



April 26, 2017

Stephen Ostroff, MD  
Acting Commissioner, Food and Drug Administration  
Division of Dockets Management (HFA-305)  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**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 American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to provide input in response to the U.S. Food and Drug Administration (FDA) request for information on the use of the term “healthy” on food labels. We support FDA updating the requirements for the use of the term “healthy” to be consistent with current research and dietary guidance. ACS CAN is the nonprofit, nonpartisan advocacy affiliate organization of the American Cancer Society dedicated to eliminating cancer as a major health problem. ACS CAN advocates for legislative, regulatory, and policy efforts that will make cancer a top national priority.

ACS CAN supports providing consumers with information that will help them make healthy dietary choices. We have supported other nutrition labeling strategies that help to achieve that goal, including updates to the Nutrition Facts Label, menu labeling in chain restaurants and other food retailers, and calorie labeling in chain vending machines. We believe that the use of the term “healthy” on food packages, if defined appropriately, can be a tool to help consumers identify nutritious choices that support long-term health, including reduced cancer risk.

**Diet and Cancer**

Poor diet, physical inactivity, excess weight, and excess alcohol consumption are major risk factors for cancer, second only to tobacco use. In fact, one in five of the estimated 1.7 million cancer cases expected to be diagnosed this year can be attributed to these factors.<sup>1</sup> Excess weight is clearly associated with an increased risk of developing cancers of the breast (postmenopausal), colon and rectum, uterus, kidney, pancreas, ovary, liver, gastric cardia, gall bladder, and thyroid, and adenocarcinoma of the esophagus, meningioma, and multiple myeloma.<sup>2</sup> As a result of the clear relationship diet and body weight have with many types of cancer, American Cancer Society guidelines for cancer prevention<sup>3</sup> and cancer survivorship<sup>4</sup> recommend eating a healthy diet, with an emphasis on

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<sup>1</sup> American Cancer Society. *Cancer Facts & Figures 2017*. Atlanta, GA: American Cancer Society, 2017.

<sup>2</sup> Lauby-Secretan B, Scoccianti C, Loomis D, et al. Body Fatness and Cancer – Viewpoint of the IARC Working Group. *N Engl J Med* 2016; 375: 8.

<sup>3</sup> Kushi LH, Doyle C, McCullough M, et al. American Cancer Society Guidelines on Nutrition and Physical Activity for Cancer Prevention. *CA Cancer J Clin* 2012; 62:30-67.

<sup>4</sup> Rock CL, Doyle C, Demark-Wahnefried W, et al. Nutrition and Physical Activity Guidelines for Cancer Survivors. *CA Cancer J Clin* 2012; doi: 10.3322/caac.21142.

plant foods. Specific dietary recommendations include choosing foods and beverages in amounts that help achieve and maintain a healthy weight, limiting processed meats and red meats, consuming fruits and vegetables and whole grains instead of refined grain products, and limiting alcohol intake for those who drink alcoholic beverages.<sup>5</sup> Recent research has found that non-smoking adults who followed American Cancer Society guidelines for weight control, diet, physical activity, and alcohol consumption lived longer and had a lower risk of dying from cancer and cardiovascular disease.<sup>6,7</sup>

## Summary of Our Recommendations for Defining “Healthy”

We recommend that FDA consider the following principles and recommendations in updating its criteria for use of the term “healthy” on food labels:

- The term “healthy” should help to guide Americans toward food categories and subcategories that are part of a healthy eating pattern, as defined by the *2015-2020 Dietary Guidelines for Americans*.
- Within a food category, “healthy” should help to identify foods and beverages in their most nutrient-dense forms.
- “Healthy” foods and beverages should both 1) provide at least a minimum amount of food from a food group that is part of a healthy eating pattern, and 2) not exceed recommended limits for certain nutrients.
- Foods that are part of a healthy eating pattern include fruits, vegetables, whole grains, fat-free or low-fat dairy products or fortified soy beverages, and certain protein foods, including fish and seafood, lean poultry, eggs, legumes, nuts, seeds, and soy products.
- The presence of positive nutrients should not be allowed to substitute for foods that are part of a healthy food pattern. If the updated “healthy” criteria requires foods and beverages to provide a minimum amount of a positive nutrient, qualifying nutrients should be the nutrients of public health concern in the *Dietary Guidelines*, or protein, and ideally occur naturally in the food and not be added through fortification.
- “Healthy” foods and beverages should meet specified limits for added sugars, saturated fats (with exemptions for some foods like avocados, nuts, and fish naturally high in saturated fat), trans fats, sodium, and cholesterol. Limits on total fat are no longer needed.
- Red meats, processed meats, and sugar-sweetened beverages should not be labeled “healthy” because regular consumption of these products directly increases the risk for cancer or for obesity, which increases the risk of several cancers.
- FDA should conduct research on the use by industry of terms that may be considered alternatives to “healthy”, consumer understanding of such terms, and their impact on consumer behavior. Use of other terms that consumers understand to mean “healthy” should be considered implied healthy claims and subject to the same criteria, to the extent allowed by law.
- Use of the term “healthy” should help to reduce consumer confusion regarding which foods and beverages are truly healthy. FDA should encourage the food and beverage industry to use the term “healthy” on products that meet the definition and increase the number of new or reformulated “healthy” products in the marketplace.

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<sup>5</sup> Kushi, 2012.

<sup>6</sup> Kohler LN, Garcia DO, and Harris RB. Adherence to Diet and Physical Activity Cancer Prevention Guidelines and Cancer Outcomes: A Systematic Review. *Cancer Epidemiol Biomarkers Prev* 2016; 25(7): 1018-28.

<sup>7</sup> McCullough ML, Patel AV, Kushi LH, et al. Following Cancer Prevention Guidelines Reduces Risk of Cancer, Cardiovascular Disease, and All-Cause Mortality. *Cancer Epidemiol Biomarkers Prev* 2011; 20(6): 1089-97.

Our recommendations are explained in more detail in the sections that follow.

### **General Principles for the Term “Healthy”**

In general, we recommend aligning the requirements for use of the term “healthy” with the *2015-2020 Dietary Guidelines for Americans (Dietary Guidelines)*. FDA should also consider other evidence-based nutrition standards and guidelines, including the National School Lunch Program and School Breakfast Program meal standards, Smart Snacks nutrition standards, National Academies reports, and the American Cancer Society guidelines, outlined above, in defining “healthy”.

**The term “healthy” should help to guide Americans toward food categories and subcategories that are part of a healthy eating pattern, as defined by the *2015-2020 Dietary Guidelines for Americans*.**

The *Dietary Guidelines* recommends consuming a healthy eating pattern at an appropriate calorie level to manage weight. A healthy eating pattern includes a variety of vegetables from all subgroups; fruits, especially whole fruits; grains, at least half of which are whole; fat-free or low-fat dairy products or fortified soy beverages; a variety of protein foods, including fish and seafood, lean meats and poultry, eggs, legumes, nuts, seeds, and soy products; and alcohol in moderation, if consumed at all.<sup>8</sup> The *Dietary Guidelines* also recommends limiting saturated and trans fats, added sugars, and sodium, and provides a quantitative limit for each nutrient. The American Cancer Society guidelines recommend limiting consumption of processed meats and red meats given that regular consumption of these foods increases the risk for colorectal cancer.<sup>9</sup> Foods and beverages labeled “healthy” should fit within this framework of a healthy eating pattern.

