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

Re: Use of the Term "Healthy" in the Labeling of Human Food Products Docket No. FDA-2016-D-2335

The Environmental Working Group, a leading nonprofit advocate for healthier products and transparency in the food industry, submits these comments in response to the Food and Drug Administration's request for input on updating its guidance on the use of "healthy" claims on packaged foods. Given the advances in nutrition research since 1994, when the FDA first proposed the framework for "healthy" labeling, a science-based revision is urgently needed.

EWG's recommendations are based on our extensive experience with EWG's Food Scores database, which serves to educate consumers about food ingredients and aims to shift the market toward healthier products. Featuring more than 80,000 products, this database rates foods based on nutrition, the presence of potentially harmful additives, and food processing. Information in the database supported EWG's recent research on the excessive amount of sugar in children's cereals and our report on the prevalence of hidden trans fat in items Americans eat every day.

For the use of the term "healthy" in food labeling, EWG believes that:

1) By definition, "healthy" is a health claim and should be regulated as such. FDA should require the same strength of evidence basis for use of the "healthy" term as the agency uses for other regulated health claims.

2) Foods with the "healthy" claim must comply with limits for nutrients known to have adverse effects when consumed in excess, such as saturated fat, sodium and added sugar. Additionally, no ingredients containing trans fat should be present.

3) "Healthy" foods should not contain any added ingredients that a public health agency, such as the National Toxicology Program, has linked to cancer, endocrine disruption or another adverse health effect.

Below, EWG provides additional details supporting our top-line recommendations and responds to the individual questions raised by FDA in the request for comments.



FDA Question: Is the term "healthy" most appropriately categorized as a claim based only on nutrient content?

EWG rejects the premise that the term "healthy" can be categorized exclusively as a nutrient content claim. The general public understands "healthy" to be "beneficial to one's physical, mental, or emotional state; conducive to health."¹ Foods with an approved "healthy" label must have solid scientific evidence to support the fact they provide a benefit to physical health and promote a healthy diet.

The most recent dietary guidelines emphasize the importance of a healthy dietary pattern rather than pointing out foods with specific nutrient profiles. According to the 2015-2020 Dietary Guidelines for Americans:

"An eating pattern is more than the sum of its parts ... dietary components act synergistically in relation to health ... the eating pattern may be more predictive of overall health status and disease risk than individual foods or nutrients."²

The guidelines describe a healthy diet as a varied diet that contains a variety of nutrientdense foods across and within all food groups.³ A framework built around uniform nutrient criteria will always fail to encompass this wide variety of beneficial foods, as seen with the current designation of "healthy," which illogically excludes nuts, fish and avocados.⁴

Instead, EWG urges FDA to define the claim "healthy" not as a nutrient content claim with a specific set of nutrient criteria, but as it does for other health claims.

According to FDA's 2005 position on health claims in food labeling, "health claims characterize a relationship between a substance (a specific food component or a specific food) and a disease or health-related condition, and are supported by scientific evidence. All health claims must undergo review by FDA through a petition process."⁵

Health claims, with their requirement for a supporting base of evidence, provide an example of strong safeguards that assure a high level of confidence, are not false or misleading to consumers, and as such adequately protect public health. FDA allows two ways foods may meet the criteria to use authorized health claims.⁶ One is based on an authoritative statement by federal scientific bodies and the other requires meeting FDA's standard for "significant scientific agreement."⁷

As market studies show, the use of nutrition and other claims that, in effect, imply healthy claims can be misleading and confusing to consumers.⁸ EWG urges FDA to



provide clarity in the marketplace by classifying "healthy" and other implied healthy claims as a health claim.

By definition, "healthy" is a health claim and should be regulated as such. FDA should require the same strong evidence base for use of the term as the agency currently does for other regulated health claims.

FDA Question: What other criteria (e.g., inclusion of foods from specific food categories) would be appropriate to consider in defining the term "healthy" for use in food labeling?

The term "healthy" should be limited for use on those foods where significant scientific agreement or authoritative statements by federal scientific bodies support that those foods promote health and can be a part of a healthy eating pattern.

EWG believes FDA should use a combination of food-based criteria and nutrient criteria to define "healthy" in a way that comports with contemporary nutrition research. EWG urges FDA to allow the label "healthy" only on products that contain a significant amount of food ingredients, such as 80 percent by weight, that would meet the level of evidence required for a health claim to be considered part of a healthy eating pattern.

