communicating that Such Foods are Healthy

KIND is asking FDA to help consumers to make informed dietary choices by explicitly allowing food producers to make labeling claims about the healthful value of the types of foods that are key components of federal dietary recommendations. The requested changes are necessary to ensure that FDA's requirements are consistent with current federal dietary recommendations and with the most recent scientific evidence, which is essential in providing uniform federal dietary guidance to consumers.

Specifically, KIND requests that FDA fully reevaluate its nutrient content claim regulations and amend those requirements as necessary to ensure consistency with current federal dietary recommendations. In particular, KIND requests that FDA amend the regulation for general nutritional claims in 21 C.F.R. 101.65(d)(2) to revise the conditions for total fat and saturated fat content to convey that, in calculating the total fat or saturated fat levels of a food to determine compliance with the requirements in the "healthy" claim regulation, producers may exclude the total fat or saturated fat content contributed to the food product by the following foods, provided that such foods are used in their whole form or have been processed in such a way that did not materially degrade their nutritional composition: fruits, vegetables, nuts, seeds, legumes, whole grains, and seafood. For example, if a food product contains nuts in addition to other ingredients, and that product contains 2.5 grams of saturated fat, of which 2 grams come from the nuts, for purposes of calculating that product's saturated fat content under 21 C.F.R. 101.65(d), the 2 grams of saturated fat from nuts would be excluded. This would mean that, for the purposes of 21 C.F.R. 101.65(d), the product would contain only 0.5 grams of saturated fat, and therefore, the product would qualify for a "healthy" nutrient content claim. The *Dietary Guidelines* recommends increased consumption of each of these foods. These changes would ensure that the regulation does not prohibit the use of a "healthy" nutrient content claim for an entire category of foods that is recommended in the *Dietary Guidelines*, such as nuts. We have proposed additional language to ensure that food producers could not exclude the total fat or saturated fat content from ingredients that are derived from the food groups listed above, but are not themselves nutrient dense.

In addition, KIND asks FDA to undertake rulemaking to define a "dietary guidance statement" as a statement in food labeling about the usefulness of a food, or a category of foods, in maintaining healthy dietary practices. This definition of "dietary guidance statement" would include a statement that focuses on general dietary patterns, practices, and recommendations that promote health (e.g., "Nuts are part of a healthy diet"). The definition of "dietary guidance statement" would also include a statement that highlights the presence or amount of a food or category of foods in relation to a general health benefit or healthful diet (e.g., "Contains healthy

whole grains”) or recommends the substitution of a food or food category that is consistent with current dietary recommendations for a food or food category that is less beneficial to health (“Eat foods made from healthy whole grains instead of refined grains”).

KIND requests that this rulemaking explicitly allow for the use of claims in food labeling to communicate that certain foods are useful in creating a diet that is consistent with current dietary recommendations so long as those claims are not misleading, which would encourage the use of such statements in food labeling. In particular, KIND requests that the rulemaking establish a meaningful amount requirement for the use of dietary guidance statements to ensure that such statements are not made on products that do not contain enough of a food to contribute any health or dietary benefit, and establish other requirements as necessary to ensure that dietary guidance statements are not misleading to consumers. The meaningful amount requirement could require that a food contain a minimum percentage by weight (e.g., 30 percent) of the food ingredient that is the subject of the dietary guidance statement. Such a requirement would mean that in order for a product to bear the statement “Contains healthy whole grains,” the product would have to consist of at least 30 percent whole grains by weight.

