



April 17, 2017

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

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

Dear Sir or Madam:

The American Society for Nutrition (ASN) appreciates the opportunity to comment on “Use of the Term “Healthy” in the Labeling of Human Food Products.” ASN brings together the world's top researchers to advance the knowledge and application of nutrition. ASN has more than 6,500 members working in academia, public health, clinical practice, industry, and government who conduct research to help all individuals live healthier lives.

**ASN Responses to Select Questions, Bold and Italicized Below, Relating to Use of the Term “Healthy” in the Labeling of Human Food Products**

***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? We are especially interested in any data or other information that evaluates whether or not consumers associate, confuse, or compare the term “healthy” with other descriptive terms and claims.***

According to the International Food Information Council (IFIC) Foundation 2016 Food and Health Survey<sup>1</sup>, 35% of consumers define a healthy food as one that doesn't contain (or has low levels of) certain components. For the open-ended response question, consumers also included ambiguous terms such as natural, fresh, no artificial ingredients or additives, nutritious, organic, and unprocessed to characterize “healthy”. These responses indicate that consumers may not understand how FDA currently defines the term “healthy”. Furthermore, based on consumers' responses to this survey, the current use of the term “healthy” may be somewhat false or misleading for consumers when used on food products. Based on the IFIC Foundation survey information, consumers appear to associate, confuse, or compare the term “healthy” with other descriptive terms and claims. Due to current misunderstanding and potential misuse of the term “healthy”, ASN suggests that any determination regarding use of

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<sup>1</sup> International Food Information Council (IFIC) Foundation. (October 2016). 2016 Food and Health Survey Executive Summary. Accessed April 4, 2017 from:

[http://www.foodinsight.org/sites/default/files/2016\\_executivesummary\\_final\\_web.pdf](http://www.foodinsight.org/sites/default/files/2016_executivesummary_final_web.pdf)

the term “healthy” needs to be thoroughly informed by consumer studies that determine consumer understanding and translation of the term “healthy”.

Given potential consumer confusion regarding use of the term “healthy”, ASN supports FDA’s efforts to reevaluate use of the term “healthy” in the labeling of human food products to ensure that use of the term is helpful to consumers when selecting food products to create a healthy overall eating pattern and that use of the term is indeed aligned with all current, evidence-based dietary recommendations. As the 2015-2020 Dietary Guidelines for Americans<sup>2</sup> emphasize, consumers do not eat foods and nutrients in isolation, but in an overall eating pattern.

***Is the term “healthy” most appropriately categorized as a claim based only on nutrient content? If not, 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?***

Given such dietary guidance, use of the term “healthy” may not be most appropriately categorized based only on nutrient content. Use of the term “healthy” may be better applied to define the characteristics of a food that would allow that food to be part of a healthy/healthful dietary pattern vs. applying that term to describe a food itself. The 2015 Dietary Guidelines note that a healthy eating pattern limits saturated fats, *trans* fats, added sugars, and sodium, but also includes a wide variety of vegetables, fruits, whole grains, fat-free and low-fat dairy, oils and protein foods. It will likely be a challenge for FDA to consider compliance with use of the term “healthy” given all the components within an individual’s diet that the Guidelines note contribute to an overall healthy eating pattern.

ASN points out the Codex Alimentarius Guidelines for use in Nutrition and Health Claims which allows claims related to healthy diets under certain conditions, including that claims are considered to be claims about the pattern of eating outlined in the dietary guidelines and must be consistent with the guidelines officially recognized by the appropriate national authority and that a food should not be described as healthy or represented in a manner that implies the food in and of itself will impart health<sup>3</sup>.

***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 (e.g.,***

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<sup>2</sup> U.S. Department of Health and Human Services and U.S. Department of Agriculture. (December 2015). *2015–2020 Dietary Guidelines for Americans*. 8th Edition. Accessed April 4, 2017 from:

<http://health.gov/dietaryguidelines/2015/guidelines/>

<sup>3</sup> Codex Alimentarius Commission. (1997). Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997). Accessed April 4, 2017 from:

[http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=3&ved=0ahUKEwjAgtPhgonTAhVL3WMKHYLWCYoQFggiMAI&url=http%3A%2F%2Fwww.fao.org%2Finput%2Fdownload%2Fstandards%2F351%2FCXG\\_023e.pdf&usg=AFQjCNFv3VAK5RzDp8vvbKfi5oByPIITzQ&bvm=bv.151325232,d.eWE](http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=3&ved=0ahUKEwjAgtPhgonTAhVL3WMKHYLWCYoQFggiMAI&url=http%3A%2F%2Fwww.fao.org%2Finput%2Fdownload%2Fstandards%2F351%2FCXG_023e.pdf&usg=AFQjCNFv3VAK5RzDp8vvbKfi5oByPIITzQ&bvm=bv.151325232,d.eWE)

