April 26, 2017

Dr. Stephen Ostroff
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: **Use of the Term "Healthy" in the Labeling of Human Food Products; Request for Information and Comments**; Docket No. FDA–2016–D–2335

Dear Acting Commissioner Ostroff:

The Center for Science in the Public Interest (CSPI) supports the Food and Drug Administration's (FDA) intention to update the definition for the term "healthy" as an implied nutrient content claim on food packages. This rulemaking presents an opportunity to update the "healthy" definition to reflect current dietary recommendations and nutrients on the new Nutrition Facts label. It is important that FDA take this opportunity to strengthen the "healthy" definition so that the claim steers consumers toward fruits, vegetables, whole grains, and other underconsumed healthy foods and away from their competitors in the processed food aisles. FDA should also retain or tighten current limits on overconsumed nutrients to ensure that "healthy" foods do not contribute to excess intakes of added sugars, sodium, cholesterol, or saturated fat. If "healthy" is not carefully defined, the claim could encourage consumers to select heavily-processed snack foods and other less healthy foods rather than whole fruits and vegetables.

CSPI is a non-profit consumer education and advocacy organization that since 1971 has been working to improve the public's health through better nutrition and food safety. The organization's work is supported primarily by the 600,000 subscribers to its *Nutrition Action Healthletter*, the nation's largest-circulation health newsletter. CSPI is an independent organization that does not accept government or corporate funding. CSPI has advocated for decades to ensure that food labeling claims in general and "healthy" claims in particular are truthful and not misleading. CSPI first submitted comments to the FDA in 1993 regarding the current definition for "healthy."

We respectfully submit the following comments regarding the update to the definition for "healthy," outlined below:

I. In general, FDA should define "healthy" to include only foods emphasized in a healthy eating pattern and in their nutrient-dense forms, which is the foundation of the *2015-2020 Dietary Guidelines for Americans* (DGA) recommendations.

II. FDA should require foods that make "healthy" claims to meet both food and nutrient criteria.

III. Nutrient criteria should include significant amounts of beneficial nutrients (potassium, vitamin D, calcium, iron, protein, and fiber) and limits on overconsumed detrimental nutrients (added sugars, saturated fat, cholesterol, and sodium).

IV. Food criteria should include a 100 percent whole grain requirement; an exemption from certain nutrient criteria when necessary to include nutrient-dense foods that make up the foundation of a healthy eating pattern; and an exclusion of foods that do not make up the core of a healthy eating pattern (fruit juices, red and processed meats, alcoholic beverages, sugar-sweetened beverages and candy, and foods that contain partially hydrogenated oil).

V. "Healthy" should be regulated as an implied nutrient content claim whenever the term is made *in connection with* an explicit or implicit claim or statement about a nutrient, not only when it appears *immediately adjacent to* an implicit claim or statement about a nutrient, as suggested by the KIND citizen petition.[1]

Discussion of CSPI's recommendations for updating the "healthy" nutrient content claim is continued below. Sections II-IV detail the specific criteria that CSPI recommends to outline a regulatory definition for the use of the term "healthy."

I. In general, FDA should define "healthy" to include only foods emphasized in a healthy eating pattern and in their nutrient-dense forms, which is the foundation of the *2015-2020 Dietary Guidelines for Americans* (DGA) recommendations.

A. The *Dietary Guidelines* recommends healthy eating patterns.

A healthy eating pattern is higher in fruits, vegetables, whole grains, fat-free or low-fat dairy, seafood, legumes, and nuts and lower in red and processed meats, sugar-sweetened foods and drinks, and refined grains.[2] Therefore, FDA should define "healthy" to include only fruits, vegetables, whole grains, low-fat or non-fat dairy, lean poultry, fish, legumes, and nuts and seeds.

The *Scientific Report of the 2015 Dietary Guidelines Advisory Committee (DGAC)* notes that the average American's diet is low in many of these foods—particularly vegetables, fruits, and whole grains—and is high in sodium, calories, saturated fat, refined grains, and added sugars. For most people, the DGAC report notes, making changes to achieve healthy eating patterns will mean "[i]ncluding more vegetables (without added salt or fat), fruits (without added sugars), whole grains, seafood, nuts, legumes, low/non-fat dairy or dairy alternatives (without added sugars)."[3] These recommendations should inform the FDA's updated definition of "healthy."

B. The *Dietary Guidelines* recommends nutrient-dense foods.

The overarching recommendations in the *Dietary Guidelines* promote a healthy eating pattern made up of nutrient-dense foods. To achieve this pattern, the *Dietary Guidelines* recommends that consumers "[s]hift to healthier food and beverage choices" by choosing "nutrient-dense foods and beverages across and within all food groups in place of less healthy choices."[4] FDA must ensure that updated criteria for "healthy" clearly distinguishes between these choices to help consumers follow the healthy eating pattern detailed in the *Dietary Guidelines*.

The *Dietary Guidelines* defines the concept of nutrient-dense as:

> A characteristic of foods and beverages that provide vitamins, minerals, and other substances that contribute to adequate nutrient intakes or may have positive health effects, **with little or no solid fats and added sugars, refined starches, and sodium** [emphasis added]. Ideally, these foods and beverages also are in forms that retain naturally occurring components, such as dietary fiber. All vegetables, fruits, whole grains, seafood, eggs, beans and peas, unsalted nuts and seeds, fat-free and low-fat dairy products, and lean meats[i] and poultry—when prepared with little or no added solid fats sugars, refined starches, and sodium—are nutrient-dense foods. These foods contribute to meeting food group recommendations within calorie and sodium limits. The term "nutrient dense" indicates the nutrients and other beneficial substances in a food have not been "diluted" by the addition of calories from added solid fats, sugars, or refined starches, or by the solid fats naturally present in the food.[5]

As the definition and illustrations in the *Dietary Guidelines*[6] demonstrate, a piece of whole fruit is nutrient-dense, whereas a sugar-sweetened grain bar with fruit filling is not. Fresh vegetables with hummus are nutrient-dense, whereas tortilla chips with cheese dip are not. Similar comparisons can be made for many grain foods (rolled oats versus sweetened or refined cold cereal, for example), dairy foods (skim milk versus chocolate milk), starchy vegetables (baked sweet potatoes versus French fries), and protein foods (lean chicken breast versus fatty ground beef). These distinctions help consumers adhere to the USDA Food Patterns, such as the Healthy U.S.-Style Eating Pattern, that are recommended in the *Dietary Guidelines.*

The USDA Food Patterns' recommendations about the types and amounts of each food group to consume—to achieve nutrient adequacy while staying within limits on calories, added sugars, saturated fat, and sodium[7]—are predicated on foods being consumed in their nutrient-dense forms.[8,9] As the *Dietary Guidelines* explains, the modeling used to develop the Food Patterns "includes using current food consumption data to determine the mix and proportions of foods to include in each group, using current food composition data to select a nutrient-dense representative for each food, and calculating nutrient profiles for each

[i] FDA should exercise caution regarding the public health impact of putting a "healthy" label on whole eggs (including egg yolks), as well as red and processed meats (including lean meats). See discussion of cholesterol in section III (eggs) and food criteria in section IV (red and processed meats).

food group using these nutrient-dense representative foods."[10] Some examples of these nutrient-dense representative foods are shown in Table 1.