KIND also requests that FDA amend its current nutrient content claim regulations to clarify that claims using the term “healthy” are nutrient content claims only when such claims characterize the level of a nutrient in a food product; otherwise claims using the term “healthy” could be regulated as dietary guidance statements. Specifically, KIND asks that FDA amend 21 C.F.R. 101.65(d)(1)(ii) to clarify that a claim using the term “healthy” suggests that a food, because of its nutrient content, may help consumers maintain healthy dietary practices, and is therefore a nutrient content claim, only when the word “healthy” is *immediately adjacent* to an explicit or implicit claim or statement about a nutrient (e.g., “healthy, contains 3 grams of fat”). KIND also asks that FDA amend 21 C.F.R. 101.65(b) to clarify that dietary guidance statements are generally not implied nutrient content claims, unless such statements are immediately adjacent to a claim or statement about a nutrient. In effect, this would mean that food producers could use the phrase “Contains healthy whole grains” as a dietary guidance statement in one part of a food label to tell consumers that whole grains are a key component of a healthy diet, and could also include nutrient content claims in another part of the same food label to identify certain nutrient-specific aspects of the food, without subjecting the “Contains healthy whole grains” statement to the nutrient content claim requirements, which are not intended to regulate claims about *foods*, solely claims about *nutrients*.

Because rulemaking is a lengthy process that requires significant FDA resources, KIND requests that FDA issue a guidance document for industry as soon as possible to clarify that a statement about the usefulness of a food, or a category of foods, in maintaining healthy dietary practices is a dietary guidance statement that is not subject to the requirements in FDA’s nutrient content claim regulations unless it is an implied nutrient content claim because it is immediately

adjacent to an explicit or implicit claim or statement about a nutrient. This guidance document could also remind industry that dietary guidance statements must not be false or misleading, and could suggest certain criteria that industry should consider when making dietary guidance statements to ensure that they aren't misleading to consumers (e.g., meaningful amount standards). As discussed above, there is an urgent need to improve and expand how federal dietary recommendations are communicated to the American public. The 2015 *DGAC Report* “encourages the food industry to market . . . improved products to consumers.”⁶⁷ Approximately half of all American adults suffer from one or more preventable chronic diseases that relate to poor quality dietary patterns, physical inactivity, and other health habits, such as type 2 diabetes, and about two-thirds of U.S. adults are overweight or obese.⁶⁸ The guidance document would immediately improve how current federal dietary recommendations are communicated, which would better enable consumers to make healthy dietary choices as soon as possible.

1. FDA Has the Legal Authority to Take the Requested Actions

Under section 403(a)(1) of the FDCA, a food is misbranded if its labeling is false or misleading in any particular. In determining whether food labeling is misleading, section 201(n) of the FDCA explicitly provides for consideration of representations made or suggested by any statement, word, or design in the labeling, and also the extent to which the labeling fails to reveal material information. Section 701(a) of the FDCA provides FDA with the authority to issue regulations for the efficient enforcement of the requirements of the FDCA in order to “effectuate a congressional objective expressed elsewhere in the [FDCA].”⁶⁹

The FDCA clearly represents a congressional objective for FDA to ensure that food labeling is not misleading. Congress has also indicated on numerous occasions that FDA has a broad responsibility to ensure that food labeling is accurate and adequate to educate consumers on dietary practices. For example, in presenting NLEA to the Senate for consideration, Senator Hatch stated that “[the government’s] effort to educate consumers on dietary practices has been less than adequate,” and that “[c]onsumers should have modern, scientific diet and health information on the label so that they can make informed judgments as they shop.”⁷⁰ Therefore, under sections 403(a)(1), 201(n), and 701(a) of the FDCA, FDA has the authority to define

⁶⁷ 2015 *DGAC Report*, Executive Summary at 10.

⁶⁸ 2015 *DGAC Report*, Executive Summary at 1.

⁶⁹ *Ass’n of Am. Physicians & Surgeons, Inc. v. FDA*, 226 F. Supp. 2d 204, 213 (D.D.C. 2002) (citing *Pharm. Mfrs. Ass’n. v. FDA*, 484 F. Supp. 1179, 1183 (D. Del. 1980)).

⁷⁰ 136 Cong. Rec. 33428 (1990).

“dietary guidance statement” by regulation and to develop requirements that will encourage food producers to use such statements in food labeling in a way that does not mislead consumers.

