



FDA's Public Meeting on the Use of the Term "Healthy" in the Labeling of Human Food Products – A Summary of Key Points

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On March 9, 2017, the Food and Drug Administration (FDA or Agency) held a public meeting in Rockville, MD, which FDA officials described as a way to engage in a dialog with the public and regulated industry and allow for opportunity to ask questions on how to redefine the term "healthy." In the opening remarks, FDA noted that the food landscape has shifted from being "nutrient-focused" to more of a "food-based" focus, and that the current regulation for the use of the term "healthy" was issued in the early 1990s at a time when food science was focused on limiting total fat intake and on ensuring that consumers were able to meet certain nutritional deficiencies that were identified to be of concern at that time (e.g., Vitamins C and A).

As science has evolved, the focus has shifted from total fat reduction to encouraging consumers to eat certain types of fats and deficiencies in Vitamin D and potassium intake. With the modernization of the Nutrition Facts panel and serving size regulations to reflect more current science, FDA is seeking to, among other things, determine how to align the use of the term "healthy" with those recent changes.

The first part of the public meeting consisted of two panel discussions that focused on consumer attitudes, beliefs, and behavior and provided stakeholders with an opportunity to share their perspectives on how "healthy" should be defined. The second half of the meeting consisted of breakout sessions covering the following three topics: 1) Healthy as a nutrient-based claim; 2) Healthy as a food component-based claim; and 3) Consumer meaning and understanding of the term Healthy. The meeting ended with presentations from interested members of the public and industry.

The major takeaways from the meeting were as follows:


- There is support for FDA to redefine the definition of "healthy," but it is not clear what that definition should be.
- Most participants agreed that a definition that is both nutrient-based and food component-based may be the most appropriate.
- There are some members of the public and industry who believe that the FDA should eliminate the claim "healthy."
- Consumers are influenced by claims on food labels; however, their attitudes and perceptions vary widely and as such, the term may mean different things to different people.
- Food/Nutrition messaging should be consistent among government agencies (USDA / FDA).
- Consumers need more education with regard to what makes a product "healthy."
- FDA should consider the use of the MyPlate icon on food labels to assist consumers in making better food choices.
- The industry should play a role in helping shape the definition of "healthy."
- FDA does not have a specific timeline for deciding whether and how to redefine the term "healthy."

We provide a more detailed summary of the meeting below.

PANEL PRESENTATIONS

Consumer Attitudes, Beliefs and Behaviors Panel

This Panel explored what the term "healthy" signals to consumers and how we could use the term to help move consumers towards following better dietary guidelines. **Linda Verrill**, a Senior Scientist at the FDA, provided the public with an overview of what FDA has learned about how consumers respond to claims on food labels. Ms. Verrill noted that food labels play a very important role and that they are seen as the best tool to provide consumers with information. According to FDA's research, 77% of U.S. adults report using the Nutrition Facts label, with 79% of adults reporting using the label when buying a product for the



first time. Moreover, 9 out of 10 adults said that they review claims when deciding what food products to buy. Claims on food products affect consumers in one of three ways:

1. Truncation – Consumers “truncate” their information search. If there is a claim, consumers are more likely not to look at the nutrition facts panel.
2. Magic Bullet – Consumers attribute additional nutritional qualities to the product.
3. Health-Halo – Consumers tend to rate products higher on health qualities not mentioned in the claim.

Ms. Verrill also shared some results from a study on food claims conducted by FDA where consumers were shown two products, one with claims and one without. Overall, products with the “healthy” claim scored higher with consumers than those products without claims. In addition, products with claims were perceived as being lower in calories, sugar and saturated fats. Thus, Ms. Verrill concluded that preliminary research on “healthy” claims indicates that they may likely have an impact on consumer’s perceptions.

