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April 26, 2017

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

Re: Docket No. FDA-2016-D-2335

Dear Sir or Madam:

On behalf of the American Heart Association (AHA), including the American Stroke Association (ASA) and more than 30 million volunteers and supporters, we appreciate the opportunity to provide comments on the request for information on "Use of the Term 'Healthy' in the Labeling of Human Food Products."

AHA is pleased that the Food and Drug Administration (FDA) intends to update the definition for the term "healthy" as an implied nutrient content claim. We commend the Agency for its efforts to better align "healthy" with the recent revisions to the Nutrition Facts label and with current science. It has been nearly 23 years since the FDA published a final rule defining the term "healthy" for food label use.¹ While components of the rule have been revised as recently as 2005,² our understanding of healthy dietary patterns has continued to evolve alongside advances in nutrition science since that time.

Consumer demand for healthier foods is also on the rise. To ensure that "healthy" remains scientifically valid and meaningful to consumers, it is appropriate for the Agency to update the conditions of use for this term. This is particularly important given the changes in dietary guidance that have occurred since the original conditions of use for "healthy" were finalized. Revised conditions of use will also help guide and encourage industry efforts to develop new products and reformulate existing offerings that can help consumers achieve recommended dietary intakes.

AHA recommends that the term “healthy” be defined using a hybrid approach that includes both food group-based and nutrient-based criteria. Only foods emphasized in a healthy eating pattern and in their nutrient-dense forms should be eligible for the “healthy” claim, such as foods outlined in AHA’s dietary guidance and the Dietary Guidelines for Americans, provided that they also meet nutrient criteria. Nutrient criteria, which could have some degree of variation by food category, should include limitations on saturated fat, sodium, and added sugars, as well as a requirement that the food contain a significant amount of beneficial nutrients. We expand on these recommendations and address the specific questions raised by the FDA in the rest of this letter.

Guiding principles

When determining eligibility criteria for the term “healthy” in food labeling, FDA must consider the philosophical questions that are inherent to this task. For example, what is the current goal and purpose of labeling foods “healthy,” and where should the bar be set for foods to be eligible for the claim? As made clear by the March 2017 public meeting on this topic, defining “healthy” is a complex task and there is a lack of consensus about how to do so. To level-set stakeholders regarding the purpose of the “healthy” claim and to help structure the process of updating its criteria, we recommend that the Agency develop a set of guiding principles to help govern its careful and thoughtful consideration of these issues.

We are aware that the Agency considered a number of philosophical issues in its original ruling on criteria for “healthy” in 1994.³ We urge FDA to thoroughly re-examine these issues in light of the current societal context, in which much has changed since that time. For example, the Agency’s review of research on consumer perception of the meaning of “healthy” led it to conclude that the term conveyed a strong message about the nutrient content of a food and was associated with recommended nutrient levels at the time. Thus, FDA stated that a chief purpose of the “healthy” claim “is to highlight those foods that, based on their nutrient levels, are particularly useful in constructing a diet that conforms to current dietary guidelines.” More recent consumer research has indicated that many consumers now consider a broader set of attributes – such as those dealing with a food’s production and sourcing – to define whether it is healthy. While changing consumer perceptions of the term may not necessitate a change in the Agency’s definition of “healthy” or its purpose for defining the term, it may warrant a new or different approach to educating consumers on its meaning such as including a claim statement on labels that use the claim.

We agree with the Agency’s original goal in defining “healthy” – that the claim be used to highlight foods that will be “most helpful” to promoting consumers’ achievement of total diets that conforms to current dietary recommendations.⁴ We also agree with the Agency’s original

¹ 59 FR 24249, May 10, 1994 <https://www.gpo.gov/fdsys/pkg/FR-1994-05-10/html/94-11145.htm>

² 70 FR 56848, Sept. 29, 2005 <https://www.gpo.gov/fdsys/pkg/FR-2005-09-29/pdf/05-19511.pdf>

³ FR 59(89), May 10, 1994 <https://www.gpo.gov/fdsys/pkg/FR-1994-05-10/html/94-11145.htm>

⁴ “FDA’s goal in defining “healthy” is to define the term in such a way that it will highlight foods that, because of their nutrient content, will be most helpful to consumers in constructing a diet that is consistent with dietary recommendations.” <https://www.gpo.gov/fdsys/pkg/FR-1994-05-10/html/94-11145.htm>

determination that the claim should be absolute, rather than relative.⁵ We support reserving “healthy” for products that satisfy the 2015-2020 Dietary Guidelines for Americans recommendation to consume a variety of nutrient-dense foods and beverages, i.e., those 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...ideally...in forms that retain naturally occurring components.”⁶ We believe this to be distinct from products that may be “better-for-you” choices (compared to other similar products within a given category, i.e., relative comparisons), but that do not have an overall composition and nutrient profile consistent with the intent of the dietary guidelines. If consumers selected foods only from the latter category, their overall eating patterns would likely fail to achieve recommendations.

The FDA should consider how foods that would be eligible for its revised definition of “healthy” fit into recommended eating patterns. Consuming foods labeled “healthy” should help consumers achieve dietary recommendations.

Is the term “healthy” most appropriately categorized as a claim based only on nutrient content? If not, what other criteria would be appropriate to consider in defining the term “healthy” for use in food labeling?