In addition, FDA has the authority, and the statutory obligation, to amend its nutrient content claim regulations in 21 C.F.R. 101.65 to amend the requirements for making a “healthy” nutrient content claim and to clarify that the use of the term “healthy” is only a nutrient content claim if it is immediately adjacent to a claim or statement about a nutrient. Section 403(r) of the FDCA directs FDA to regulate as a nutrient content claim any claim that, expressly or by implication, characterizes the level of a nutrient in a food product. Specifically, section 403(r)(2)(A) of the FDCA provides that a nutrient content claim may only be made in food labeling if the claim uses terms that have been defined by FDA by regulation. Under this authority, FDA has defined the term “healthy” as a nutrient content claim when it is used in a way to suggest that a food, because of its specific nutrient content, may help consumers to maintain healthy dietary practices. As discussed in detail above, when 21 C.F.R. 101.65 was promulgated more than twenty years ago, “healthy dietary practices” involved, almost exclusively, limiting the levels of certain nutrients, including total fat, in the diet and trying to consume more of other specific nutrients through the diet.

However, evolving scientific evidence now requires a different approach to “healthy dietary practices,” one that focuses consuming certain types of fat, rather than eliminating fat, and one that focuses on consuming more of certain categories of foods and limiting consumption of other categories of foods. Given this, the term “healthy” could be used on a food containing certain ingredients that are recommended for increased consumption by current federal guidelines, even if those ingredients contribute some total fat content to the finished product that cause the finished product not to be “low fat.” Furthermore, the term “healthy” could be used in the labeling of food *without* suggesting that a food, *because of its specific nutrient content*, may help consumers maintain healthy dietary practices. Instead, the term “healthy” could be readily used to suggest that a food, because of its *properties as a food*, may help consumers maintain healthy dietary practices. FDA must amend its regulations to ensure that requirements that FDA imposes on the use of the term “healthy” as a nutrient content claim reflect current federal dietary recommendations, and also to ensure that the term “healthy” is regulated as a nutrient content claim only when it characterizes the level of a specific nutrient in a food (e.g., “healthy, contains 10 g of fiber”).

2. FDA Plays a Crucial Role in Ensuring that Consumers are Aware of Current Dietary Recommendations and FDA’s Current Regulatory Approach is Not Consistent with those Recommendations

FDA and HHS have both recognized the critical role that the federal government plays in helping consumers make sound dietary decisions by ensuring that food labeling contains truthful

and nonmisleading information about current dietary recommendations and by encouraging the use of food labeling statements to convey this information. When FDA launched the CHIBNI in 2002, it did so with the goal of encouraging “makers of conventional foods and dietary supplements to make accurate, up-to-date, science-based claims about the health benefits of their products,” in order to help consumers “improve their understanding of how their dietary choices may influence their health, to promote competition among product developers to find better ways to help improve health through better diets, and ultimately to prevent serious and life-threatening diseases through better dietary choices by Americans.”⁷¹ At the time, then HHS Secretary Tommy G. Thompson said, “By putting credible, science-based information in the hands of consumers, we hope to foster competition based on the real nutritional value of foods rather than on portion size or spurious and unreliable claims. Such labeling can help empower consumers to make smart, healthy choices about the foods that they buy and consume.”⁷² More recently, in a 2009 speech to the National Food Policy Conference, then FDA Commissioner Dr. Margaret Hamburg acknowledged that certain requirements promulgated under NLEA could be outdated, stating that “the public health importance of food labeling as an essential means for informing consumers about proper nutrition . . . has not been substantially addressed since the FDA implemented the Nutrition Labeling and Education Act, more than 16 years ago.”⁷³

Similarly, research has repeatedly recognized the value of truthful and nonmisleading food labeling in communicating health information to consumers. For example, according to data from recent NHANES, the percent of working age adults that reported using the Nutrition Facts Panel (NFP) when making purchasing decisions increased from 34 percent in 2007-2008 to 42 percent in 2009-2010.⁷⁴ FDA’s Health and Diet Surveys show that, in 2008, more than fifty percent of consumers reported that they read food labels when purchasing a product for the first time.⁷⁵ A recent study evaluated whether food label use impacted dietary quality, and concluded that food label use is related to dietary quality and choice, and that individuals who paid more attention to nutrition information on package fronts were more likely to consume a healthy

⁷¹ FDA, *Consumer Health Information for Better Nutrition Initiative: Task Force Final Report* (July 2003), <http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm096010.htm>.