Table 1. Examples of Nutrient-Dense Representative Foods Used in the USDA Food Pattern Modeling[11]

Nutrient-Dense Representative Food	**Type of Food that it Represents**
Plain, raw fruits and vegetables	Raw fruits and vegetables
Water-packed canned fruit	Canned fruit
Raw or boiled, unsalted vegetables	Cooked vegetables
Boiled, unsalted beans	Cooked beans
Unsalted tomato puree	Cooked tomatoes
Unsalted, oven-baked frozen fries	French fries
Fat-free potato chips	Potato chips
Low-sodium pickles	Pickles
Air-popped popcorn	Popcorn
Unsalted, unsweetened quick oats	Oatmeal and all other cooked cereals
Reduced-fat whole-wheat crackers	Snack bars containing whole grains
Cheerios cereal (1g sugar per serving)	Whole-grain oat cereal
Shredded wheat (sugar- and salt-free)	Whole-grain wheat cereal
Skim milk	All fluid and flavored, sweetened milk
Fat-free ice cream	Ice cream
Fat-free yogurt with low-calorie sweetener	Flavored yogurt
Fat-free, low-fat, or reduced-fat cheese	Cheese
Unsweetened soymilk	Soymilk
Unsalted nuts and seeds	Whole nuts and seeds

A food pattern modeling analysis completed for the 2010 Dietary Guidelines Advisory Committee evaluated the impact of making "typical"—rather than nutrient-dense—food choices while consuming the quantities that the Food Patterns and the *Dietary Guidelines* recommend to consumers.[12] For example, USDA researchers modeled the effect of choosing fruits canned in syrup or in juice, vegetables prepared with added salt and fat, fast-food French fries, regular potato chips, granola bars, frosted shredded wheat, tortilla chips, fattier cuts of meat, salted nuts, full-fat cheeses, and sugar-sweetened yogurt.[13] With these and other "typical" choices, the 2,000-calorie pattern exceeded its target by about 375 calories. Across all patterns, calories were 15 to 30 percent (350 to 450 calories) above the target levels.[14]

This analysis demonstrates the potential consequences of allowing a "healthy" claim on foods that contribute to food-group needs but are not in nutrient-dense forms. The 2,000-calorie USDA Healthy U.S.-Style Eating Pattern allows for only 270 calories remaining after food-group needs are met with nutrient-dense forms of foods.[15] (Those calories can be used for added sugars, added refined starches, solid fats, alcohol, and/or additional servings of food groups.) And at most calorie levels, the Healthy Eating Patterns do not have room for 10 percent of calories from added sugars and 10 percent from saturated fat.[16] The updated definition of "healthy" must align with the nutrient-dense foods included in the Food Patterns and recommended in the *Dietary Guidelines* to ensure that consumers who eat "healthy" foods meet their nutrient needs without consuming too many calories.

II. FDA should require foods that make "healthy" claims to meet both food and nutrient criteria.

To develop a strong and enforceable definition for "healthy," the agency should retain the existing regulatory framework in 21 C.F.R. 101.65(d), update and add certain nutrient criteria, and add certain food criteria. Nutrient criteria are necessary to ensure that processed foods contain significant amounts of the beneficial nutrients of public health concern and limit nutrients that Americans typically overconsume. Food criteria are necessary to include all fruits, vegetables, whole grains, nuts, seeds, or fish that make up a healthy eating pattern and to exclude refined grains, processed meat, and other foods that should be limited in a healthy eating pattern.

However, FDA should not set higher limits on detrimental nutrients for products in "tiers" that contain one or more servings of "food groups to encourage," as some members of the food industry have suggested.[ii] This approach would lead to weak standards for added sugars, sodium, and saturated fat in "healthy" foods. The agency's original regulation for "healthy" set more generous limits for meals and main dishes,[iii] as opposed to individual foods, and FDA should continue to rely on this distinction.

III. Nutrient criteria should include significant amounts of beneficial nutrients (potassium, vitamin D, calcium, iron, protein, and fiber) and limits on overconsumed detrimental nutrients (added sugars, saturated fat, cholesterol, and sodium).

A. Minimums for Beneficial Nutrients

1. FDA should require "healthy" foods to contain significant amounts of beneficial nutrients per Reference Amount Customarily Consumed (RACC).

CSPI objects to proposals that would entirely replace beneficial nutrient criteria with food criteria for "healthy" claims. The regulatory definition for "healthy" would apply to a myriad of processed foods, such as granola bars, trail mixes, chips, crackers, cookies, fruit snacks, frozen desserts, spreads, and sweetened yogurts. Simply requiring that these or similar foods contain at least a certain amount of a food or food group would not ensure that the food is healthy or that a serving of it would make a meaningful contribution toward underconsumed nutrients of concern. For example, **Lay's Classic potato chips** contain fried potatoes that USDA would count as vegetables,[iv] but a serving of those chips does not contain 10 percent of the Daily Value (DV) for potassium (4,700 milligrams) or any other

[ii] This suggestion was made at the March 9, 2017 FDA public meeting on the use of the term "healthy."
[iii] As defined in 21 C.F.R. 101.13(l) and 21 C.F.R. 101.13(m).
[iv] The 2011-2012 Food Patterns Equivalents Database credits 100 grams of white potato chips as 1 ¾ cup-equivalents of vegetables. See https://www.ars.usda.gov/northeast-area/beltsville-md/beltsville-human-nutrition-research-center/food-surveys-research-group/docs/fped-databases/.

beneficial nutrient that should qualify a food as "healthy" (see below). Likewise, while **Honey Maid Honey Grahams crackers** contain eight grams of whole grains per 31-gram serving, they contain predominantly refined grains and do not contain 10 percent of the DV for any beneficial nutrient that should qualify a food as "healthy." Thus, products should contain minimum amounts of select beneficial nutrients per RACC—at least 10 percent of the DV of one such nutrient for most foods, or two or three for main dishes or meals[v]—as a measure of nutrient density to qualify for a "healthy" claim.