We recommend that FDA move away from a nutrient-only-based claim to one that requires foods to meet both food and nutrient criteria. This change would be consistent with dietary recommendations, which have evolved from nutrient-based to food-based dietary patterns that are more easily translated for consumers. Food-based guidelines may also help minimize or avoid the unintended consequences of a focus solely on individual nutrients. At the same time, meeting nutrient needs is important and is accomplished by choosing a variety of nutrient-dense foods across and within all food groups in recommended amounts. In that context, underconsumption of whole grains, vegetables, fruits, and nonfat and low-fat dairy by the vast majority of the population has resulted in inadequate intakes of dietary fiber, potassium, calcium, and vitamin D, all considered nutrients of public health concern.⁷

⁵ The usefulness of a food labeled “healthy” is not based on how it compares to a similar food, but on how it contributes to achieving a total diet consistent with dietary recommendations. In contrast, the purpose of comparative claims is to distinguish those foods that contain modified levels of the specified nutrient when compared to the level of that nutrient in an appropriate reference food. Thus, the purpose of a “healthy” claim is significantly different from that of a comparative claim. <https://www.gpo.gov/fdsys/pkg/FR-1994-05-10/html/94-11145.htm>

⁶ U.S. Department of Health and Human Services and U.S. Department of Agriculture. 2015–2020 Dietary Guidelines for Americans. 8th Edition. <https://health.gov/dietaryguidelines/2015/resources/2015-2020-Dietary-Guidelines.pdf> (Page 12, “Terms to Know”)

⁷ Van Horn L, Carson JAS, Appel LJ, et al.; on behalf of the American Heart Association Nutrition Committee of the Council on Lifestyle and Cardiometabolic Health; Council on Cardiovascular Disease in the Young; Council on Cardiovascular and Stroke Nursing; Council on Clinical Cardiology; and Stroke Council. Recommended dietary pattern to achieve adherence to the American Heart Association/American College of Cardiology (AHA/ACC) guidelines: a scientific statement from the American Heart Association. *Circulation* 2016;134:XXX–XXX. doi: 10.1161/CIR.0000000000000462.

AHA is aware of proposals that the term “healthy” incorporate other factors beyond nutrient content, such as the degree of processing and the absence of artificial colors or preservatives, production method and treatment of the environment, and accessibility and affordability.⁸ In addition, consumers’ views of health and wellness are becoming more inclusive, reflecting a rising wariness of “chemical,” “artificial,” and “processed” ingredients, for example.⁹ However, definitions for many of these factors are not clearly defined in law nor agreed upon by stakeholders. Furthermore, and perhaps more importantly, there is not sufficient scientifically sound evidence linking them to health outcomes.

Unlike many other attributes that some have proposed to characterize “healthy,” intakes of food and its corresponding nutrient content are strongly linked to health outcomes. In 2013, the AHA and the American College of Cardiology (ACC) published the AHA/ACC Guideline on Lifestyle Management to Reduce Cardiovascular Risk.¹⁰ The lifestyle guideline, initiated by the National Heart, Lung, and Blood Institute, was based on a systematic evidence analysis of predominantly randomized controlled trials that focused on diet and physical activity modifications to reduce cardiovascular risk. These guidelines are closely aligned with the 2015–2020 Dietary Guidelines for Americans (DGA) and are designed to help achieve the AHA’s 2020 Strategic Impact Goals for cardiovascular health promotion and disease reduction.¹¹ Ensuring that criteria for “healthy” are linked to health outcomes is an opportunity to educate consumers about what credible science – as opposed to the popular media – indicates is meaningful for human health.

In the following sections, we expand on the nutrient content and food group-based dietary considerations that we recommend to define “healthy.”

If criteria other than nutrient content (e.g., amount of whole grain) are to be included in the definition of the term “healthy,” how might we determine whether foods labeled “healthy” comply with such other criteria for bearing the claim?

As stated above, we recommend a hybrid approach, i.e., a food-based approach in synergy with nutrient requirements, to define “healthy.” While dietary recommendations have evolved from nutrient-based to food-based dietary patterns, the latter are intended to guide consumers toward optimal health by making food choices that support achievement of recommended nutrient intakes.

⁸ E.g., Prevention Institute. *Setting the Record Straight: Nutrition and Health Professionals Define Healthful Food*. Prevention Institute: Oakland, CA, 2009.

https://www.preventioninstitute.org/sites/default/files/publications/SA_Setting%20the%20Record%20Straight_040511.pdf

⁹ Sloan, AE. Top 10 functional food trends. *Food Technology*, April 2016.

¹⁰ Eckel RH, Jakicic JM, Ard JD, 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. *Circulation* 2014;129(suppl 2):S76–S99.

¹¹ Lloyd-Jones DM, Hong Y, Labarthe D, et al. American Heart Association Strategic Planning Task Force and Statistics Committee. Defining and setting national goals for cardiovascular health promotion and disease reduction: the American Heart Association’s strategic Impact Goal through 2020 and beyond. *Circulation* 2010;121:586–613. doi: 10.1161/CIRCULATIONAHA.109.192703.