⁷² *Id.*

⁷³ Commissioner of Food and Drugs Margaret A. Hamburg, M.D., Keynote Address at the National Food Policy Conference (Sept. 8, 2009).

⁷⁴ 79 Fed. Reg. 11880, 11887 (March 3, 2014) *citing* Todd JE, Economic Research Service, USDA, *Changes in Eating Patterns and Diet Quality Among Working-Age Adults, 2005–10*, EER–161 (2014), available at <http://www.ers.usda.gov/media/1259670/err161.pdf>.

⁷⁵ 79 Fed. Reg. at 11887.

diet.⁷⁶ The authors of this study noted that their findings lend support to the idea that food label information is being utilized to consume healthier foods.

FDA acknowledges, in a recent guidance document, that “dietary guidance statements” are a distinct category of claims that can be made in food labeling to communicate information about general dietary patterns, practices, and recommendations that promote health, and that “dietary guidance statements” generally make reference to a food or category of foods and not a specific substance.⁷⁷ However, in the same guidance document, FDA states that the term “healthy” has been defined by regulation “as an implied nutrient content claim that characterizes a food that has ‘healthy’ levels of total fat, saturated fat, cholesterol, other nutrients, and sodium.”⁷⁸ This guidance document does not clarify, as FDA did in the nutrient content claim rulemaking and in the actual regulation defining the term “healthy” as a nutrient content claim, that the term “healthy” is *only* an implied nutrient content claim when it is used in association with an explicit or implicit statement about the level of a nutrient. There appears to be significant confusion within industry, amongst regulators, and amongst consumers regarding what the term “healthy” means when used in food labeling, when that term implies that a food is beneficial because of its specific nutrient content (e.g., because it is low in fat or high in fiber), and when that term implies that a food is beneficial because of the food ingredients that it contains (e.g., carrots, which are good for health).

The currently regulatory framework prohibits the use of a “healthy” nutrient content claim on products that are nutrient dense, meet current federal dietary recommendations, and contain ingredients that Americans should be consuming. FDA’s regulatory framework also prevents consumers from receiving critical information about the healthful value of a wide range of food products. FDA cannot prohibit the use of nutrient content claims that are truthful, nonmisleading, and consistent with current federal dietary recommendations. FDA also cannot regulate statements as nutrient content claims if those statements do not, explicitly or implicitly, characterize the level of a nutrient in a food. FDA’s nutrient content claim authority does not extend to dietary guidance statements that communicate information about general dietary patterns, practices, and recommendations that promote health, and foods or categories of foods

⁷⁶ Miller LMS et al., *Relationships among food label use, motivation, and dietary quality*, NUTRIENTS. 2015;7:1068–80.

⁷⁷ CFSAN, FDA, *Guidance for Industry and FDA: Dear Manufacturer Letter Regarding Food Labeling* (Jan. 2007), available at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm053425.htm>.

⁷⁸ *Id.*

that can help consumers meet dietary recommendations, but that do *not* imply that a product is healthy because of its specific nutrient content.

This distinction is particularly relevant in light of current national and global dietary recommendations, discussed earlier, which encourage consumers to focus primarily on the types of foods that they are consuming instead of the specific nutrient content of each food product that they consume when constructing a healthy dietary pattern.⁷⁹ Under FDA's current application of the "healthy" nutrient content claim regulations, entire categories of foods that are recommended for increased consumption in the 2010 *Dietary Guidelines*, as well as the 2015 *DGAC Report*, such as nuts, seafood, and avocados, cannot be the subject of a claim communicating their health benefits. Further, the conclusions that FDA reached during the nutrient content claim rulemaking in 1993 are no longer supported by scientific evidence. Therefore, FDA should amend its nutrient content claim regulations as requested, and should explicitly authorize the use of dietary guidance statements, as requested, to encourage food producers to communicate this information.