2. "Beneficial nutrients" should include at least one of only six nutrients: calcium, vitamin D, iron, potassium, fiber, or protein.

Although the DGAC report identified a number of underconsumed nutrients, the report classified only calcium, vitamin D, iron, potassium, and fiber as nutrients that may pose a public health concern based on intake, biomarker, and health outcomes data.[17] Thus, CSPI supports the FDA's recent decision to exercise enforcement discretion by allowing "healthy" claims on food products that contain at least 10 percent of the DV of calcium, vitamin D, iron, potassium, fiber, or protein.[18] (Although protein is not a nutrient of concern, it is an important nutrient to qualify otherwise healthy, nutrient-dense protein foods, such as fish and lean poultry, that contain less than 10 percent of the DV for iron or another nutrient of public health concern.)

However, after July, 2018, when foods produced by large companies must bear the new Nutrition Facts labels without vitamins A or C, FDA should no longer allow those vitamins to qualify as beneficial nutrients. Those vitamins are not underconsumed nutrients that pose a substantial public health concern,[19] and they are often present in fruit snacks, fruit drinks, frozen novelties, chips, and other foods that are not nutrient-dense and do not fit into a healthy eating pattern.

As shown in Table 2, this list is broad enough to reflect major nutrients intrinsic to all of the food groups that the *Dietary Guidelines* encourages (e.g., fiber and potassium in fruits and vegetables; fiber and iron in whole grains; protein in protein foods; and protein, calcium, and vitamin D in dairy). Limiting nutrients to those required on the Nutrition Facts label will also reduce the burden on FDA for enforcement and on companies for compliance.

Table 2. Percent contribution of each food group to selected nutrient totals in the USDA Food Patterns[20]

Food Group	Percent (%) of Total Nutrient in USDA Food Patterns					
	Fiber	Calcium	Vitamin D	Potassium	Protein	Iron
Fruits	16	3	0	17	2	4
Vegetables	38	7	0	36	10	19
Whole Grains	32	12	8	10	12	42
Protein Foods	3	3	25	13	38	13
Dairy	2	67	64	21	28	2

[v] As defined in 21 CFR 101.13(l) and 21 CFR 101.13(m).

3. FDA should not allow "healthy" claims on foods of low nutrient density fortified with vitamins, minerals, or added fiber.

FDA requires that foods labeled "healthy" and fortified to meet the existing 10 percent DV requirement adhere to the agency's fortification policy in 21 C.F.R. 104.20. This policy stipulates that it is not appropriate to fortify "snack foods"[21] such as cookies, candies, cakes, soft drinks, and chips, which are not nutrient-dense. A recent study from FDA reported that consumers were more likely to choose a potato chip or vegetable chip and to perceive it as healthier if it was vitamin fortified.[22] Consumers were also less likely to view the Nutrition Facts label before deciding to buy vitamin-fortified foods.[23]

At a minimum, FDA should retain this rule to ensure that "healthy" claims do not appear on vitamin-fortified processed chips, cookies, beverages, and other foods of low nutrient density. But FDA also could strengthen the "healthy" regulation by requiring that qualifying beneficial nutrients occur naturally in the food product—as FDA did for health claims in 21 C.F.R. 101.14(e)(6)—to ensure that foods eligible for "healthy" claims reflect the overall body of evidence on the components of healthy eating patterns.

In particular, FDA should address the isolated "fibers" added to bars, cookies, frozen novelties, cold cereals, and other foods. Certain isolated or synthetic non-digestible carbohydrates may have a physiological effect that the FDA deems beneficial to health and therefore meet the definition of dietary fiber on new Nutrition Facts labels.[24] However, the evidence that fiber lowers the risk of disease comes from studies of people who consume foods rich in the intrinsic, intact fiber in plants.[25] Fibers that are added to foods do not necessarily have the same health effects as fibers that are intrinsic and intact in plants. For example, a **Fiber One Chocolate Fudge Brownie** made with white flour, chicory root extract, sugarcane fiber, xanthan gum, and locust bean gum may contain 5 grams of fiber, but FDA should not equate its healthfulness with bulgur wheat, a whole grain that provides 5 grams of intact fiber per 45-gram (dry) serving.

FDA has already made such distinctions about fiber in its regulations for health claims. The agency prohibited the use of fortification to meet the dietary fiber minimums to qualify for health claims about fiber-containing fruits, vegetables, and grains and the risk of cancer or coronary heart disease in 21 C.F.R. 101.76 and 101.77. Similarly, only intrinsic, intact fiber should count toward the 10 percent DV requirement for fiber in "healthy" foods.

B. Maximums for Overconsumed Nutrients

1. Limit added sugars to five percent of the DV.

It is critical that FDA update the "healthy" definition to limit added sugars. On average, Americans have consumed between 16 and 23 teaspoons (about 270 to 370 calories' worth) of added sugars per day, according to National Health and Nutrition Examination Survey (NHANES) data and United States Department of Agriculture (USDA) average per-capita loss-adjusted food availability data, and some segments of the population consume

far more.[26,27] Evidence shows that overconsumption of added sugars is associated with excess body weight in children and adults[28] and an increased risk of type 2 diabetes in adults that is not fully explained by body weight.[29] Evidence also links higher intakes of added sugars to an increased risk of hypertension, stroke, and coronary heart disease in adults[30] and to the development of dental caries in children and adults.[31]

There is little room for added sugars in a healthy eating pattern. The USDA Food Patterns included in the DGAC report allow for 3 to 9 percent of calories from added sugars across all calorie levels. (The committee reasoned that these patterns allow a total of 8 to 19 percent of calories as "empty calories" and based on current consumption patterns, 45 percent of those calories are allocated to added sugars and 55 percent are allocated to solid fats.)[32] Furthermore, the added sugar DV on FDA's revised Nutrition Facts label is only 50 grams—10 percent of calories in a 2,000-calorie diet.

FDA should allow foods that make "healthy" claims to contain only three grams of added sugars, or about five percent[vi] of the DV (50 grams), per RACC. This limit is consistent with the "low" levels of saturated fat (one gram, or about five percent of the DV) and total fat (three grams, or about five percent of the DV) that the agency set in the original "healthy" definition.[vii] The five percent limit is reasonable because a "healthy" claim is a stamp of approval that encourages people to eat a food more often.