After Ms. Verrill’s presentation, there was some additional discussion about consumer perception amongst the other panelists with some noting that it is unclear whether consumers understand that the term “healthy” is regulated by FDA. Overall, the consensus seemed to be that consumers may have different expectations of what it means for a product to be “healthy” and that perhaps FDA can redefine the term to help consumers incorporate more foods into their diets that are more aligned with the [2015-2020 Dietary Guidelines for Americans](#).


Stakeholder Perspectives on “Healthy” Definition Panel

There were several different perspectives shared by stakeholders from the suggestion for FDA to no longer allow the use of the term healthy on food products to redefining the term “healthy,” to among other things, remove the threshold for “good” nutrients.

Lindsay Moyer, Senior Nutritionist for the Center for Science in the Public Interest. Ms. Moyer urged the FDA to redefine “healthy” to: 1) ensure that products labeled as “healthy” are made from foods that are the foundation for healthy dietary patterns (i.e., nutrient-dense foods); 2) exclude foods that contain more than a few grams of added sugars; 3) maintain limits on sodium intake; 4) eliminate the requirement for total fats or exempt foods that are high in fats, but are in other ways considered healthy (e.g., avocado, fatty fish, nuts, vegetable oils); 5) continue to require that foods be low in saturated fats with the exception of foods like salmon and sunflower seeds; 6) keep cholesterol limits; and 7) limit red and processed meats. She concluded that a product with a “healthy” label should not be marketed to compete with fruits and vegetables.

Justin Marvis, Senior Vice President & General Counsel, KIND Snacks. Mr. Marvis’ presentation also urged FDA to redefine the term “healthy” to include 4 key principles: 1) “healthy” food products should contain a meaningful amount of foods that are part of a healthy eating pattern (e.g., 2015 dietary guidelines which include vegetables, fruits, whole grains, low-fat dairy, lean protein, and certain oils); 2) the “healthy” definition does not need thresholds for “good” nutrients; 3) the “healthy” definition should include limits on nutrients to avoid if those nutrients are not intrinsic to foods that are part of a healthy eating program (e.g., saturated fats, sugar, sodium coming from sources other than health promoting foods); and 4) the “healthy” definition should exclude food products that contain low or no-calorie sweeteners or synthetic color additives.

Pepin Tuma, Senior Director, Government & Regulatory Affairs, Academy of Nutrition & Dietetics. Unlike the other two panelists, Mr. Tuma proposed that FDA no longer allow the use of the term “healthy” on food packaging. Mr. Tuma recognized that the science of nutrition has evolved in the last 24 years and that there have been significant changes to the dietary guidelines. However, he noted that due to the conflicting messages about what is “healthy” the Academy did not have an answer with regard as to how to redefine the definition to make sure that it can help consumers make better dietary choices. As such, he suggested that the definition of “healthy” be eliminated.



Kristin Reimers, Director of Nutrition, ConAgra Brands. Ms. Reimers opened her presentation giving an overview of ConAgra Brands and their line of products “Healthy Choice.” Ms. Reimers noted that “healthy” is an important brand that needs to remain on the market. Interestingly, Ms. Reimers noted that the “healthy” claims are losing ground with consumers as they are lured to other foods with claims that are not regulated. Ms. Reimers urged FDA to redefine “healthy” by merging the current nutrient-focused definition with the dietary guidelines “foods to encourage” that comprise healthy dietary patterns. Under that definition, as “foods to encourage” increase, higher levels of “nutrients to limit” would be permitted. She also suggested some parameters for redefining the term. For example, the cholesterol criteria should be removed due to the weakening connection between cholesterol and heart disease; a limit for added sugars should be included in the definition; and saturated fats from foods (avocado, nuts, salmon) should be exempted from the definition to create a path for foods with saturated fats that are part of a healthy diet.

BREAKOUT SESSIONS

The breakout sessions provided an opportunity for members of the public and industry to address specific topics. The sessions were moderated by FDA and focused in three areas: 1) Healthy as a nutrient-based claim; 2) Healthy as a food component-based claim; and 3) Consumer meaning and understanding of the term “healthy.”