**Within a food category, the term “healthy” should help to identify foods and beverages in their most nutrient-dense forms.**

The *Dietary Guidelines* recommends eating a healthy eating pattern made up of nutrient-dense foods. To achieve this pattern, the *Dietary Guidelines* recommends that consumers “shift 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.”<sup>10</sup>

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. Ideally, these foods and beverages also are in forms that retain naturally occurring components, such as dietary fiber. . . . 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.<sup>11</sup>

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<sup>8</sup> U.S. Department of Health and Human Services (HHS) and U.S. Department of Agriculture (USDA). *2015–2020 Dietary Guidelines for Americans*. 8th Edition. December 2015. Available at: [https://health.gov/dietaryguidelines/2015/resources/2015-2020\\_Dietary\\_Guidelines.pdf](https://health.gov/dietaryguidelines/2015/resources/2015-2020_Dietary_Guidelines.pdf)

<sup>9</sup> Kushi, 2012.

<sup>10</sup> Ibid.

<sup>11</sup> Ibid.

Foods that are labeled “healthy” should meet this definition of nutrient dense. In other words, they should have little or no solid fats, added sugars, refined starches, or sodium. Foods and beverages in their nutrient dense forms help consumers meet nutrient needs within calorie limits.

### **Overarching Criteria for the Term “Healthy”**

**To be labeled “healthy”, we recommend that foods and beverages both: 1) provide at least a minimum amount of food from a food group that is part of a healthy eating pattern, and 2) not exceed recommended limits for certain nutrients.**

Given that the *Dietary Guidelines* recommends following a healthy eating pattern and consuming foods and beverages that are nutrient-dense, we believe that it is essential for “healthy” foods and beverages to both meet food-based criteria and not exceed limits for certain nutrients.

We do not support a tiered approach that relaxes the nutrient-based criteria for foods that provide a greater contribution of a food that is part of a healthy food pattern or that relaxes the food-based criteria based on a product’s nutrient profile. Foods and beverages that meet only the food-based or the nutrient-based criteria should not be allowed to be labeled “healthy”; both type of criteria should be met.

### **Food-Based Criteria for “Healthy”**

As noted above, we recommend that “healthy” foods and beverages be part of a healthy eating pattern in the *Dietary Guidelines*. **More specifically, we recommend that a serving of a “healthy” food or beverage provide a full serving from one or more of the following food groups, or a combination thereof:**

- **fruits, especially whole fruits;**
- **vegetables;**
- **whole grains;**
- **fat-free or low-fat dairy products or fortified soy beverages;**
- **Certain protein foods, including fish, seafood, lean poultry, eggs, legumes, nuts, seeds, and soy products.**

Foods should be minimally processed so that most of their naturally-occurring components and nutrients remain intact. Main dishes and meals with multiple components should be required to provide multiple servings from “healthy” food groups.

#### ***Whole Grains***

**We recommend that grain-based products meeting the criteria for “healthy” provide nearly 100 percent whole grain.** Whole grains are grain products in their most nutrient-dense forms and typically provide fiber, which is underconsumed in the population. Additionally, while research shows that Americans are eating enough grain products overall, consumption of whole grains is low.<sup>12</sup> This means that for people to eat enough whole grains, they must shift some of their consumption of refined grains to whole grains. For products that provide foods from multiple food groups, the nearly 100 percent whole grain requirement should apply to the portion of the food that is grain-based.

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<sup>12</sup> HHS and USDA, 2015.

We do not support requiring “healthy” foods to provide a minimum absolute amount of whole grains (e.g., 8 grams of whole grain, the minimum amount required by the Whole Grains Council for a whole grain stamp)<sup>13</sup>, because while these foods provide a small amount of whole grain, they may provide an even larger amount of refined grains. Consumption of these foods would do little to reduce overconsumption of refined grains. Similarly, we believe that a 50 percent whole grain standard for “healthy” foods would also be too low because most people do not consume only “healthy” foods.

### ***Positive Nutrients and Fortification***

**We do not support allowing the presence of positive nutrients to substitute for the food-based criteria.** The *Dietary Guidelines*,<sup>14</sup> and other evidence-based guidelines,<sup>15</sup> emphasize the importance of meeting nutrient needs through the consumption of a variety of nutrient-dense foods following an overall healthy dietary pattern at an appropriate calorie level. Therefore, evidence supports the recommendation that, for optimal health, individuals follow an overall healthy dietary pattern comprised primarily of nutrient-dense, whole foods, rather than focusing on individual nutrients.