FDA should not simply limit added sugars to 10 percent of total calories because higher-calorie foods that meet this criterion could contribute a substantial proportion of the daily value for added sugars per serving (e.g., 12 grams of added sugars, or nearly 25 percent of the daily value, in a 500-calorie serving of food). For example, a 10 percent limit would allow 10 grams of added sugar in a premium ice cream that has roughly 400 calories per 2/3 cup (the RACC on the new Nutrition Facts label), but only 3 grams of sugar in a light ice cream with roughly 150 calories per 2/3 cup. Yet the premium ice cream, if anything, is the less healthy option. However, FDA could require that all foods contain no more than 3 grams of added sugars per RACC and no more than 10 percent of total calories from added sugars to ensure that lower-calorie foods do not derive a substantial proportion of their calories from added sugars.

Just 12 oz. of a typical sugar-sweetened beverage supplies much of a day's added sugars allowance, and one 16 oz. bottle exceeds it.[viii] Thus, consumers could easily exceed the DV for added sugars if they were to consume a 12 oz. sugar-sweetened beverage and just a few servings of "healthy" foods with more than five percent of the DV for added sugars.

[vi] Five percent of the DV is equal to 2.5 grams, which has been rounded to 3 grams.

[vii] Five percent of the DV is a reasonable limit for added sugars given FDA's reasoning for defining "low" levels of total fat and saturated fat and setting those criteria for "healthy" foods (see 58 Fed. Reg. 2302 at 2336 and 59 Fed. Reg. 24232 at 24238). FDA allowed "healthy" foods to contain more than a "low" level of cholesterol to avoid excluding some seafood and more than a "low" level of sodium because this limit would have disqualified many healthy foods—even fresh, unprocessed foods—including some legumes and low-fat dairy products (see 59 Fed. Reg. 24232 at 24241, 24239).

[viii] A 12 oz. can of Coke contains 39 grams of sugar, or 78 percent of the DV (50 g) for added sugars.

Furthermore, sugars are added to a wide range of foods, from ketchup to peanut butter, making it easy for people to exceed the DV without eating foods that are noticeably sweet.

A three-gram limit on added sugars would still give consumers a wide range of "healthy" foods to choose from. Table 3 includes a sampling of foods and beverages that would and would not be eligible for a "healthy" claim with a three-gram added sugar limit. Unsweetened products and products with just a few grams of added sugars are available within each eligible food group. The list of eligible foods and beverages also aligns with the representative nutrient-dense choices in the USDA Food Patterns (see Table 1).[33]

Table 3. Examples of foods in select food groups that are and are not likely to qualify for a "healthy" claim with an added sugar limit of three grams per RACC

Food Category	Eligible Foods and Beverages	Ineligible Foods and Beverages
Fruits	Raw fruits, frozen fruits without added sugar, canned fruits packed in water or juice, dried fruits without added sugar	Sweetened applesauce, frozen fruits with added sugar, canned fruits packed in syrup, juice drinks, sweetened dried fruits*
Grains	Whole-grain pasta, whole-grain bread*, whole-grain crackers*, intact whole grains, cold cereals low in added sugar (e.g., original Cheerios) or without added sugar (e.g., shredded wheat)	Cakes, cookies, snack bars*, muffins, sweetened cold cereals* (e.g., frosted shredded wheat)
Dairy	Skim and low-fat milk, plain yogurt, yogurt with low-calorie sweeteners	Chocolate milk, flavored sugar-sweetened yogurt*, frozen yogurt*
Protein	Most lean protein foods, nuts, and seeds	Chocolate-flavored nut butters,* sugar-coated nuts,* nut-based trail mixes with added sugar*

*Indicates that the category of "eligible" or "ineligible" is likely for most products, but specific brands' added sugar content may vary.

2. Eliminate the total fat limit.

FDA recently announced its intent to exercise enforcement discretion with respect to the current requirement that "healthy" foods be low in fat. CSPI agrees that the type of fat, rather than simply the total amount of fat, is most important for health.[34] However, we suggest that the FDA clarify that its enforcement discretion only applies to the "low fat" limit, not the "low saturated fat" limit, which remains at one gram per RACC for an individual food. FDA's guidance states that "[f]oods that use the term 'healthy' on their labels that are not low in total fat should have a fat profile makeup of predominantly mono and polyunsaturated fats (i.e., sum of monounsaturated fats and polyunsaturated fats are greater than the total saturated fat content of food)." This sentence might lead companies to conclude that FDA will disregard the saturated fat limit if a food's fat is predominantly unsaturated. For example, industry might conclude that some hot dogs could be labeled "healthy" because a serving contains roughly 15 grams of fat but only 6 grams of saturated fat. Therefore, we recommend that FDA clarify the guidance by explicitly stating its intent to continue enforcing the "low saturated fat" limit.

In addition, FDA should consider the potential unintended consequences of eliminating the "low fat" requirement for "healthy" foods. Many processed foods—such as potato chips, tortilla chips, and French fries—may be low in saturated fat because they are deep-fried in oils that are largely unsaturated. However, these are not nutrient-dense foods, as defined in the *Dietary Guidelines* and in USDA's food pattern modeling. Furthermore, they compete (as snacks or side dishes) with fresh fruits and vegetables, which most Americans underconsume. If FDA's updated definition for "healthy" does not have criteria that exclude such foods of low nutrient density, the agency should consider another approach. For example, FDA could retain a total fat limit but exempt any fat contributed by whole foods in a healthy eating pattern that are high in heart-healthy, unsaturated fats (such as nuts, seeds, fish, soybeans, and avocado).

3. Retain limits on saturated fat.

CSPI strongly recommends that FDA retain the current requirement that "healthy" foods be low in saturated fat. The recommendation to limit saturated fat intake to less than 10 percent of calories per day is one of the *Dietary Guidelines*' Key Recommendations.[35] And the evidence to support that advice has only grown stronger in recent years.[36] The DGAC report included a focused review of published systematic reviews and meta-analyses on saturated fat intake and cardiovascular disease (CVD). The committee found strong and consistent evidence—from both randomized controlled trials (RCTs) and prospective cohort studies—that replacing saturated fat with polyunsaturated reduces the risk of CVD events and coronary mortality. Although the evidence for replacement with monounsaturated fats is limited—in part because the main sources of monounsaturated fat in a typical American diet are animal fat—the committee also noted that "evidence from RCTs and prospective studies has demonstrated benefits of plant sources of monounsaturated fats, such as olive oil and nuts on CVD risk." [37]

Unfortunately, a few flawed or misconstrued studies have created the false impression that the evidence on saturated fat has weakened. For example:

- A flawed 2014 meta-analysis concluded that replacing saturated with polyunsaturated fats failed to lower the risk of heart disease in clinical trials.[38] However, the meta-analysis was heavily criticized.[39,40,41] For example, as a graph in the supplement makes clear, those clinical trials found a statistically significant 19 percent lower risk of heart disease when the authors (appropriately) excluded the Sydney Heart Study, which used a trans-fat laden margarine as a source of polyunsaturated fats and, not surprisingly, reported an increase in risk.[42]

- A 2015 meta-analysis concluded that saturated fats are not associated with heart disease.[43] However, as the authors state, the "[r]isks associated with higher or lower intakes of macronutrients are sensitive to choice of replacement nutrient(s). In a pooled analysis of 11 prospective cohort studies (not included in our quantitative syntheses to avoid duplication of data), replacement of saturated fats with polyunsaturated fat reduced coronary risk by 13%, consistent with results of

randomized controlled trials…." That point was echoed by a 2016 analysis of two prospective cohort studies, which noted that "without a specified replacement, the comparison is largely with refined starch and sugar because these are the dominant sources of calories in the US diet." The 2016 analysis concluded that "higher dietary intakes of major SFAs are associated with an increased risk of coronary heart disease."[44]

- A 2016 paper made headlines such as "How the Sugar Industry Shifted Blame to Fat"[45] by revealing that scientists who reviewed the evidence on sugar and heart disease received undisclosed payments from the sugar industry.[46] The paper states that "consulting the original clinical studies cited to substantiate reducing dietary cholesterol and substituting polyunsaturated fat for saturated fat reveals that they were not well controlled." In fact, the authors provide little substantiation for the claim that the latter studies were not well controlled.[ix]

- A 2015 Cochrane review of long-term randomized clinical trials reported that reducing saturated fat intake lowered the risk of cardiovascular events by 17 percent.[47] The lead author noted that the absence of an effect on all-cause or cardiovascular mortality "perhaps was not surprising with mean trial durations 4–5 years."[48] Needless to say, this review deserves greater credibility than the better publicized reviews of observational studies.

- The media has publicized cohort studies raising the possibility that "butter is back."[49] However, clinical trials using controlled diets confirm that diets high in saturated fat (primarily from dairy fat) raise LDL, including medium and small LDL, and that replacing saturated fats with polyunsaturated fats lowers LDL.[50,51] Moreover, the evidence that lowering LDL reduces the risk of heart disease is no longer in doubt.[52]

Thus, the FDA should retain the saturated fat limit to encourage people to substitute healthy fats for foods that contain more than a trivial amount of saturated fat from sources like palm or palm kernel oil, coconut, dairy, fatty meats, and butter.

4. Strengthen limits on sodium.

The FDA's definition of "healthy" has led companies to market entire lines of frozen entrées and canned soups—such as ConAgra's Healthy Choice and Campbell's Healthy Request—that are lower in sodium than many competitors' offerings. These companies demonstrated that it was both feasible and profitable to market reduced-sodium foods. Without the sodium limits in FDA's "healthy" regulation, it is unlikely the companies would have made these lower-sodium options available to consumers for the last two decades.

[ix] The substantiation (cited in eTable 6) consists entirely of the following sentences from a 1966 report on one trial: "The intake of pure sugar had been restricted. However, abundant use of marmalade, jam, and fruit juice, etc. had been recommended. Nevertheless, sugar consumption was low."

However, Americans still consume far too much salt. One of the *Dietary Guidelines'* Key Recommendations is to consume less than 2,300 mg per day of sodium,[x] yet Americans' average intake is 3,440 mg per day (and that doesn't include salt added at the table). In addition, the *Dietary Guidelines* recommends that adults with prehypertension or hypertension—the majority of U.S. adults[53]—can benefit from reducing their intake further to 1,500 mg per day.[54]

It is essential that FDA strengthen the sodium limits for "healthy" claims to help Americans meet these goals. At a minimum, FDA should lower the sodium limits for a "meal product or main dish" to 570 mg (25 percent DV) and to 460 mg (20 percent DV) for all other foods[xi] to reflect the change in the DV from 2,400 mg to 2,300 mg. However, further reductions are warranted to reflect the industry's technological advances in reducing sodium and to align these limits with the agency's draft long-term Voluntary Sodium Reduction Goals, [55] particularly for foods—like frozen entrées and canned soups—which are commonly labeled "healthy." For example, a 9 oz. (255 g) frozen dinner would have a long-term voluntary sodium goal of 460 mg per labeled serving (the proposed target mean is 180 mg/100 g). In FDA's 1994 "healthy" rulemaking, the agency suggested limits of 480 mg (for meal products and main dishes) and 360 mg (for all other foods),[56] before raising the limits to 600 mg and 480 mg, respectively. FDA should return to its initial limits of 480 mg (for meal products and main dishes) and 360 mg (for all other foods) to broadly align the "healthy" definition with the draft long-term Voluntary Sodium Reduction Goals and with the sodium-reduction progress that industry has made over the last 23 years.

5. Retain limits on cholesterol.

CSPI urges FDA to retain current limits on cholesterol in the "healthy" definition. The absence of a quantitative limit for dietary cholesterol in the *Dietary Guidelines* does not change the fact that **dietary cholesterol raises LDL cholesterol, should be limited in healthy eating patterns, and is overconsumed by many Americans**[xii]:

- **Dietary cholesterol raises LDL cholesterol.** The DGAC report stated that it "will not bring forward [the recommendation in previous editions of the *Dietary Guidelines* to limit cholesterol to 300 mg/day] because available evidence shows no appreciable relationship between consumption of dietary cholesterol and serum cholesterol, consistent with the conclusions of the AHA/ACC report."[57] However, the AHA/ACC report did *not* conclude that there is no appreciable relationship between dietary and serum cholesterol. It concluded that "there is insufficient evidence to determine whether lowering dietary cholesterol reduces LDL-C."[58] The DGAC report did not present evidence to support its conclusion that there is "no appreciable relationship" between dietary cholesterol and serum cholesterol. In

[x] The *Dietary Guidelines* limit sodium to less than 2,300 mg per day for adults and children ages 14 years and older and to the age- and sex-appropriate Tolerable Upper Intake Levels of sodium for younger children.
[xi] Limits are per RACC and labeled serving, and per 50 grams if the RACC is less than or equal to 30 grams.
[xii] See the attached dietary cholesterol comment sent from CSPI and scientists to the Secretaries of the U.S. Department of Health and Human Services and the U.S. Department of Agriculture in advance of the final 2015-2020 *Dietary Guidelines* for more details.

fact, that conclusion directly contradicts the AHA/ACC conclusion, which specifically states that there are insufficient data to make a statement.