Healthy as a nutrient-based claim

The following are some of the general themes that emerged during the discussion of healthy as a nutrient-based claim:

- Most participants agreed that the nutrient-based criteria should be updated.
- A combined approach that uses food groups and nutrients, rather than just nutrient-based, was favored.
- Important to still consider nutrients because not all foods/food groups are created equal. Nutrients are important information that must still be conveyed to consumers.
- Saturated fat or cholesterol should not be disqualifying nutrients if they are naturally occurring in the food.
- Alignment of food/nutrition messaging among government agencies (FDA/USDA).
- Some nutrients should be disqualified from the definition (e.g., sodium, trans fats).
- Fortification:
 - There were mixed views on whether FDA should allow fortified foods to be called “healthy.”
 - Some suggested that it should be allowed due to the current lack of vitamin D in most diets. There are regulations and policies in place that govern the issue of fortification.
 - Need to look at the totality of the product.
- Nutrient-density:
 - A good concept, but hard to implement.
 - Needs to be relative to caloric intake.

Healthy as food component-based claim

The following are some of the general themes that emerged during the discussion of healthy as a food component-based claim:

- Participants of this group also agreed that the definition of “healthy” should be updated.
- The definition of “healthy” should be consistent with the Dietary Guidelines for Americans.
- The best approach for a definition may be a combination of nutrients and foods. Application of one set of criteria may be too restrictive. One size does not fit all.
- There must be consistent messaging for consumers and education.



Consumer meaning and understanding of the term “healthy”

The following are some of the general themes that emerged during the discussion of how consumers understand the term “healthy.”

- Consumer’s perceptions of what “healthy” means vary widely.
 - Consumers have different levels of literacy, education, personal influences.
 - There is a rising importance of “absence claims” – GMOs, GF, Organic.
- Consumers vary in how much information they seek or use to decide if a product is “healthy” for them.
- Consumers may associate “healthy” with other things:
 - Less tasty
 - Higher costs
 - Broader context of healthy (i.e., healthy lifestyle)
- Healthy may be confusing or carry less meaning when crowded by other terms/claims.
- Changing the term is only a part of it – education is also key.
- Some suggested that because consumer’s understanding of the term is so varied, FDA should consider not allowing the claim on food labels. However, there were concerns that food manufacturers may use other terms to convey healthy (e.g., natural, wholesome).
- Healthy products need to contribute to a healthy dietary pattern.
 - Consider combining with the MyPlate icon (also may help with literacy issues).
- Use of “healthy” on specific foods may detract consumers from understanding what constitutes a healthy diet.

CONCLUSION AND NEXT STEPS

FDA concluded the meeting with several public statements that emphasized the same points that were raised during the presentations and breakout sessions. FDA reinstated that they will continue to accept comments on this topic until April 26, 2017 and encouraged meeting attendees to submit formal comments to the docket. Electronic comments may be submitted [here](#). To date, more than 900 comments have been submitted to the docket. After the comment period closes, FDA will carefully review all the comments in order to determine whether and how to redefine “healthy.” Mr. Balentine, Director, Office of Nutrition and Food Labeling, Center for Food Safety and Applied Nutrition (CFSAN), noted that the Agency did not have a specific timeline for when the Agency may issue some type of communication on the issue; however, he encouraged the public and industry to continue the dialog on the topic.

In the meantime, the Agency issued a guidance document in December 2016, entitled “Use of the Term “Healthy” in the Labeling of Human Foods” notifying manufacturers of the Agency’s intent to exercise enforcement discretion in relation to the use of the implied nutrient content claim “healthy” on the labels of food that:

- (1) Are not low in total fat, but have a fat profile makeup of predominantly mono and polyunsaturated fats; or
- (2) Contain at least 10 percent of the Daily Value (DV) per reference amount customarily consumed (RACC) of potassium or vitamin D.

A copy of the guidance document is available [here](#).

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