3. Most Americans are not Consuming a Diet Consistent with Current Dietary Recommendations

The evidence set forth in the 2010 *Dietary Guidelines*, and again in the 2015 *DGAC Report*, demonstrates the urgent need to improve the dietary patterns of the American public, based primarily on recent data that show that approximately *half* of all American adults suffer from one or more *preventable* chronic diseases that relate to poor quality dietary patterns, physical inactivity, and other health habits, and that about two-thirds of U.S. adults are overweight or obese.⁸⁰ The 2015 *DGAC Report* concluded that the majority of the U.S. population has low intakes of key food groups that are a critical component of a healthful diet, including vegetables, fruits, and whole grains.⁸¹ This reinforces conclusions reached in the 2010 *Dietary Guidelines*, which compares the typical U.S. intake, by adults, of a variety of food groups to the recommended intake for a healthy eating pattern. This analysis found that Americans are, on average, consuming fewer vegetables, fruits, whole grains, seafood, nuts, seeds, and oils than what is recommended.⁸² For example, the typical U.S. daily intake of whole grains is 0.6 ounces, while the USDA Food Pattern recommends a daily intake of at least 3

⁷⁹ See, e.g., 2015 *DGAC Report*, Part D, Chapter 2, at 2-3.; WHO, *Joint WHO/FAO Expert Consultation on Diet, Nutrition and the Prevention of Chronic Diseases* 45 (2003), available at http://whqlibdoc.who.int/trs/WHO_TRS_916.pdf.

⁸⁰ 2015 *DGAC Report*, Executive Summary at 1.

⁸¹ *Id.* at 2.

⁸² 2010 *Dietary Guidelines* at 51.

ounces; similarly, the typical U.S. daily intake of seafood is 0.5 ounces, while the USDA Food Pattern recommends a daily intake of 1.2 ounces.⁸³

Further, in FDA's 2004 report on obesity, *Calories Count: Report of the Working Group on Obesity*, FDA concluded that while consumers generally report that they understand what comprises a healthy diet, focus group research showed that *approximately 40 percent of consumers perceive the quality of their diets to be better than they actually are.*⁸⁴ This demonstrates the importance of better and more messaging about healthy dietary patterns. FDA recognized the need to focus its education strategy on influencing behavior, as well as imparting knowledge, in the context of healthy choices for consumers, and the report recommended that education programs be aimed at helping consumers make more informed food choices that result in better weight management and should be crafted to reach a variety of audiences.

As discussed earlier, the CHIBNI Task Force, convened in 2002, considered data from the, at that time, most recent Food Marketing Institute Trends in the United States Survey.⁸⁵ This survey indicated that the percentage of consumers who recognize the importance of eating healthfully and who are interested in trying foods that may improve their health was increasing: 86% agreed or strongly agreed that "in most cases, eating healthfully is a better way to manage illness than medications," up from 76% in 2001, and 54% said they were very interested in trying health-promoting foods.⁸⁶ However, this survey also indicated that the percentage of consumers who acknowledge unhealthy eating behaviors was also increasing: 72% of consumers agreed or strongly agreed with the statement, "I eat foods I enjoy, even if they're not good for me," up from 64% in 2001, and 34% agreed or strongly agreed with the statement, "I eat whatever I want and don't think much about how it affects my health," up from 25% in 2001.⁸⁷ Based on all of

⁸³ *Id.*

⁸⁴ FDA, *Calories Count: Report of the Working Group on Obesity* (March 2004), <http://www.fda.gov/Food/FoodScienceResearch/ConsumerBehaviorResearch/ucm081770.htm>, citing Variyam J et al., *Consumer Misperceptions of Diet Quality*, J NUTR EDUC BEHAV. 2001; 33: 314.