Furthermore, FDA relied on the recommendations in the *Dietary Guidelines* and the National Academy of Medicine's 2002 Dietary Reference Intakes (DRI) report when it decided to retain the 300 mg DV for cholesterol on the new Nutrition Facts label.[59] The 2002 DRI report included a dose-response analysis of clinical trials to evaluate the relationship between dietary cholesterol and blood total cholesterol and concluded that cholesterol consumption should be as low as possible while consuming a nutritionally adequate diet.[60] Likewise, the *Dietary Guidelines* recommends eating "as little cholesterol as possible while consuming a healthy eating pattern," citing the DRI report's conclusion.[61] In fact, the DRI report did not set a Tolerable Upper Intake Level because any incremental increase in cholesterol intake increases the risk of coronary heart disease.[62]

- **Dietary cholesterol is limited in healthy eating patterns.** USDA's Healthy U.S.-Style Eating Pattern, which forms the basis for the food-group recommendations in the *Dietary Guidelines*, contains approximately 100 mg to 300 mg of cholesterol, depending on the calorie level.[63] In fact, the USDA Food Patterns at the 2,000-calorie level include only three eggs (three ounce-equivalents) per week.[64] Cholesterol is also limited to 150 mg at the 2,100-calorie level in the Dietary Approaches to Stop Hypertension (DASH) diet.[65]

- **Dietary cholesterol is overconsumed by many Americans.** As FDA noted, a "significant portion" of U.S. adults—59 percent of men and 17 percent of women—consume more than 300 mg of cholesterol per day.[66] FDA therefore retained a mandatory cholesterol declaration and DV to help consumers maintain healthy dietary practices.

Finally, it is critical to note that a single (large) egg contains about 62 percent of the DV of cholesterol, and a serving of eggs often includes at least two eggs. Allowing a "healthy" claim on eggs would send an "eat more" message to consumers. That message would greatly increase the risk of overconsuming cholesterol and the risk of heart disease.

IV. Food criteria should include a 100 percent whole grain requirement; an exemption from certain nutrient criteria when necessary to include nutrient-dense foods that make up the foundation of a healthy eating pattern; and an exclusion of foods that do not make up the core of a healthy eating pattern (fruit juices, red and processed meats, alcoholic beverages, sugar-sweetened beverages and candy, and foods that contain partially hydrogenated oil).

A. Food group equivalents should not be criteria for "healthy" claims.

CSPI urges FDA not to adopt a food group "servings" or "equivalents" approach to qualifying products for a "healthy" claim. In the approach ConAgra suggested during the FDA's March 9 public meeting on the term "healthy," a food with less than **½ serving** of a "food group to encourage" per RACC would qualify for "healthy" if it contained 10 percent of the DV for a "beneficial nutrient" (including vitamins A and C) and a food with at least **one serving** of a "food group to encourage" per RACC would qualify for "healthy" **without** meeting any beneficial nutrient criteria. Meeting food-based criteria should not alter beneficial nutrient minimums. Moreover, this approach would create large loopholes for the food industry to market healthy-sounding processed foods that compete with fruits, vegetables, and other truly healthy foods.

1. **A food group "serving" or "equivalent" approach would equate whole, unprocessed forms of "food groups to encourage" with their highly processed forms.**

A food group "serving" or "equivalent" approach might count all forms of fruits and vegetables—including juices or dry, powdered, or concentrated forms—to qualify for a "healthy" claim. Such a standard would likely lead to a raft of "healthy" processed foods that are not as healthful as fresh fruits or vegetables, such as (see Appendix):

- "veggie" chips, crackers, pastas, juices, etc.
- "fruit" snacks, bars, frozen desserts, smoothies, juices, cookies, bars, breakfast pastries, cereals, spreads, muffins, etc.

Consuming foods with added processed (juiced, dried, powdered, or concentrated) fruit or vegetable ingredients does not have the same impact on satiety, blood glucose, or insulin levels as eating whole fruits or vegetables. Intact fruit leads to greater satiety than fruit purée, which leads to greater satiety than fruit juice, even though they contain the same quantity of carbohydrate.[67,68,69] Similarly, intact fruit leads to less extreme responses in blood sugar and insulin levels.[70] Furthermore, eating an apple before a meal reduces calorie intake more than either applesauce or juice, with or without added fiber.[71]

Researchers suggest that the structure provided by the intact cell walls in unprocessed produce leads to greater satiety and lower glucose and insulin levels. Moreover, fresh fruit and vegetables have lower calorie density than many foods with added fruit or vegetable ingredients. It is highly unlikely that processed fruit or vegetable purées, powders, or concentrates have the same nutrients and phytochemicals as unprocessed fruit or vegetables. However, even if they did, foods made with purées, powders, or concentrates would not be as healthful, because obesity and type 2 diabetes are a far greater threat to Americans' health than nutrient or phytochemical deficiencies. Using food group servings to define "healthy" foods would therefore mislead consumers and create an incentive for companies to market a flood of processed foods that compete with fresh fruit and vegetables.

Similarly, in the absence of a strict limit on saturated fat, added sugars, and other detrimental nutrients, a "serving" approach would lead companies to market a wide variety of processed foods—such as beverages, cookies, bars, chips, crackers, muffins, frozen desserts, spreads, snacks, etc.—made with nuts, beans, yogurt, or other dairy ingredients. These marketing efforts mislead consumers who are trying to eat a healthful diet.

2. A food group "serving" or "equivalent" is not a meaningful amount for many foods.

For grains and other foods with large RACCs, a "serving" or "equivalent" is a trivial amount. For example, the *Dietary Guidelines* considers 16 grams of whole grain as one ounce-equivalent. But many grain products have much larger RACCs, such as bagels, toaster pastries, and muffins (110 g RACC) and ready-to-eat breakfast cereals weighing 43 g or more per cup (60 g RACC). If grains make up roughly half the weight of bread products and up to 100 percent of the weight of ready-to-eat breakfast cereals,[xiii] such a standard would allow a bagel or dense breakfast cereal to be labeled "healthy" even if far less than 50 percent of its grains were whole. Consumers eating those so-called "healthy" foods would end up eating more refined grain than whole grain. The *Dietary Guidelines* encourages Americans to replace refined grains with whole grains, not to simply reach a minimal whole grain intake (see below). Likewise, just one ounce of chopped nuts or a quarter cup of dried fruit mixed into a muffin (110 g RACC) or cake (125 g RACC) made of predominantly white flour, sugar, and oil could allow the food to qualify as "healthy." Clearly, "healthy" claims on those foods would not lead consumers to eat truly healthy diets.