**If the updated criteria for “healthy” requires foods and beverages to provide a minimum amount of certain positive nutrients, qualifying nutrients should be the nutrients of public health concern in the *Dietary Guidelines* - calcium, vitamin D, potassium, fiber, and iron - or protein.** Calcium, vitamin D, potassium, and fiber are underconsumed by the general population, iron is underconsumed by certain subpopulations, and inadequate consumption of these nutrients leads to adverse health outcomes. After July 2018, when most foods will be required to have the updated Nutrition Facts label that will not require inclusion of vitamins A or C, these vitamins should no longer be allowed to qualify as positive nutrients for a “healthy” claim. They are not nutrients of public health concern<sup>16</sup> and 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.

FDA requires that foods labeled “healthy” and fortified to meet the existing requirement for positive nutrients 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”<sup>17</sup> like cookies, candies, cakes, soft drinks, and chips, which are not nutrient-dense. **At a minimum, FDA should retain this requirement but may want to consider strengthening the “healthy” criteria by requiring that qualifying nutrients occur naturally in the food and are not added through fortification.**

### **Nutrient-Based Criteria for “Healthy”**

To ensure that foods and beverages labeled “healthy” are in nutrient-dense forms, as recommended by the *Dietary Guidelines*, limits are needed on certain nutrients that are overconsumed in the population. We recommend requiring foods labeled “healthy” to meet limits for added sugars, saturated fat, trans fat, sodium, and cholesterol. Consistent with FDA’s current enforcement discretion, we concur that a limit on total fat is no longer needed.

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<sup>13</sup> Oldways Whole Grain Council. Whole Grain Stamp. Available at <https://wholegrainscouncil.org/whole-grain-stamp>. Accessed April 14, 2017.

<sup>14</sup> HHS and USDA, 2015.

<sup>15</sup> Kushi, 2012.

<sup>16</sup> Dietary Guidelines Advisory Committee, 2015.

<sup>17</sup> FDA. November 2015. Questions and Answers on FDA’s Fortification Policy: Guidance for Industry. Available at: <https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM471087.pdf>.

## **Added Sugars**

**We strongly recommend adding a limit on added sugars to the criteria for use of the term “healthy”.**

Added sugars increase the risk for obesity and reduce dietary quality by adding calories to the diet without any nutrients. Strong evidence shows that overconsumption of added sugars is associated with excess body weight in children and adults.<sup>18</sup> Moderate evidence also links higher intakes of added sugars to an increased risk of hypertension, stroke, and coronary heart disease in adults.<sup>19</sup> On average, Americans consume about 270 calories per day from added sugars, more than 13 percent of total calories.<sup>20</sup> Numerous evidence-based guidelines from governmental and non-governmental institutions including HHS and USDA (*Dietary Guidelines*),<sup>21</sup> the American Cancer Society,<sup>22</sup> the American Heart Association,<sup>23</sup> and the World Health Association<sup>24</sup> recommend reducing consumption of added sugars. The *Dietary Guidelines* recommends that Americans consume less than 10 percent of calories from added sugars. This recommendation is based on food pattern modeling and data that demonstrates the public health need to limit calories from added sugars to meet food group and nutrient needs within calorie limits.<sup>25</sup> World Health Organization guidelines also recommend that adults and children reduce their daily intake of added sugars to less than 10 percent of calories per day and notes that a further reduction to below 5 percent of calories would provide additional health benefits.<sup>26</sup> The American Heart Association recommends limits on added sugars of no more than 100 calories per day for women and no more than 150 calories for men,<sup>27</sup> equal to 5 or 7.5 percent of a 2,000 calorie diet.

Given the research on the health harms of added sugars and the evidence-based recommendations to limit consumption, we recommend that the limit on added sugars for products labeled “healthy” be no more than 10 percent of calories from added sugars, and FDA may want to consider establishing an even stricter limit. The addition of a limit on added sugar as part of the criteria for “healthy” would be consistent with the addition to the Nutrition Facts label of the amount and percent daily value for added sugar based on a daily limit of 10 percent of calories for a 2,000 calorie diet.