EWG points to two successful examples of FDA-approved health claims that can serve as a model framework for setting criteria as the agency redefines "healthy."

- The health claim for "whole grain foods with moderate fat content and risk of heart disease" uses a combination of a food-based criteria by requiring a minimum of 51 percent whole grains together with nutrient criteria set for certain nutrients to limit such as saturated fat, cholesterol, total fat, and trans fat.⁹
- The health claim for "fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease," uses a combination of food-based criteria by applying to a fruit, vegetable or grain product in combination with nutrient criteria that limit saturated fat, cholesterol, total fat, and require a minimum amount of soluble fiber so as to qualify for using the claim.¹⁰

EWG emphasizes to FDA that a "healthy" claim should incorporate food-based criteria that comport with a healthy eating pattern as defined in the 2015-2020 Dietary Guidelines such as:

- A variety of vegetables—dark green vegetables, red and orange vegetables, legumes (beans and peas), and other types of vegetables.
- Fruits, especially whole fruits.
- Whole intact grains.



• A variety of protein foods, including seafood low in mercury, lean poultry, eggs, legumes (beans and peas), and nuts and seeds.

The dietary guidelines include lean meats as part of a healthy eating pattern. However, red and processed meats are believed to cause cancer and heart disease, and their production is bad for the environment.^{11,12} Red and processed meats and seafood high in mercury should not be allowed as ingredients in foods with a "healthy" claim.

When consumers seek out "healthy," they are looking for foods that nourish their bodies and also are not known to cause adverse effects. "Healthy" foods should not contain any added ingredients that a public health agency, such as NTP has linked to cancer, endocrine disruption or another adverse health effect.

To illustrate this recommendation, EWG urges FDA to prohibit foods containing the preservatives nitrate and nitrite, as well as chemicals such as potassium bromide and BHA, to be added as ingredients in foods with a "healthy" claim.

The World Health Organization has declared nitrites and nitrates as probable human carcinogens.¹³ In a 2015 survey of the market using the Food Scores database, EWG found potassium bromate in at least 86 supermarket foods,¹⁴ despite the fact that it is listed by the state of California as a known carcinogen¹⁵ and has no necessary use. Additional examples of problematic additives are listed in EWG's Dirty Dozen Guide to Food Additives.¹⁶ Such harmful additives have no place in foods bearing the label claim "healthy."

FDA Question: 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?

FDA should take advantage of research by public health agencies from trading partner countries such as the United Kingdom. For example, a nutrient profiling system has been effectively used in the U.K. to set a bar for limiting the advertising of unhealthful foods to children.^{17,18} This model counterbalances negative factors such as calories, saturated fat, sugar and sodium content, and awards points for positive factors such as protein, fiber and minimally processed fruit, vegetable or nut content.

EWG recommends that FDA establish a list of qualifying food ingredients similar to the U.K. model.¹⁹ This list should contain ingredients covered under authoritative statements by federal scientific bodies or that FDA has determined as meeting the "significant scientific agreement" standard for promoting health.



"Healthy" foods should primarily be composed of one of these foods or a combination of foods that meet this standard, and should make up greater than 80 percent of the product by weight. FDA enforcement could be accomplished through the use of quantitative ingredient declarations, which many multinational food companies already use both in the U.S. and elsewhere.

FDA Question: What types of food, if any, should be allowed to bear the term "healthy?" Should all food categories be subject to the same criteria? Please provide details of your reasoning.

EWG urges FDA to limit the use of the term "healthy" to food products where authoritative statements by federal scientific bodies or "significant scientific agreement" exists to support that the main ingredients in those foods promote health and are part of a healthy eating pattern.

FDA Question: What other words or terms might be more appropriate (e.g., "nutritious")?

The challenge of using additional terms such as "nutritious" is ensuring that consumers interpret these terms in the way that public health agencies and the Dietary Guidelines interpret them. EWG urges FDA to establish a strong scientific basis for the use of the "healthy" term so it becomes meaningful and helpful to shoppers.