Food-based criteria should be predicated on a food's status in modern dietary guidance. If the product is not among the nutrient-dense foods and beverages recommended by dietary guidelines, it should not pass the food-based benchmark of eligibility for "healthy" labeling. The AHA/ACC dietary guidelines recommend a dietary pattern focused on vegetables, fruits, and whole grains, low-fat and non-fat dairy products, lean and extra-lean meats, poultry, fish, legumes, non-tropical (not coconut or palm kernel oil) vegetable oils, and nuts and seeds. The AHA/ACC guidelines are similar to the Dietary Guidelines regarding recommended choices within food groups, and both emphasize nutrient-dense foods where "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."¹²

The FDA could determine if a product meets the food-based criteria by assessing whether it falls into a RACC category¹³ that is eligible for the claim. FDA would need to first identify which RACC categories encompass the recommended food groups listed above. If a product falls into a RACC category that is eligible for the claim, FDA may consider additional food-based criteria, such as the amount of whole grain. If food-based criteria are satisfied, then the food's nutrient content can then be assessed (see Figure below) to determine its ultimate eligibility for "healthy."

We recommend that FDA consider designating certain RACC categories ineligible for "healthy" labeling, such as selected bakery products (brownies, toaster pastries, all types of cakes, cookies, ice cream cones, pies), desserts, and sugars and sweets. While products in these categories may be manufactured to have a favorable nutrient profile, it could be confusing to consumers because the usual or traditional forms of these foods are not congruent with dietary guidelines. It could also cause consumers to choose more of these types of foods at the expense of foods such as fruits and vegetables that are inherently nutrient-dense and have low levels of nutrients to limit. Again, we believe that the purpose of "healthy" labeling is to highlight the nutrient-dense foods that will be most helpful to promoting achievement of total diets that meet guidelines.

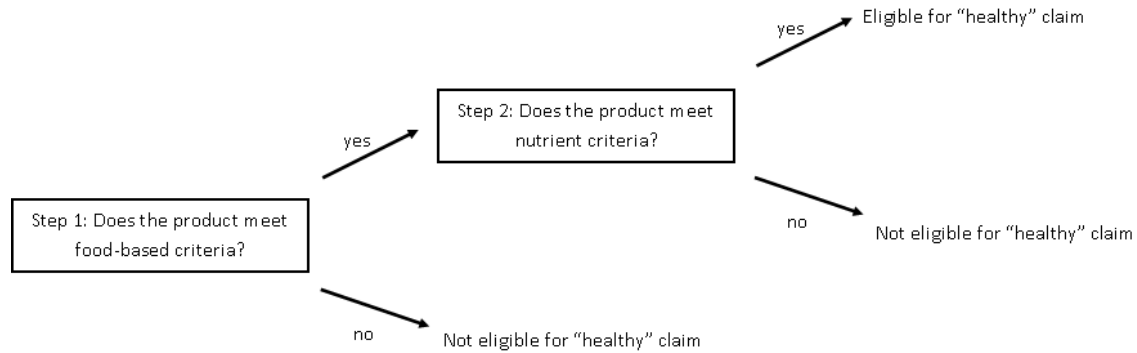
What types of food, if any, should be allowed to bear the term "healthy?" Should all food categories be subject to the same criteria?

As noted above, foods emphasized in a healthy eating pattern and in their nutrient-dense forms should be eligible for the "healthy" claim. The AHA/ACC dietary guidelines recommend a dietary pattern focused on vegetables, fruits, and whole grains; include low-fat and non-fat dairy products, lean and extra-lean meats, poultry, fish, legumes, non-tropical (not coconut or palm kernel oil) vegetable oils, and nuts and seeds.¹⁴ These types of foods should be eligible to bear the term "healthy" provided that they also meet nutrient criteria. Requiring foods to meet nutrient criteria will help control for unintended consequences such as excess amounts of added sugars or sodium that may be added to foods advocated by the guidelines (for example, candy-coated nuts or frozen vegetables in a creamy, salty sauce). A simplistic illustration of this two-step, hybrid approach follows:

¹² U.S. Department of Health and Human Services and U.S. Department of Agriculture, op.cit. Page 12.

¹³ As outlined in 21 CFR 101.12(b) and <https://www.regulations.gov/document?D=FDA-2004-N-0258-0136>

¹⁴ Van Horn et al., 2016



We recommend some degree of variation in nutrient criteria by food category. For example, most raw fruits and vegetables with no additional ingredients may be given blanket approval to be labeled "healthy," while canned or frozen fruits and vegetables may be subject to additional guidelines for added sugars and sodium. The Agency should consider intrinsic differences in the nutrient content of different food groups when establishing nutrient criteria for these groups.

What nutrient criteria should be considered for the definition of the term "healthy?" Should nutrients for which intake is recommended to be limited be included? Should nutrients for which intake is encouraged continue to be included?

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

Below, we provide our specific recommendations for the role of selected macro- and micronutrients in the definition of "healthy."

Fats

Total Fat

We recommend removing total fat as a criterion for "healthy".

As the Agency is aware, current science indicates that the quality of fat is more important than the overall quantity of fat that is consumed. For example, lowering total fat intake (fat reduction alone) does not clearly have a benefit on cardiovascular events, while replacing some saturated fat with unsaturated fats (fat reduction and fat modification, or fat modification alone) may reduce the incidence of cardiovascular events.¹⁵

Current dietary recommendations no longer emphasize total fat. The AHA/ACC dietary guidelines do not set an upper limit on total fat, but affirm that total energy intake should

¹⁵ Hooper L, et al. Reduced or modified dietary fat for preventing cardiovascular disease. *Cochrane Database of Systematic Reviews* 2012, Issue 5. Art. No.: CD002137. DOI: 10.1002/14651858.CD002137.pub3.

support weight control efforts.¹⁶ Similarly, the Dietary Guidelines do not specify an upper limit but recommend an intake of total fat that is within the National Academy of Science's acceptable macronutrient distribution range and maintains total calorie intake within limits.¹⁷

In addition, removing the total fat requirement would allow the "healthy" claim on foods such as non-tropical oils, fish, avocados, nuts, and seeds that are higher in unsaturated fats, provided that these foods are not disqualified from the claim based on other nutritional attributes.