## **Saturated and Trans Fats**

**We recommend that FDA retain the current requirement that “healthy” foods be low in saturated fat.**

The *Dietary Guidelines* recommends limiting saturated fat intake to less than 10 percent of calories per day.<sup>28</sup> The 2015 *Dietary Guidelines Advisory Committee* found strong and consistent evidence that replacing saturated fat with polyunsaturated fat reduces the risk of cardiovascular disease and related mortality. While the evidence for replacement with monounsaturated fats is limited, the Committee noted that research has demonstrated benefits of plant sources of monounsaturated fats, such as olive

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<sup>18</sup> Te Morenga L, Mallard S, Mann J. Dietary sugars and body weight: systematic review and meta-analyses of randomised controlled trials and cohort studies. *BMJ*. 2013;346:e7492. DOI: 10.1136/bmj.e7492

<sup>19</sup> Te Morenga LA, Howatson AJ, Jones RM, Mann J. Dietary sugars and cardiometabolic risk: systematic review and meta-analyses of randomized controlled trials of the effects on blood pressure and lipids. *American Journal of Clinical Nutrition*. 2014;100(1):65-79. DOI: 10.3945/ajcn.113.081521

<sup>20</sup> HHS and USDA, 2015.

<sup>21</sup> HHS and USDA, 2015.

<sup>22</sup> Kushi, 2012.

<sup>23</sup> 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.

<sup>24</sup> World Health Organization. Sugars Intake for Adults and Children: Guideline. 2015. Available at [http://www.who.int/nutrition/publications/guidelines/sugars\\_intake/en/](http://www.who.int/nutrition/publications/guidelines/sugars_intake/en/). Accessed April 17, 2017.

<sup>25</sup> HHS and USDA, 2015.

<sup>26</sup> World Health Organization, 2015.

<sup>27</sup> Johnson, 2009.

<sup>28</sup> HHS and USDA, 2015

oil and nuts, on cardiovascular risk.”<sup>29</sup> Thus, the FDA should retain the saturated fat limit to encourage people to substitute unsaturated, 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.

**Given that some nutrient-dense vegetables, such as avocados, and protein foods, such as certain fish and nuts, have levels of saturated fat that exceed the saturated fat limits, we recommend providing an exemption from the saturated fat criterion for vegetables (including non-tropical vegetable oils), nuts, seeds, fish, and seafood without added fats.** These foods may exceed the saturated fat limits because they have a large amount of total fat, although their fat profile is predominantly unsaturated. The consumption of these foods is consistent with a healthy eating pattern, so they should be allowed to be labeled “healthy” if the remainder of the “healthy” criteria is met.

**We recommend adding to the criteria for “healthy” a limit of 0 grams for *trans* fats.** The *Dietary Guidelines* recommends reducing intake of *trans* fats to as low as possible by limiting foods that contain synthetic sources of *trans* fats, such as partially hydrogenated oils in margarines, and by limiting other solid fats. The *Dietary Guidelines* also recommends limiting natural *trans* fats present in meats and dairy products by consuming fat-free or low-fat dairy products and lean meats and poultry.<sup>30</sup> In addition, based on a review of the scientific evidence, in 2015 FDA concluded that partially hydrogenated oils, the main source of artificial *trans* fats, is no longer “generally recognized as safe” (GRAS) for use in the food supply.<sup>31</sup> Consistent with FDA’s determination and the *Dietary Guidelines* recommendations, we do not support the use of the term “healthy” on products that contain *trans* fats.