⁸⁵ See FDA, *Consumer Health Information for Better Nutrition Initiative: Task Force Final Report* (July 2003), <http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm096010.htm>.

⁸⁶ *Id.* (emphasis omitted).

⁸⁷ *Id.* (emphasis omitted). The Task Force also recognized the growing concern about obesity and related health issues, concluding that, while "there [had] been a number of public and private sector efforts in the United States aimed at reducing obesity" in recent decades, none had been successful in actually reversing the trend in the increase in overweight and obesity each year. For example, "in 1999, an estimated 61% of U.S. adults were overweight or obese, with nearly twice as many overweight children and almost three times as many overweight adolescents as there were in 1980." *Id.* (footnote omitted).

this information, the Task Force concluded that “finding more effective ways to improve consumer understanding and behavior is an urgent public health priority.”⁸⁸

Similarly, a 2014 USDA Report examining the eating habits of working-age adults between 2005 and 2010 specifically considered to what extent study respondents used the NFP or package health claims when deciding whether to buy a food.⁸⁹ For 2009-2010, a period when consumers reported embracing healthy foods, consuming fewer calories, and eating more fiber, 42 percent of respondents reported using the NFP “always or most of the time” and 31 percent reported using package health claims “always or most of the time.” “In contrast, only one-quarter of working-age adults report that they have *tried* to implement the MyPyramid plan (a dietary plan derived from the *Dietary Guidelines for Americans*).”⁹⁰

D. FDA Cannot Prohibit Labeling Statements that are Truthful and Nonmisleading

FDA’s current nutrient content claim regulatory approach prevents the dissemination of truthful and nonmisleading information about the role of certain foods in maintaining healthy dietary practices in violation of the First Amendment. Claims made in food labeling are commercial speech and are entitled to protection so long as they are truthful and not inherently misleading.⁹¹ If commercial speech is truthful and not inherently misleading, then the government can restrict such speech only under certain limited circumstances: (1) the asserted governmental interest must be substantial; (2) the restriction must directly advance the asserted governmental interest; and (3) the restriction must not be more extensive than is necessary to serve the governmental interest.⁹² The Supreme Court has emphasized that “[i]t is a matter of public interest that [economic] decisions . . . be intelligent and well informed.”⁹³ In furtherance of this goal, “the free flow of commercial information is indispensable.”⁹⁴

⁸⁸ *Id.*

⁸⁹ Todd JE, Economic Research Service, USDA, *Changes in Eating Patterns and Diet Quality Among Working-Age Adults, 2005-10*, ERR-161, at iii, iv (2014) (emphasis added), available at <http://www.ers.usda.gov/media/1259670/err161.pdf>.

⁹⁰ *Id.* at 19 (emphasis added).

⁹¹ See, e.g., *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 366-67 (2002).

⁹² *Cent. Hudson Gas & Elec. Corp. v. Public Svc. Comm’n*, 447 U.S. 557, 566-571 (1980).

⁹³ *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 765 (1976).

⁹⁴ *Id.*

KIND recognizes that the use of claims such as “healthy” in food labeling has the potential to mislead consumers, and that FDA has an interest in ensuring that such claims are used in a way that truthfully and accurately reflects the value of a food. Courts have recognized substantial government interests both in the promotion of the public health⁹⁵ and the prevention of consumer fraud and confusion.⁹⁶ In order to show that a speech prohibition “directly advance[s]” a government interest, FDA must prove that the restriction will “in fact alleviate [the harms of the allegedly misleading speech] to a *material* degree.”⁹⁷ Furthermore, the link between the regulation and the interest must be supported by more than “anecdotal evidence and educated guesses.”⁹⁸ FDA’s current application of the “healthy” nutrient content claim requirements to a broad range of claims about the healthful value of a food or its ingredients, rather than about a food’s nutrient composition, is far more extensive than necessary to ensure that labeling claims are not misleading, and prevents the dissemination of truthful, beneficial, and scientifically valid information to consumers. Specifically, FDA’s current requirements for the use of a “healthy” nutrient content claim exclude an entire category of foods that is recommended in the dietary guidelines—nuts—from bearing such a claim because nuts are not low in fat.