The FDA should, however, consider the potential unintended consequences of eliminating the total 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. 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.

Saturated Fat

Saturated fat should remain a criterion for the "healthy" claim.

The AHA/ACC dietary guidelines and the DGAs advise consumers to limit consumption of saturated fats and to replace them with monounsaturated and polyunsaturated fats. Specifically, AHA recommends reducing saturated fat to <7 percent of total daily calorie intake (<6 percent of total daily calorie intake for patients at cardiovascular risk). Currently, Americans (ages 2 and older) consume 11 percent of calories from saturated fats.¹⁸

To help Americans lower their saturated fat consumption, "healthy" foods should be required to meet an absolute gram limit and/or a threshold on the percent of calories (per labeled serving size) from saturated fat. Limits could vary by food category, which would allow for naturally-occurring levels of saturated fat in recommended foods (e.g., low-fat dairy products, olive oil, and nuts and seeds) while preventing the addition of saturated fats to other recommended foods (e.g., frozen vegetables in a butter sauce).

Trans Fat

Foods that contain industrially-produced *trans* fats should not be eligible for the "healthy" claim.

AHA recommends avoiding *trans* fats and replacing them with unsaturated fats. A number of studies have observed a positive association between *trans* fat intake and risk of CVD, due in

¹⁶ Van Horn et al., 2016.

¹⁷ U.S. Department of Health and Human Services and U.S. Department of Agriculture, op. cit. (Page 25 and notes in Table 1-1, 1-2, and A3-1)

¹⁸ U.S. Department of Agriculture, Agricultural Research Service. 2016. Energy Intakes: Percentages of Energy from Protein, Carbohydrate, Fat, and Alcohol, by Gender and Age, What We Eat in America, NHANES 2013-2014. https://www.ars.usda.gov/ARSUserFiles/80400530/pdf/1314/Table_5_EIN_GEN_13.pdf

part to its LDL-cholesterol raising effect. Given the health risks associated with *trans* fats, the FDA should prohibit any food that includes in its ingredient list any industrially-produced *trans* fats such as partially hydrogenated oils from using the “healthy” claim. This is in alignment with FDA’s June 2015 determination that partially hydrogenated oils are not generally recognized as safe for use in human food.

Added Sugars

The FDA should include added sugars as a criterion for the “healthy” claim.

Strong and consistent evidence has demonstrated that added sugars are associated with excess body weight in children and adults. Conversely, reducing added sugars and sugar-sweetened beverages reduces BMI in both groups.¹⁹ Strong evidence supports the association of added sugars with increased cardiovascular disease risk in children through increased energy intake, increased adiposity, and dyslipidemia.²⁰ Strong evidence also demonstrates that consuming more added sugars, especially sugar-sweetened beverages, increases adult type 2 diabetes risk. This relationship is not fully explained by body weight.²¹ Moderate evidence has linked higher added sugars intake, especially sugar-sweetened beverages, with increased risk of adult hypertension, stroke, and coronary heart disease.²²

A number of expert groups recommend limiting added sugars intake. AHA recommends a limit of no more than 6 teaspoons (100 calories) per day for women and for children ages 2-18 years, and no more than 9 teaspoons (150 calories) per day for men.^{23,24} The Dietary Guidelines specify a limit of calories from added sugars to less than 10 percent of total daily calories. The rationale is based on the public health need to limit added sugars calories so Americans can meet food group and nutrient needs within calorie limits.²⁵ The World Health Organization set a strong recommendation to limit free sugars (defined as monosaccharides and disaccharides added to foods and beverages by the manufacturer, cook or consumer, and sugars naturally present in honey, syrups, fruit juices and fruit juice concentrates) to less than 10 percent of total energy intake.²⁶

¹⁹ Dietary Guidelines Advisory Committee (DGAC). 2015. Scientific Report of the 2015 Dietary Guidelines Advisory Committee: Advisory Report to the Secretary of Health and Human Services and the Secretary of Agriculture. <https://health.gov/dietaryguidelines/2015-scientific-report/PDFs/Scientific-Report-of-the-2015-Dietary-Guidelines-Advisory-Committee.pdf> (Part D, Chapter 6, Conclusions – line 703; PDF page 460)

²⁰ Vos MB, Kaar JL, Welsh JA, et al. AHA Statement on Added Sugars and CVD Risk in Children. *Circulation* 2016 <http://circ.ahajournals.org/content/early/2016/08/22/CIR.0000000000000439>

²¹ DGAC, op. cit. (Part D, Chapter 6, Conclusions – line 711-13; PDF page 460)

²² DGAC, op. cit. (Part D, Chapter 6, Conclusions – line 703; PDF page 460)

²³ Johnson RK, Appel LJ, Brands M, et al.; Dietary sugars intake and cardiovascular health: a scientific statement from the American Heart Association. *Circulation* 2009;120:1011–1020. <http://circ.ahajournals.org/content/circulationaha/120/11/1011.full.pdf>

²⁴ Vos et al., 2016

²⁵ U.S. Department of Health and Human Services and U.S. Department of Agriculture, op. cit. (Executive Summary and footnote 2)

²⁶ World Health Organization. Guideline: Sugars intake for adults and children. Geneva: World Health Organization; 2015. http://apps.who.int/iris/bitstream/10665/149782/1/9789241549028_eng.pdf?ua=1.