FDA should not allow "healthy" to be used as broadly and nonspecifically as the term "natural" is currently used. Without a strong underlying regulation, a "healthy" claim might have little to no meaning or benefit. Even worse, the inappropriate use of "healthy" claims, with or without the direct use of the word "healthy," can mislead consumers about the true healthfulness of the product. To prevent this, FDA must rein in the use of these implied "healthy" claims on products that do not meet the criteria for use of the term "healthy." Currently, misleading "healthy" claims are already commonly made in the marketplace without the use of the word "healthy."

For example, a 2017 study found that nearly 15 percent of foods and 35 percent of beverages studied use a "low-content" claim.²⁰ Marketing research finds that shoppers tend to generalize a product's healthfulness based on nutrient content claims²¹ and "perceive foods and beverages labeled with nutrient and health claims as 'healthier' than foods without such claims,"²² indicating that these claims imply healthiness for a large portion of consumers. A recent review noted that "consumers are misled by such claims



to underestimate total calorie content in the product and overestimate a product's overall positive attributes. [Packaging] claims can create a 'health halo' around the product."^{23,24} In a 2012 report, the Institute of Medicine found that most American shoppers are susceptible to the influence of nutrition-related claims.²⁵ And a 2010 publication found that nearly half of shoppers who participated in the study considered a food carrying a "97 percent fat free" claim on the package as "definitely a healthy food."²⁶

In our 2014 market survey of cereals, EWG found evidence that promotional labeling on cereal boxes can distract consumers from focusing on the unhealthy sugar content. Such marketing materials can include claims that a product provides important nutrients, for example calling a product an "Excellent Source of Vitamin D" or "Good Source of Fiber." The labels on seven of the 10 most heavily sugared children's cereals in EWG's 2011 cereal report featured a marketing claim promoting their nutrient content.²⁷

To address this situation, keep the term "healthy" meaningful, and protect consumers, FDA must tighten the regulations surrounding all nutrient content claims, because this is where the most misleading claims are made. FDA needs to stand strong to protect consumers from potentially misleading information and inappropriate or implied "healthy" claims, which in practice also includes nutrient content claims.

FDA Question: 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?

Foods with the "healthy" claim must comply with limits for nutrients known to have adverse effects when consumed in excess, such as saturated fat, sodium and added sugar. Additionally, no trans fat-containing ingredients should be present.

Sodium

Reasonable limits on sodium must be continued and further strengthened in the criteria for healthy food. FDA must change its practice of allowing too much sodium in packaged food, especially for foods that carry a "healthy" label. According to the Institute of Medicine, "no segment of the population is immune from the adverse health effects [of sodium], despite the common misunderstanding that sodium intake is a concern only for the 'salt sensitive' and the elderly."²⁸

In 2010, the Institute of Medicine advised FDA to revise the Daily Value for sodium to the Adequate Intake of 1,500 mg, based on a 2,000 calorie diet.²⁹ So far, FDA has failed to implement this advice. FDA must further strengthen the sodium limits for foods with a



"healthy" claim based not on the Tolerable Upper Intake Level, but instead on the Institute of Medicine's recommendation to use the Adequate Intake for sodium.

Added sugars

American adults ingest an average of 152 pounds of sugar a year, contributing to the nation's ongoing obesity epidemic³⁰ and far exceeding the limit recommended by the Dietary Guidelines for Americans.³¹ According to EWG's analysis of the market in 2014, a child eating a bowl of the average kids' cereal a day for a year would consume 10 pounds of sugar from that source alone,³² and five more pounds of sugar a year than their parents might believe, due to outdated serving sizes on labels.³³ FDA must establish a limit on added sugars in foods that carry a "healthy" label.

Saturated and trans fat ingredients

Reasonable limits on saturated fat should continue, as the damage to the heart and other body systems caused by excessive intake is well established by extensive research. Although, if otherwise healthy foods, such as walnuts with 2 grams of saturated fat per RACC,³⁴ continue to be excluded, the agency should consider other approaches. Further, since 2002 the Institute of Medicine has stated that there is no safe level of trans fat in food.³⁵ In 2015, FDA removed the "Generally Recognized As Safe" classification for partially hydrogenated oils.³⁶ Yet, they remain in products in the marketplace. In a 2015 survey of the market using the Food Scores database, EWG found that trans fat hides in at least a quarter of supermarket food and many kids' foods, including products such as Froot Loops with Fruity Shaped Marshmallows, which currently meet the regulatory definition of "healthy."³⁷ EWG believes that partially hydrogenated vegetable oils and other trans-fat ingredients have no place in foods with the "healthy" claim.