### **Total Fat**

**We recommend eliminating the limit on total fat because research shows that the type of fat consumed is more important than the total amount of fat.**<sup>32, 33</sup> In addition, the *Dietary Guidelines* no longer includes a limit on total fat, but instead recommends shifting intake from solid fats, which are high in saturated fats, to oils, predominantly comprised of unsaturated fats.<sup>34</sup> While FDA is completing its rulemaking on “healthy”, we support the agency continuing to exercise enforcement discretion that “healthy” foods do not need to be low in total fat, provided that the product contains primarily unsaturated fats. FDA should clarify that the current enforcement discretion regarding the fat requirement only applies to total fat, and the saturated fat limits should still be met.

### **Sodium**

It is important that the “healthy” criteria retain a limit on sodium, and FDA should consider strengthening the limits on sodium consistent with current science. Sodium intake currently far exceeds recommendations, with adult men consuming an average of 4,240 mg and adult women an average of 2,980 mg of sodium per day, compared with the recommended limit of 2,300 mg per day for the general

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<sup>29</sup> USDA and HHS. Scientific Report of the 2015 Dietary Guidelines Advisory Committee. February 2015. Available at <https://health.gov/dietaryguidelines/2015-scientific-report/PDFs/Scientific-Report-of-the-2015-Dietary-Guidelines-Advisory-Committee.pdf>. Accessed April 18, 2017.

<sup>30</sup> HHS and USDA, 2015.

<sup>31</sup> FDA. News Release: The FDA Takes Step to Remove Artificial Trans Fats in Processed Foods. June 16, 2015. Available at <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm451237.htm>. Accessed April 17, 2017.

<sup>32</sup> Hu FB, Stampfer MJ, Manson JE, et al. Dietary Fat Intake and the Risk of Coronary Heart Disease in Women. *N Engl J Med* 1997;337:1491-9.

<sup>33</sup> Estruch R, Ros E, Salas-Salvado J, et al. Primary Prevention of Cardiovascular Disease with a Mediterranean Diet. *N Engl J Med* 2013; 368(14): 1279-1290.

<sup>34</sup> HHS and USDA, 2015.

population and 1,500 mg per day for certain sensitive groups.<sup>35</sup> FDA should consider current dietary recommendations and FDA’s draft long-term Voluntary Sodium Reduction Goals,<sup>36</sup> in establishing an updated sodium limit for the “healthy” criteria.

### ***Cholesterol***

We also recommend retaining limits on cholesterol in the “healthy” definition, consistent with current science. While the *Dietary Guidelines* does not include a quantitative limit for dietary cholesterol, it recommends eating “as little cholesterol as possible while consuming a healthy eating pattern”. Our recommendation is also consistent with FDA’s recent decision that cholesterol content and percent daily value must continue to be reported on the updated Nutrition Facts label.

### **Foods and Beverages that Should Not Be Labeled “Healthy”**

**There are certain categories of foods that should not be labeled “healthy,” even if they meet both the food-based and nutrient-based criteria. These include red meats, processed meats (including processed poultry products), and sugar-sweetened beverages.** We recommend that these foods and beverages not be labeled “healthy” because their consumption directly increases the risk for cancer or for obesity, a risk factor for many types of cancer.

#### ***Red Meats and Processed Meats***

American Cancer Society guidelines recommend limiting consumption of processed meats and red meats. There is convincing evidence that diets high in red meat (e.g., beef, pork, lamb) and processed meat (e.g., hot dogs, bacon, sausage, deli meats, etc.) are associated with increased risk of colorectal cancer, according to the World Cancer Research Fund and the American Institute for Cancer Research, whose Continuous Update Project is the world’s most comprehensive resource of scientific literature on food, nutrition, physical activity, and cancer.<sup>37, 38</sup> In addition, the International Agency for Research on Cancer (IARC) has concluded that processed meat is carcinogenic to humans (Group 1), based on sufficient evidence that its consumption causes colorectal cancer.<sup>39</sup> IARC also concluded that red meat is probably carcinogenic to humans (Group 2A).<sup>40</sup> Given this research, the American Cancer Society recommends choosing healthier protein sources in place of red meats and processed meats, including lean poultry, fish and seafood, nuts and legumes, and other plant-based proteins (e.g., soy). The term “healthy” could be used to guide consumers towards protein sources that are healthier alternatives to red meats and processed meats.