While added sugars intake decreased for both males and females across all age groups between 2001-2004 and 2007-2010, Americans still eat too many added sugars across all age and sex groups.²⁷ On average, Americans take in about 270 added sugar calories per day, more than 13 percent of total daily calories.²⁸ This is equivalent to almost 17 teaspoons of sugar, well in excess of the AHA guidance.²⁹

As noted above, added sugars should be a criterion for “healthy.” In accordance with AHA/ACC’s dietary guidelines we support the allowance of limited amounts of added sugars to healthy eating patterns. The threshold for added sugars levels could vary by food category, but any relative limits should not exceed 5 to 10 percent of calories per serving, which is generally consistent with our recommended limits for added sugar intake.³⁰ This will allow the use of small amounts of added sugars to sweeten and improve the palatability of nutrient-dense foods. It will also allow the “healthy” claim on products in food categories that tend to contain added sugars (e.g., flavored low-fat and non-fat dairy products, canned fruits, and some whole grain cereals) but also make a positive contribution to the diet.

Sodium

Sodium should remain a criterion for the “healthy” claim.

As the Agency is well aware, excess sodium consumption is strongly linked to high blood pressure. Evidence includes results from animal studies, epidemiological studies, clinical trials, and meta-analyses of these data. More than 50 randomized trials examining the effects of sodium on blood pressure have been conducted, including a number of rigorously controlled, dose-response trials. The evidence is persuasive – there is a statistically significant, clinically relevant, progressive dose-response relationship between sodium intake and blood pressure.³¹ Individuals with hypertension are at increased risk for coronary heart disease, stroke, heart failure, kidney failure, gastric cancer, and osteoporosis. A number of studies have modeled significant health benefits and reduced medical costs with decreasing population sodium consumption.³²

²⁷ DGAC, op. cit. (Page 26 – Conclusion, and page 36 – Conclusion)

²⁸ U.S. Department of Health and Human Services and U.S. Department of Agriculture, op. cit. (Figure 2-9)

²⁹ 270 calories divided by 4 calories/gram for added sugars = 67.5 g added sugars, divided by 4 grams/tsp = 16.9 tsp

³⁰ AHA recommends up to 6 teaspoons (100 calories) of added sugar/day for women and up to 9 teaspoons (150 calories) for men. 100 calories is 5% of a 2,000 calorie diet (women) and 6% of a 2,500 calorie diet (men).

³¹ Whelton P, et al. Sodium, blood pressure, and cardiovascular disease: Further evidence supporting the American Heart Association sodium reduction recommendations. *Circulation* 2012;126:2880-2889.

³² E.g., Palar K, Sturm R. Potential societal savings from reduced sodium consumption in the U.S. Adult population. *Am J Health Promot* 2009;24:49-57; Coxson P, et al. Mortality benefits from US population-wide reduction in sodium consumption: projections from three modeling approaches. *Hypertension* 2013, vol. 61, pp. 564-570; He FJ, et al. Salt reduction in England from 2003 to 2011: its relationship to blood pressure, stroke and ischemic heart disease mortality. *BMJ Open*. 2014;4:e004549. doi:10.1136/bmjopen-2013-004549.

Nearly one-third of U.S. adults have high blood pressure or hypertension, and an additional one-third has pre-hypertension. These numbers may worsen as modeling predicts that an estimated 41.4 percent of U.S. adults will have hypertension by 2030.³³ Children may also be at risk of developing elevated blood pressure at an early age, because nine out of ten school-age kids consume sodium in excess of recommendations.³⁴ Available data are sufficiently robust to recommend a lower sodium intake beginning early in life as an effective, well-tolerated approach to minimize the risk of children developing elevated blood pressure, a condition that extends into adulthood.³⁵

AHA recommends sodium intake of <2,300 mg/day, or further reduction to 1,500 mg/day as needed for enhanced blood pressure lowering. Sodium reductions by at least 1,000 mg/day are recommended even if the desired daily sodium intake is not achieved.³⁶ Currently, Americans (ages 2 years and older) consume more than 3,400 mg/d sodium,³⁷ with more than three-quarters of this amount estimated to come from packaged, processed, and restaurant foods, not salt added at the table.

For these reasons, sodium should continue to be a criterion for “healthy” with thresholds that vary by food category. In the AHA Heart-Check Food Certification Program, products are limited to 140mg, 240mg, or 360mg per label serving, or 480mg per label serving and per RACC, or 600mg for main dish or meal products. A chart of the category-specific sodium levels used in our program is available on the [AHA website](#). These category-specific sodium levels were established based on a review of the products available in the marketplace at the time and understood to be achievable.

If nutrients for which intake is encouraged are included in the definition, should these nutrients be restricted to those nutrients whose recommended intakes are not met by the general population, or should they include those nutrients that contribute to general overall health? Should the nutrients be intrinsic to the foods, or could they be provided in part—or in total—via fortification?