FDA Question: Should nutrients for which intake is encouraged continue to be included?

EWG strongly disagrees with the position that the definition of "healthy" should include "nutrients to encourage." Under FDA's current guidelines, products such as Sunny D, Essential Everyday Chocolate Pudding Snacks, and Duncan Hines Signature Angel Food Cake Mix—a product that is 61 percent sugar by weight—qualify for a "healthy" claim due to the added nutrients that FDA considers "nutrients to encourage."

This practice must stop, because it skews shoppers' understanding of the healthiness of the products and contributes to consumption of products that contain excessive amounts of problematic ingredients.



FDA Question: 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?

EWG's position is that the "nutrients to encourage" *should not be included* in the definition of "healthy." But if "nutrients to encourage" remained a part of the definition, these nutrients should be intrinsic to the foods.

EWG's 2014 report, "How Much Is Too Much? Excess Vitamins and Minerals in Food Can Harm Kids' Health," found 114 cereals fortified with 30 percent or more of the adult Daily Value and 27 snack bars fortified with 50 percent or more of the adult Daily Value for vitamin A, zinc and/or niacin. Excessive amounts of nutrients, in particular high doses of vitamin A, can cause short or long-term health problems. Because the current dietary Daily Values for most vitamins and minerals correspond to adults' dietary needs, some over-fortified foods can contain levels of added nutrients that may be unsafe for children. Therefore, EWG urges FDA to prohibit the use of the "healthy" claim on foods whose claim to healthiness comes exclusively from fortified vitamins and minerals. Instead, the "healthy" claim should apply to nutrients that are intrinsic to foods.

Conclusion

EWG encourages FDA to establish criteria for the use of the term "healthy" that will comply with the evidence-based approach the agency requires for other health claims. Foods full of empty calories and a few fortified vitamins should not carry a "healthy" label, direct or implied, that may mislead shoppers into buying a product that does not provide balanced nutrition.

Sincerely.

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¹ www.merriam-

webster.com/dictionary/healthy?utm_campaign=sd&utm_medium=serp&utm_source=jsonId

² health.gov/dietaryguidelines/2015/guidelines/chapter-1/

³ health.gov/dietaryguidelines/2015/guidelines/executive-summary/#the-guidelines



⁴ health.gov/dietaryguidelines/2015/guidelines/executive-summary/#key-recs

⁵ www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm207974.htm

⁶www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/u cm064919.htm

⁷ 21 U.S.C. § 343(r)(3).

⁸ Jennifer L. Pomeranz, A Comprehensive Strategy to Overhaul FDA Authority for Misleading Food Labels. American Journal of Law & Medicine, 2013, 39: 617-647.

⁹ www.fda.gov/food/ingredientspackaginglabeling/labelingnutrition/ucm073634.htm ¹⁰ www.ecfr.gov/cgi-

bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21. 2.101&r=PART#se21.2.101_177

¹¹ Veronique Bouvard et al., Carcinogenicity of Consumption of Red and Processed Meat. The Lancet Oncology, 2015, 16(16):1599-1600.

¹² Climate and Environmental Impacts. www.ewg.org/meateatersguide/a-meat-eaters-guide-to-climate-change-health-what-you-eat-matters/climate-and-environmental-impacts/

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¹⁸ Peter Scarborough et al., Testing Nutrient Profile Models Using Data from a Survey of Nutrition Professionals. Public Health Nutrition, 2007, 10(4):337-45.

¹⁹ Peter Scarborough et al., Application of the Nutrient Profiling Model: Definition of 'Fruit, Vegetables and Nuts' and Guidance on Quantifying the Fruit, Vegetable and Nut Content of a Processed Product. 2005. Available at www.food.gov.uk/sites/default/files/multimedia/pdfs/nutprofpguide.pdf [Accessed April 24, 2017].

²⁰ Lindsey Smith Taillie et al., No Fat, No Sugar, No Salt . . . No Problem? Prevalence of "Low-Content" Nutrient Claims and Their Associations with the Nutritional Profile of Food and Beverage Purchases in the United States. Journal of the Academy of Nutrition and Dietetics, 2017, 1-15.

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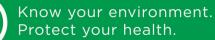
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