B. Whole Grains

CSPI strongly supports a requirement that 100% of the grains in "healthy" foods be whole grains or bran.[xiv] Likewise, FDA should remove the current exemption from beneficial nutrient criteria for any "enriched cereal-grain product" that conforms to a standard of identity in 21 C.F.R. 136, 137, or 139. Certain products currently labeled "healthy" (see Figure 1) are made entirely of refined grains and are inconsistent with dietary recommendations in the *Dietary Guidelines* to consume whole grains.

[xiii] For example, Thomas' 100% Whole Wheat Bagels contain 55 g whole grains per 95 g serving. Post Shredded Wheat Original Big Biscuit ready-to-eat 100% whole-grain cereal contains 47 g whole grains per 47 g serving.

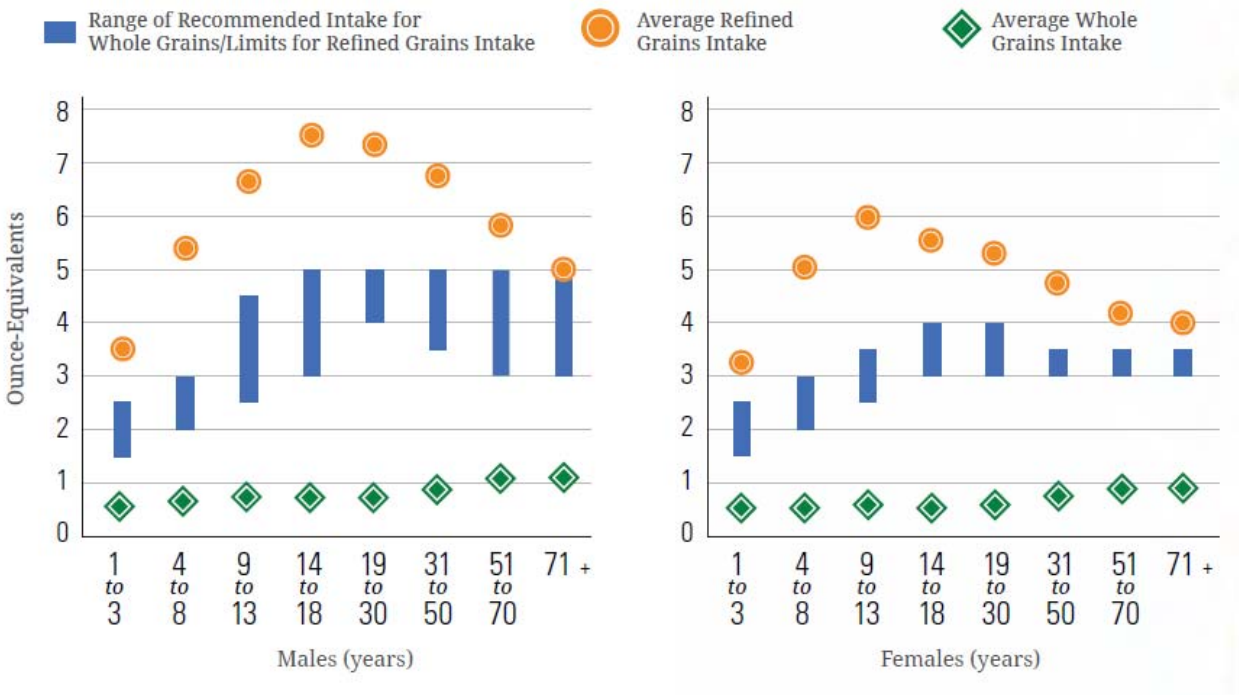
[xiv] The FDA should include wheat, oat, or other bran and germ along with whole grains because the bran and germ are the two key components of whole grains that are missing from refined grains. The FDA should exclude refined starches, such as tapioca starch and potato starch, in addition to refined grains because they are not nutrient dense.

Figure 1. Products labeled "healthy" on the front or back of package that contain only refined grains

A 100-percent whole-grain requirement is of particular importance because whole-grain foods are among the most underconsumed foods, while refined grains are overconsumed (see Figure 2). As the DGAC report noted, the whole grain recommendations in the USDA Food Patterns "are well above the 95th percentile of usual intakes for all age/sex groups. Conversely, refined grain recommendations in the patterns are very low compared to usual intakes—about the 5th percentile for most age/sex groups. This indicates that a major shift from refined to whole grains is needed to meet recommendations."[72]

In other words, Americans don't need to simply boost whole grain intake. They need to replace refined grains with whole grains. Requiring a minimal level of whole grains (e.g., at least eight grams of whole grain, which is one-half of an ounce-equivalent) in "healthy" foods would do little to reduce the overconsumption of refined grains. In fact, it might exacerbate the problem by encouraging people to eat "healthy" foods with a minimal level of whole grains and a larger quantity of refined grains. Furthermore, because nearly 100 percent of the population consumes less than the recommended levels of whole grains,[73] a 50-percent whole-grain standard for "healthy" foods sets the bar far too low. Most people will not consume only "healthy" foods. So even an individual who consumed, say, three servings of 50-percent whole grain "healthy" foods and three servings of refined grain foods per day would only meet half of their total whole grain needs.

Figure 2. Average Whole & Refined Grain Intakes in Ounce-Equivalents per Day by Age-Sex Groups, Compared to Ranges of Recommended Daily Intake for Whole Grains & Limits for Refined Grains[74]



Source: *2015-2020 Dietary Guidelines for Americans*

C. Foods to Exempt from Beneficial Nutrient Minimums

In general, most foods present in high amounts in a healthy eating pattern, as defined by the DGAC report,[75] are eligible for a "healthy" claim because they contain 10 percent of the DV for at least one of the beneficial nutrients listed in Section III (calcium, vitamin D, iron, potassium, fiber, or protein). However, certain fruits and vegetables do not meet this minimum. FDA should continue to exempt these foods—whole, raw fruits or vegetables, and single-ingredient or mixtures of frozen or canned fruits and vegetables—from the criteria to help consumers identify foods that form the foundation of a healthy eating pattern, to increase fruit and vegetable intake, and to avoid confusing consumers. Likewise, FDA should exempt single-ingredient or mixtures of whole grains, nuts, and seeds (such as whole-grain brown rice, walnuts,[xv] and Brazil nuts) that do not meet the beneficial nutrient criteria. FDA should also exempt plain or sparkling water—without added caloric, low-calorie, or calorie-free sweeteners or other caloric ingredients—from the beneficial nutrient minimums to encourage consumers to choose water instead of sugar drinks.