There must be a reasonable fit between any restriction on commercial speech and the ends to be achieved.⁹⁹ The reasonable fit standard is not satisfied where the government “place[s] an absolute prohibition on certain types of potentially misleading information . . . if the information also may be presented in a way that is not deceptive.”¹⁰⁰ Furthermore, the government cannot simply state that less restrictive means would not be effective; it has the burden of showing as much.¹⁰¹ FDA has taken an overly broad approach that effectively prohibits the use of terms such as “healthy” about certain foods that inherently do not meet

⁹⁵ *Pearson v. Shalala*, 164 F.3d, 650, 656 (D.C. Cir. 1999) (*Pearson I*), citing *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 485 (1995).

⁹⁶ *Pearson I*, 164 F.3d at 655-56.

⁹⁷ *Edenfield v. Fane*, 507 U.S. 761, 770, 771 (1993) (emphasis added) (citations omitted).

⁹⁸ *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 490 (1995).

⁹⁹ *Bd. of Trs. v. Fox*, 492 U.S. 469, 480 (1989).

¹⁰⁰ *In re R.M.J.*, 455 U.S. 191, 203 (1982); see also *Central Hudson*, 447 U.S. at 562 (stating that even when speech “communicates only an incomplete version of relevant facts, . . . some accurate information is better than no information at all”); *Pearson v. Thompson*, 141 F. Supp. 2d 105, 112 (D.D.C. 2001) (*Pearson III*) (noting that there is a “very heavy burden” to satisfy if the government wishes to totally suppress a particular claim).

¹⁰¹ *Western States*, 535 U.S. at 373.

FDA's strict nutrient content claim requirements, even though "healthy" claims could be readily used in a way that is not misleading to consumers. This approach is not a "reasonable fit" to FDA's interest in ensuring that labeling claims are not misleading. Instead, FDA is prohibiting food producers from dispensing an entire class of information that is vital to the nation's health—that consumers should eat more of certain categories of food in order to have a healthy diet. This prohibition is diametrically opposed to the Supreme Court's explicit purpose of protecting the dissemination of information which may benefit consumers.¹⁰²

There are several less restrictive ways that FDA could further its intended interest of preventing consumer confusion. Specifically, as KIND has requested, FDA could amend its "healthy" nutrient content claim regulation to impose conditions that are consistent with current federal dietary recommendations, and could explicitly allow for the use of dietary guidance statements to communicate information about the health value of foods and categories of foods and establish certain requirements for the use of dietary guidance statements. This would allow FDA to ensure that terms such as "healthy" are used only with regard to products that contain a meaningful amount of a food or category of foods that is part of a healthy diet. Furthermore, amending FDA's nutrient content claim regulations to clarify when the statement "healthy" is a nutrient content claim would satisfy FDA's interest in preventing consumer confusion because it would allow the use of terms such as healthy only where this language is not placed immediately adjacent to an explicit or implied claim or statement about a nutrient. Thus, this approach would allow for the dissemination of truthful dietary guidance statements without risking consumer confusion about whether the language is a statement about a product's nutrient contents. FDA's current approach does not satisfy the "reasonable fit" standard and must be altered to allow for the dissemination of truthful and non-misleading information so as to not violate food manufacturers' First Amendment rights to tell consumers of foods that contribute to healthy dietary patterns.

III. Conclusion

For the reasons set forth above, KIND requests that FDA take the actions requested 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).

¹⁰² See, e.g., *id.* at 366-67.

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

- Appendix 1: References
- Appendix 2: Letters of Support