To qualify as “healthy”, foods should be required to contain significant amounts of at least one of the following beneficial nutrients: calcium, vitamin D, iron, potassium, fiber, or protein.

³³ Benjamin EJ et al. Heart disease and stroke statistics—2017 update: a report from the American Heart Association. *Circulation* 2017;135:000-000 DOI: 10 1161/CIR 000000000000485

³⁴ Quader ZS, Gillespie C, Sliwa SA, et al. Sodium intake among US school-aged children: National Health and Nutrition Examination Survey, 2011-2012. *J Acad Nutr Diet* 2017; 117(1): 39-47.e5.

³⁵ Appel LJ, Lichtenstein AH, Callahan EA, et al. Reducing sodium intake in children: A public health investment. *J Clin Hypertens* 2015; 17(9):657-662.

³⁶ Van Horn et al., 2016

³⁷ U.S. Department of Agriculture, Agricultural Research Service. 2016. Nutrient Intakes from Food and Beverages: Mean Amounts Consumed per Individual, by Gender and Age, What We Eat in America, NHANES 2013-2014.

https://www.ars.usda.gov/ARUserFiles/80400530/pdf/1314/Table_1_NIN_GEN_13.pdf (page 5)

Although the *Scientific Report of the 2015 Dietary Guidelines Advisory Committee* (DGAC) 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.³⁸ Thus, we support 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.³⁹ (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.)

In addition, because Vitamins A and C will no longer be mandatory declarations on the revised Nutrition Facts label, they should no longer qualify as beneficial nutrients. Vitamins A and C are not underconsumed nutrients that pose a substantial public health concern,⁴⁰ and they are often present in snacks, chips, frozen novelties and other foods that are not nutrient-dense and do not fit into a healthy eating pattern.

This list of six nutrients 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).

We do, however, recommend that the Agency consider including language in this provision that will allow it to be nimble in updating this list of beneficial nutrients as warranted by the latest evidence.

Keeping the 10 percent minimum beneficial nutrient content requirement will increase the utility of the "healthy" claim in differentiating foods that are most useful in helping consumers achieve recommended dietary patterns. This will also help meet consumers' expectations for "healthy" foods, which they define in part by the food's possession of positive attributes, not merely its absence of negative attributes.⁴¹ At the same time, we support continued exemptions from this requirement for the food groups identified in 21 CFR 101.65(d)(2)(i).

We believe that the beneficial nutrients that establish a food's "healthy" claim should occur intrinsically in food. This will help to reserve the "healthy" claim for foods that are most helpful in achieving dietary recommendations. This does not necessarily mean that fortified foods cannot bear the "healthy" claim, but rather that they could not rely on fortification to establish eligibility for the claim. For example, we support fortification of foods bearing the "healthy"

³⁸ DGAC, op. cit. (Part D, Chapter 1, page 13)

³⁹ Food and Drug Administration. September 2016. Use of the Term "Healthy" in the Labeling of Human Food Products: Guidance for Industry. <https://www.fda.gov/downloads/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm521692.pdf>

⁴⁰ DGAC, op. cit. (Part D, Chapter 1, page 13)

⁴¹ International Food Information Council. 2016 Food and Health Survey. Slide 18.

http://www.foodinsight.org/sites/default/files/2016-Food-and-Health-Survey-Report_FINAL1.pdf

claim to the extent that fortification is used to contribute shortfall nutrients to otherwise nutrient-dense foods (such as the addition of calcium to 100 percent orange juice, folic acid to whole-grain cereal, and vitamins A and D to non-fat milk) or to meet a standard of identity (such as products containing enriched grains). Any fortification should be in accordance with FDA's fortification policy which, among other provisions, does not consider it appropriate to fortify sugars or snack foods such as candies and carbonated beverages.⁴²

Are there current dietary recommendations (e.g., the DGAs) or nutrient intake requirements, such as those described in the final rule updating the Nutrition Facts label or those provided by the National Academy of Medicine in the form of Dietary Reference Intakes, that should be reflected in criteria for use of the term “healthy?”

We believe that criteria for “healthy” should be based on the latest science available, including the most current Dietary Reference Intakes, and be as congruent as possible with other federal dietary guidance as reflected in the Dietary Guidelines for Americans and the Nutrition Facts label nutrient intake requirements. We recommend that the Agency include language in the regulations that will allow it to be nimble in updating the criteria for “healthy.” This could take the form of a five-year review in coordination with updates to the Dietary Guidelines for Americans and any other significant updates to dietary guidance such as DRIs.

What are the public health benefits, if any, of defining the term “healthy” or other similar terms in food labeling?

We are aware that some stakeholders do not support use of the term “healthy” on food labels. They claim, for example, that it reflects undue focus on individual foods rather than the overall diet, and that what is “healthy” for one individual may not hold true for another. Indeed, the AHA/ACC dietary guidelines stress the importance of the overall daily pattern of food choices rather than individual foods in isolation. The current regulations state that “healthy” and related terms may be used in labeling of a food that is useful in creating a diet that is consistent with dietary recommendations. It is also understood that some individuals may have health conditions warranting dietary restrictions and should follow the advice of a healthcare professional regarding a dietary pattern that would be “healthy” for their particular condition, which may exclude some products in the marketplace that are labeled “healthy” (for the general population). The Agency may consider executing a public education campaign – or authorizing a disclaimer or claim statement that foods labeled “healthy” may carry – that emphasizes these key points, especially to emphasize the purpose of the claim.