[xv] FDA already exempts walnuts, for example, from a similar nutrient requirement for a qualified health claim about nuts and heart disease. See https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm064923.htm.

In addition, FDA should exempt fish, nuts and seeds (except coconut), and most vegetable oils (except palm, palm kernel, and coconut) from the saturated fat limit because they are high in unsaturated fats and consistent with a healthy eating pattern.

D. Foods that Should not be Eligible for "Healthy"

1. Fruit Juices

The "healthy" definition should encourage the healthiest form of fruit—whole fruit—and exclude fruit juice. Experimental evidence demonstrates that intact fruit is more satiating than fruit juice,[76] and that people are less likely to compensate for calories consumed from juice by eating less food.[77,78] Fruit juice is also more likely to lead to extreme responses in blood sugar and insulin levels than whole fruit.[79] Furthermore, fruit juice was prospectively associated with the risk of weight gain among normal-weight adults in the Nurses' Health Studies and the Health Professionals Follow-Up Study.[80] In addition, the 2010 DGAC report noted that juice intake has been prospectively associated with increased adiposity in children who are overweight or obese.[81] (FDA should not rely on recent meta-analyses of fruit juice and weight status in children. One concluded that fruit juice is associated with little or no weight gain, but its conclusions were based on insufficient evidence from a small number of both over-and under-adjusted observational studies with limited exposure data.[82] Many studies inappropriately control for calorie intake, which is likely to be in the causal pathway.[83] Adjusting for calorie intake is no more appropriate for studies on fruit juice than for studies on sugar-sweetened beverages.[84]) Too much fruit juice may also increase the risk for type 2 diabetes. Among women in the Nurses' Health Study, an increase of one serving per day in fruit juice was associated with an increased risk of developing type 2 diabetes.[85]

The *Dietary Guidelines* limits juice to half of a person's fruit servings, or 1 cup per day in a 2,000-calorie diet.[86] Other health authorities also recommend limits on 100% fruit juice. In 2015, the World Health Organization (WHO) issued a "strong recommendation" on free sugars, which includes the sugars naturally present in fruit juices. The WHO recommended that both adults and children reduce their intake of free sugars to less than 10% of total energy intake" based on the relationship of free sugars intake to body weight and dental caries.[87] In addition, the American Academy of Pediatrics recommends that young children consume no more than 4 to 6 ounces of juice per day.[88]

A "healthy" claim on juice, even 100% fruit juice, would likely promote excess consumption of calories from fruit juice, which may lead to weight gain among both children and adults. Moreover, companies boast that their juices, smoothies, and similar beverages contain "two servings" of fruit (which is true for all fruit juices, because a USDA serving is only a half cup). And companies can easily add fruit juice to a variety of fruit snacks, bars, frozen novelties, and other processed foods that compete with whole fruit.

2. Red and Processed Meats

A "healthy" claim should encourage consumers to select the protein foods consistently present in healthy eating patterns, by including fish, lean poultry, and beans, and excluding all red and processed meats, including lean meats. The DGAC report found "strong and consistent" evidence that dietary patterns linked to a lower risk of heart disease are lower in red and processed meat.[89] In addition, a recent review by the WHO International Agency for Research on Cancer found that frequent consumption of processed meat is carcinogenic.[90] Because both red and processed meats should clearly be limited in healthy eating patterns, CSPI urges FDA to prohibit a "healthy" claim on these foods and products that contain them.

3. Alcoholic Beverages

The *Dietary Guidelines* notes that excessive drinking causes 88,000 deaths per year in the United States—including 1 in 10 deaths among working-age adults—and increases the risk of many chronic diseases, violence, and impairment of cognitive function over time.[91] In addition, many individuals, including those younger than 21 and women who are or may be pregnant, should not consume alcohol. Therefore, FDA should expressly prohibit "healthy" claims on alcoholic beverages.

4. Sugar-Sweetened Beverages and Candy

FDA should prohibit a "healthy" claim on sugar-sweetened beverages, candy, and other foods and beverages with empty calories that come predominantly from added sugars.

5. Foods Containing Partially Hydrogenated Oils

Given the FDA's final determination that partially hydrogenated oils (PHOs) are not generally recognized as safe and pose significant health risks,[92] FDA should ban PHOs from foods labeled "healthy," even if the agency ultimately permits small amounts of PHOs in certain foods.

V. "Healthy" should be regulated as an implied nutrient content claim whenever the term is made *in connection with* an explicit or implicit claim or statement about a nutrient, not only when it appears *immediately adjacent to* an implicit claim or statement about a nutrient, as suggested by the KIND citizen petition.

The KIND citizen petition requested that FDA amend 21 C.F.R. 101.65(d) (pertaining to general nutritional claims) "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."[93] FDA should not accept such an amendment because it would mislead consumers. Consumers would expect a claim that a food is "healthy" to mean what it says—whether or not the claim appears "immediately adjacent" to a nutrient claim. FDA should continue to enforce the definition of "healthy" when the term is used as an implied nutrient content claim in

conjunction with an explicit or implicit statement about a nutrient that appears anywhere on the label, including brand names.[94]

The KIND citizen petition also requested 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."[95] CSPI opposes the request for such an amendment, which could also mislead consumers. Instead, FDA should consider whether dietary guidance statements are implied nutrient content claims on a case-by-case basis in the context of a product's entire label. In addition, the KIND citizen petition asked FDA to "[u]ndertake 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." CSPI urges FDA to exercise caution regarding rulemaking for dietary guidance statements. Dietary guidance statements—if not rigorously defined—have the potential to supplant or compete with "healthy" claims in the marketplace and confuse consumers seeking truly healthy foods. If FDA undertakes rulemaking to define dietary guidance statements, the agency should require foods that make dietary guidance statements to also meet the criteria for "healthy." This approach is the only way to ensure that food labels give consumers a consistent, evidence-based message about which foods are the foundation of a healthy dietary pattern.

VI. Conclusion

In conclusion, CSPI strongly urges FDA to assist consumers in maintaining healthy dietary practices by expeditiously updating the definition of "healthy" to reflect current dietary recommendations and nutrients on the new Nutrition Facts label.

Respectfully submitted,

Lindsay Moyer, M.S., R.D.N.
Senior Nutritionist

Bonnie F. Liebman, M.S.
Director of Nutrition

Center for Science in the Public Interest

VII. Endnotes

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