#### ***Sugar-Sweetened Beverages***

American Cancer Society guidelines recommend reducing consumption of sugar-sweetened beverages (including sodas, fruit drinks, sports drinks, energy drinks, sweet teas, and any other non-alcoholic

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<sup>35</sup> HHS and USDA, 2015.

<sup>36</sup> FDA. Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods: Guidance for Industry. Draft Guidance. June 2016. Available at: <https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM503798.pdf>.

<sup>37</sup> World Cancer Research Fund (WCRF) and American Institute for Cancer Research (AICR). *Food, Nutrition, and the Prevention of Cancer: A Global Perspective*. Washington, DC: AICR, 2007.

<sup>38</sup> WCRF and AICR. *Colorectal Cancer 2011 Continuous Update Project Report*. 2011. Available at [http://www.dietandcancerreport.org/cancer\\_resource\\_center/downloads/cu/Colorectal-Cancer-2011-Report.pdf](http://www.dietandcancerreport.org/cancer_resource_center/downloads/cu/Colorectal-Cancer-2011-Report.pdf).

<sup>39</sup> Bouvard V, Loomis D, Guyton KZ, et al, on behalf of the International Agency for Research on Cancer Monograph Working Group. Carcinogenicity of consumption of red and processed meat. *The Lancet Oncology* 2015; 16(16): 1599-1600.

<sup>40</sup> Ibid.



beverage with added caloric sweeteners), the leading source of added sugar and one of the leading sources of calories in Americans' diets. In fact, 39 percent of all added sugars come from sugar-sweetened beverages.<sup>41</sup> Added sugars increase the risk for obesity and reduce dietary quality by adding calories to the diet without any nutrients. Several studies have found that both children and adults who drink more sugar-sweetened beverages gain more weight.<sup>42, 43</sup> One reason why sugar-sweetened beverages contribute to weight gain is that when calories are consumed as beverages, it does not make people feel full the way eating food does.<sup>44</sup>

While we recommend that all foods and beverages using the term “healthy” meet added sugar limits, as noted previously, because sugar-sweetened beverages supply added sugar without any nutritional benefits, they should not be allowed to use the term “healthy.”

### **Beverages Exempt from the Food- and Nutrient-Based Criteria**

**We recommend that water, with or without carbonation, and with or without natural flavoring, be exempt from both the food- and nutrient-based criteria and allowed to use the term “healthy”.** This exemption should not apply to sugar-sweetened beverages or beverages with non-nutritive sweeteners, including aspartame, acesulfame-K, saccharin, sucralose, and stevia. While non-nutritive sweeteners appear to be safe,<sup>45</sup> we do not recommend labeling “diet” beverages as “healthy” because consumption of these beverages does not provide health benefits.

### **Implied Healthy Claims**

Relatively few foods in the marketplace currently make “healthy” claims because companies can instead use largely unregulated claims—such as “smart,” “fit,” “good for you,” “wholesome,” “nutritious,” or “nourishing” – on products that may or may not meet the “healthy” criteria. Use of these and other similar terms on products that do not meet the requirements for “healthy” may mislead consumers. **We strongly recommend that FDA conduct research on the use by industry of terms that may be considered alternatives to “healthy”, consumer understanding of such terms, and their impact on consumer behavior. Following the publication of this research, to the extent allowed by law, FDA should extend the requirements for use of the term “healthy” to other terms that consumers understand to mean “healthy”.** Use of other terms that consumers understand to mean “healthy” should be considered implied “healthy” claims and subject to the same requirements.