***“nutritious”)? We encourage submission of any studies or data related to descriptors used to communicate the overall healthfulness of a food product.***

While terms such as nutrient dense or nutrient-rich may provide a better sense of the combination of nutrients needed in an overall diet to provide healthfulness, these terms still do not capture all the components within an individual’s diet that the Guidelines note contribute to an overall healthy eating pattern. Again, it would be challenging for FDA to determine compliance with these additional descriptors. Furthermore, these descriptors must be better defined and consumer research would be needed to determine if consumers understand better the use of these terms vs. “healthy” on human food product labels. There are a number of factors that would need to be considered if FDA were to use the terms nutrient dense, nutrient-rich, etc. including: What definition of nutrient dense or nutrient-rich is appropriate? What is the role of fortification in these definitions? Would the definition still require restrictions on nutrients to limit? ASN encourages FDA to examine use of other terms/descriptors on human food product labels to imply that product provides a meaningful amount of a food group or nutrients that are necessary as part of an overall healthful diet.

ASN questions whether use of such a term as “healthy” is appropriate and beneficial for food labeling purposes given the challenges with finding the best term to characterize foods that should be encouraged to build healthy/healthful dietary practices or patterns. There also appears to be a lack of evidence that there are public health benefits to defining and using the term “healthy” in food labeling, while the availability of broader evidence-based dietary guidance are currently available to help individuals develop healthy eating patterns. More nuanced terms may need to be explored if the FDA still wishes to label human food products as “healthy”.

***We invite interested persons to comment on the petitioner's requests... With regards to “healthy”, the petition requested that we:***

***Amend § 101.65(d)(2) so that the term “healthy” or related terms may be used if the food “meets the following conditions for fat, saturated fat, and cholesterol exclusive of the fat and saturated fat contributed to the food product by the following foods, provided that such foods are used in their whole form or have been processed in such a way that did not materially degrade their nutritional value: Fruits, vegetables, nuts, seeds, legumes, whole grains, and seafood; and the food meets the following conditions for other nutrients;”***

With regard to the petitioner’s request, ASN acknowledges that fruits, vegetables, nuts, seeds, legumes, whole grains, seafood, and other foods may provide meaningful amounts of nutrients that are necessary as part of an overall healthful diet. ASN supports current dietary guidance which states that saturated fat should be 10% or less of total calories, and recommends that the saturated fat, fat and cholesterol not be considered in isolation with regard to use of the term healthy. It is important to look at the total range of nutrients contributed by a food, perhaps

looking at the saturated fat to unsaturated fats ratio contributed by various foods, such as fruits, vegetables, nuts, seeds, legumes, whole grains, and seafood, when determining if a food product is part of a healthful diet and determining whether or not a product may bear the “healthy” label.

***While the rulemakings to amend § 101.65 are pending, issue a guidance document to “clarify that a statement about the usefulness of a food, or a category of foods, in maintaining healthy dietary practices is a dietary guidance statement that is not subject to the requirements in FDA’s nutrient content claim regulations unless it is an implied nutrient content claim because it is immediately adjacent to an explicit or implicit claim or statement about a nutrient”.***

Use of “Dietary Guidance” statements, as suggested by the petitioner, could be useful, although FDA must first create conditions for use of such statements and these claims should not replace nutrient content claims. “Dietary Guidance” statements could allow a claim if a food makes a meaningful contribution to the intake of a recommended food group (e.g. fruits, vegetables, whole grains, etc.). However, FDA would need to define what is a meaningful amount of a food group in a serving and set limits for nutrients to limit such as saturated fat, trans fat, sodium, added sugars, etc. so that the product is consistent with dietary guidance that makes scientific evidence-based recommendations for a healthful diet.

ASN commends the Agency’s efforts to improve consumer literacy of the food label and improve public health. Clarity in the use of the term “healthy” will help consumers make more informed food choices for themselves and their families. Thank you for your consideration of ASN’s comments. Please contact Sarah Ohlhorst, Senior Director of Advocacy and Science Policy [[sohlhorst@nutrition.org](mailto:sohlhorst@nutrition.org); 240.428.3647], if ASN may provide additional information.

Sincerely,



Marian L. Neuhouser, Ph.D., R.D.  
ASN President, 2016-2017