Notwithstanding the preeminence of overall dietary patterns in achieving health, we believe that there is more potential benefit than harm in allowing individual products to bear the claim “healthy.” First, it will promote consist, uniform, enforceable use of the claim, establishing a level playing field for food manufacturers who wish to inform consumers that their products are aligned with recommended dietary guidance. This is expected to help reduce consumer

⁴²FDA fortification policy: [21 CFR 104.20](#)

confusion about what foods are “healthy” and may also reduce consumer mistrust of corporate claims. Second, food manufacturers may be incentivized to reformulate their offerings to gain eligibility for “healthy” labeling, which can help improve the healthfulness of the food supply. Third, it enables the Agency to maintain a uniform standard for “healthy” in food labeling, thereby avoiding a patchwork of different and potentially conflicting standards.

Is “healthy” the best term to characterize foods that should be encouraged to build healthy dietary practices or patterns? What other words or terms might be more appropriate?

We believe that “healthy” (and its derivatives, e.g., “healthful”) is an appropriate term to characterize foods that should be encouraged to build recommended dietary patterns. Our consumer materials use this term when discussing recommended eating patterns. We have not conducted studies to identify other terms that may better guide consumers toward recommended dietary patterns, but we encourage the Agency to conduct consumer research that could identify the most effective terminology for consumer messaging.

In addition, the FDA should also consider recognizing “healthy” as synonymous with similar terms such as “nutrient-rich” or “nutrient-dense,” which can be implied nutrient content claims when they appear in a nutritional context on a label or in labeling. Anecdotally, these kinds of terms are relatively pervasive in marketing and advertising messages for food products. Extending eligibility criteria for “healthy” to apply to these phrases may help prevent replacement of “healthy” on food labels with similar terms that are not regulated. This in turn may help prevent consumer confusion and strengthen the consistency and utility of these terms in differentiating foods that are most useful in promoting achievement of recommended dietary patterns. We urge the Agency to conduct research to help it determine whether to recognize these terms as synonymous with healthy, or to establish separate definitions for their use. In either case, it will be important to educate consumers about the meaning and/or the distinctions of these terms in food labeling.

What is consumers’ understanding of the meaning of the term “healthy” as it relates to food? What are consumers’ expectations of foods that carry a “healthy” claim?

As previously stated, consumers’ views of health and wellness are becoming more inclusive as they are defined by more than nutrient content. For example, respondents in the IFIC 2016 Food and Health survey reported that a healthy food is defined, in part, by being organic, fresh, unprocessed, natural, free of artificial ingredients and additives, and having few ingredients. Thirty-five and 17 percent responded that a healthy food is defined in part by what it does not contain (or contains only low levels of) and by what it does contain (certain foods/components), respectively. The most commonly-cited attributes to define a healthy eating style were “the right mix of different foods,” “limited or no artificial ingredients or preservatives,” and “natural foods.”⁴³ In another survey, the top health and wellness product claims that U.S. grocery

⁴³ International Food Information Council, op. cit. (slides 18, 20)

shoppers sought in 2016 included low sodium, low sugar, no *trans* fat, no artificial ingredients or preservatives, whole grain, and high fiber.⁴⁴

These findings indicate that nutrient content – both the presence of desired nutrients/food components and the absence or limitation of undesired nutrients/food components – remains an important factor in consumers’ definitions of “healthy” foods. While some of these desirable attributes may confer benefits, many of their definitions are not clearly defined nor agreed upon by stakeholders. Moreover, there is a lack of scientific evidence to conclusively link them to health outcomes in the general population.

The AHA has not conducted consumer research in this area, but we encourage the Agency to consider focus groups, surveys, and other research methodologies to clarify consumers’ understanding of and expectation for foods that carry a “healthy” claim. We also urge FDA to examine whether there are other terms that consumers construe as having the same general meaning and connotation as healthy. If such terms exist, FDA should consider making them synonymous with healthy only to the extent that they too can be clearly defined and linked to health outcomes.

Would this change in the term “healthy” cause a shift in consumer behavior in terms of dietary choices? For example, would it cause a shift away from purchasing or consuming fruits and vegetables that do not contain a “healthy” claim and towards purchasing or consuming processed foods that bear this new “healthy” claim?

Because the “healthy” claim is voluntary, the extent to which consumer behavior may be shifted depends on the extent to which food manufacturers use the claim. Based on existing research demonstrating that food package information can influence consumers (some more than others, including those with less knowledge or interest in nutrition),⁴⁵ we might reasonably expect that a change in “healthy” would cause a shift in consumer behavior. Given the current consumer demand for healthy foods, making the definition of “healthy” more robust is expected to help them make appropriate choices for successful adaptation of recommended dietary patterns.

How will the food industry and consumers regard a change in the definition of “healthy?”

We are not aware of quantitative data on this topic, but our anecdotal experience indicates that most consumers – and some food industry stakeholders – are not aware that “healthy” is a regulated term and thus are unaware of its defining criteria. Therefore, it is unclear whether there would be any significant effect on their perception following a change in its definition, unless there is an accompanying education campaign with the goal of raising awareness.