### **Improving Consumer Understanding and Access to “Healthy” Foods**

The use of the term “healthy” on food packages provides an opportunity to educate consumers about which foods and beverages are healthy, and help them identify and make healthy choices. American

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<sup>41</sup> U.S. Department of Health and Human Services and U.S. Department of Agriculture. Figure 2-9: Average Intakes of Added Sugars as a Percent of Calories per Day by Age-Sex Group, in Comparison to the Dietary Guidelines Maximum Limit of Less Than 10 Percent of Calories. *Dietary Guidelines for Americans, 2015-2010*. Available at <http://health.gov/dietaryguidelines/2015/guidelines/chapter-2/a-closer-look-at-current-intakes-and-recommended-shifts/>. Accessed July 17, 2016.

<sup>42</sup> Mozaffarian D, Hao T, Rimm EB, Willett WC, Hu FB. Changes in diet and lifestyle and long-term weight gain in women and men. *N Engl J Med*. 2011;364:2392-404.

<sup>43</sup> Malik VS, Pan A, Willett WC, and Hu FB. Sugar-sweetened beverages and weight gain in children and adults: a systematic review and meta-analysis. *Am J Clin Nutr*. 2013 Oct; 98(4): 1084–1102.

<sup>44</sup> Pan A, Hu FB. Effects of carbohydrates on satiety: differences between liquid and solid food. *Curr Opin Clin Nutr Metab Care*. 2011;14:385-90.

<sup>45</sup> Academy of Nutrition and Dietetics. Position of the Academy of Nutrition and Dietetics: Use of Nutritive and Non-Nutritive Sweeteners. *J Acad Nutr Diet*. 2012;112:739-758.

Cancer Society research has found that consumers face informational and environmental challenges in eating a healthy diet and engaging in a lifestyle that will reduce their long-term cancer risk. In December 2015 and January 2017, the American Cancer Society conducted online focus groups on the relationship between nutrition, physical activity, and cancer and how factors in people’s schools, workplaces, homes, and communities influence their diet and physical activity-related behaviors. Focus groups were conducted with individuals of varying ages, race/ethnicities, weight categories, and cancer survivor status. As part of this research, participants were asked what the word “healthy” means to them, what they do to promote good health and reduce cancer risk or recurrence and/or manage their symptoms, and how much they feel they can affect change related to these factors in their communities.

An important finding from this research is that consumers define healthy in different ways, and sometimes in ways not consistent with evidence-based recommendations. Cancer survivors are often motivated by their cancer to improve their lifestyle, even years after diagnosis, but often lack the knowledge and resources that they need to eat a healthy diet. In addition, many cancer survivors face challenges in accessing and preparing healthy meals because of fatigue, management of their cancer or other chronic conditions, or a busy lifestyle.

Requiring that foods and beverages labeled “healthy” meet a consistent, science-based definition could help to increase consumer understanding and reduce confusion regarding which foods and beverages are truly health-promoting. FDA should ensure that updated requirements for use of the term “healthy” help to reduce consumer confusion regarding which foods and beverages are truly healthy. **In addition, FDA should encourage the food and beverage industry to use the term “healthy” on products that meet the definition and increase the number of new or reformulated “healthy” products.** FDA should offer training, technical assistance, or guidance to the industry, as needed, to help achieve these goals.

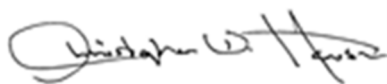
## Conclusion

In summary, we commend FDA for initiating the regulatory process to update the requirements for use of the term “healthy” on food labels to be consistent with current science and dietary recommendations. We strongly recommend requiring that “healthy” foods and beverages meet both food-based and nutrient-based criteria, as outlined in our comment letter. We believe that once the requirements for “healthy” are updated to be consistent with current science, if used in the marketplace, the term “healthy” could be beneficial in helping consumers select foods and beverages important for long-term health, including reduced cancer risk.

If you have any questions or we can provide any additional information, please contact Melissa Maitin-Shepard, MPP, Senior Analyst, Policy Analysis and Legislative Support, at [Melissa.maitin-shepard@cancer.org](mailto:Melissa.maitin-shepard@cancer.org) or 202-585-3205.

Thank you very much for your consideration of our comments and recommendations.

Sincerely,



Christopher W. Hansen  
President  
American Cancer Society Cancer Action Network