⁴⁴ Food Marketing Institute. 2016 U.S. Grocery Shopper Trends Report. <http://www.fmi.org/docs/default-source/webinars/fmi-2016-us-grocery-shopper-trends-overview-webinar5ce7030324aa67249237ff0000c12749.pdf?sfvrsn=2> (page 34)

⁴⁵ Institute of Medicine (IOM). Front of Package Nutrition Rating Systems and Symbols: Promoting Healthier Choices. Washington, DC: The National Academies Press, 2012. Chapter 6, summary. <https://www.nap.edu/read/13221/chapter/8#67>

Generally, we believe that the food industry will appreciate an updated, robust definition of “healthy” that reflects current science. We believe that it will also welcome guidance to ensure consistent, uniform, enforceable use of the claim. Food industry stakeholders’ perception of the change will likely depend on how the revised definition affects their products’ eligibility to bear the claim.

What would be the costs to industry of the change?

Food manufacturers that currently carry products with a “healthy” claim will need to re-evaluate those products for adherence to a revised definition of the claim. They may also choose to re-evaluate products that do not meet the current “healthy” claim criteria to determine whether they meet the new criteria. The results of these evaluations may necessitate changes in product labels. Manufacturers will also be making label changes to comply with the May 2016 final rules for revising the Nutrition Facts panel as well as GMO disclosures. They will likely request an implementation process that does not require multiple sequential label changes and considers the time and cost in making the changes. We urge the Agency not to delay final rules and implementation of updates to “healthy” labeling, and to be strategic in aligning compliance deadlines with other mandated label changes to the extent possible.

While the “healthy” claim is voluntary, we hope that the food industry will choose to label its eligible products with this claim to help guide consumers in selecting foods that constitute healthy dietary patterns. We also hope that the industry will reformulate more of its products to be eligible for the “healthy” claim.

ADDITIONAL COMMENTS

Consumer Education Campaign

A consumer education and outreach campaign will help make the nutrient content claim “healthy” a successful aid in helping consumers make nutritious food and beverage choices. AHA is aware that the Agency intends to update its existing educational materials and to create new educational opportunities – including partnerships with other Federal government agencies, state health departments, health professional organizations, food manufacturers, retailers, and non-profit organizations – to explain how to use the revised Nutrition Facts label to help consumers make healthy dietary choices. Given that educational efforts for both the Nutrition Facts label and “healthy” labeling are under the Agency’s purview, we recommend combining these efforts wherever possible in order to maximize resources and help consumers understand that the term “healthy” is regulated, defined by food-based criteria that include nutrient content.

Combining an education campaign on the Nutrition Facts label and the “healthy” claim will also allow the Agency to emphasize the importance of serving sizes when evaluating a food’s contribution to a healthy diet. For example, a food may be “healthy” if an individual consumes one serving of that food. However, there are instances where eating two or more servings of a food labeled “healthy” would be “unhealthy” due to too much saturated fat, added sugars, or

sodium. An education campaign could explain that the “healthy” label applies to one serving or a reasonable consumption of the food.

Closing

In closing, we reiterate our overall support for the FDA’s decision to reexamine conditions of use for the term “healthy” in food labeling. Nutrition-related claims, branding, and promotions have been shown to influence consumers’ product attitudes, preferences, and choices, at least in controlled and experimental settings.⁴⁶ Revising the definition of “healthy” in alignment with current science is expected to make it easier for consumers to select more nutritious foods and cultivate healthy dietary patterns.

We urge the Agency to set a high bar of eligibility for “healthy,” reserving its use as an absolute, rather than a relative term to highlight nutrient-dense foods that will be *most helpful* to promoting consumers’ achievement of total diets that conforms to current dietary recommendations.

In summary, we recommend that a revised definition of “healthy” should:

- Adopt a hybrid approach that includes both food group-based and nutrient-based criteria
- Limit the claim to nutrient-dense foods recommended in the AHA’s dietary guidance: vegetables, fruits, whole grains, low-fat and non-fat dairy products, lean and extra-lean meats, poultry, fish, legumes, non-tropical (not coconut or palm kernel oil) vegetable oils, and nuts and seeds, or the Dietary Guidelines for Americans, provided that they also meet nutrient criteria
- Establish food-based nutrient criteria for saturated fat, sodium, and added sugars
- Prohibit the claim on foods that contain artificial trans fats and/or that fall into designated RACC categories that do not naturally align with dietary recommendations to consume nutrient-dense foods
- Include naturally-occurring vitamin D, protein, fiber, iron, calcium, and potassium as the beneficial nutrients that may be used to establish eligibility for the claim
- Be accompanied by a consumer education effort to increase awareness of the criteria underpinning the claim and their well-established link to health outcomes
- Leave room for revision as warranted, perhaps a five-year review in coordination with updates to the Dietary Guidelines for Americans and any other significant updates to dietary guidance such as DRIs
- Consider developing a required claim statement that explains the meaning of the “healthy” claim on food and beverage packaging

We are eager to work with the FDA on this initiative and offer our assistance.

⁴⁶ IOM, 2012.

If you have any questions or need any additional information, please do not hesitate to contact Susan Bishop of AHA staff at (202) 785-7908 or susan.k.bishop@heart.org.

Thank you for your consideration of our comments.

Sincerely,

A handwritten signature in black ink that reads "Steven R. Houser". The signature is written in a cursive style with a large, prominent "S" at the beginning.

Steven R. Houser, PhD
President
American Heart Association