

**FDA Public Meeting:
FDA's Comprehensive, Multi-Year Nutrition Innovation Strategy
Facilitated Breakout Session:
Claims and Statements Used on Food Labels & Icon for "Healthy"**

Claims and Statements Used on Food Labels

Topic Overview: Claims and other nutrition-related labeling statements provide key information to consumers about the nutritional benefits of foods and beverages. FDA is seeking input on how claims and other nutrition-related labeling statements may facilitate innovation to produce more healthful foods and more healthful consumer food and beverage choices. In addition, FDA is interested in ideas for how to create a more efficient strategy for reviewing qualified health claim petitions.

Background: The FDA is responsible for ensuring that foods sold in the United States are safe, wholesome, and properly labeled. The Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Fair Packaging and Labeling Act are the Federal laws governing food products under FDA's jurisdiction. The Nutrition Labeling and Education Act, which amended the FD&C Act, requires most foods to bear nutrition labeling. It also allows for voluntary use of claims and other nutrition-related labeling statements on foods and beverages in accordance with regulatory requirements.

Industry and consumers have long been interested in finding easier ways to communicate about and to identify healthful foods when marketing a food or beverage product or looking at the label when shopping. Claims and other nutrition-related food labeling statements can be quick signals for consumers about what nutritional benefits a food or beverage might have, and such claims and labeling statements can also be incentives for industry to innovate and offer products with healthy attributes to gain competitive advantages in the marketplace.

There are three types of claims that are defined by the FD&C Act and/or FDA regulations and may be used on food and dietary supplement labels: health claims, nutrient content claims, and structure/function claims. Please see Attachment 1 for a description and examples of each of these types of claims, as well as other nutrition-related labeling statements that may be used on food and beverage labels.

Discussion Questions: FDA is interested in hearing from industry on how and why manufacturers choose to use, or not to use, claims (health claims, nutrient content claims, etc.) and other nutrition-related labeling statements on food packages, as well as how claims and other nutrition-related labeling statements may stimulate innovation by the food industry to formulate products with more healthful attributes. It is also interested in hearing about what types of claims and other labeling statements are most helpful to consumers.

1. What factors are considered when choosing to use or not to use claims and other nutrition-related labeling statements on food and beverage products?
2. What types of claims or other nutrition-related labeling statements are most helpful in facilitating product innovation to promote healthful eating patterns?
3. What types of claims and other labeling statements are most helpful to consumers in selecting foods consistent with the Dietary Guidelines for Americans?

4. Regarding the 2003 Interim Procedures for Qualified health claims, are the factors discussed in the guidance for prioritizing FDA's review (see Attachment 2 for prioritization criteria) of qualified health claim petitions still relevant?
 - o Are there additional factors not discussed in the 2003 guidance that FDA should consider when prioritizing its review of qualified health claim petitions?

Additional Resources:

- Label Claims for Conventional Foods and Dietary Supplements (<https://www.fda.gov/Food/LabelingNutrition/ucm111447.htm>)
- A Food Labeling Guide, revised 2013 (<https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM265446.pdf>)
- Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements (July 10, 2003), <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm053832.htm>
- FDA's Implementation of "Qualified Health Claims: Questions and Answers" (May 12, 2006), <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm053843.htm>
- Evidence-Based Review System for the Scientific Evaluation of Health Claims (January 2009), <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm073332.htm>

Icon for “Healthy”

Topic Overview: This session will discuss a standard icon or symbol for the claim “healthy” that could facilitate innovation to promote healthful eating patterns.

Background: FDA is exploring different voluntary options for manufacturers to standardize the presentation of “healthy” claims on food packages, which suggest that a food may help consumers maintain healthy dietary practices. Examples of the options include a front of package icon to communicate to consumers that a serving of a food meets the FDA definition for “healthy.”

Discussion Questions:

1. In what ways, would you propose standardizing the presentation of “healthy” to make the claim visible and effective for identifying healthy food choices, and why?
2. What recommendations do you have with respect to the use of text or images (i.e., icons) for communicating the healthy claim to consumers, and why?
3. What recommendations do you have with respect to placement or size of healthy claims or icons on food packages, and why?

Attachment 1: Types of Claims and Other Nutrition-Related Labeling Statements Summary Chart¹

Claim Type	Description	Regulatory Process	Example
Health Claims	Describe a relationship between a food substance (a food, food component, or dietary supplement ingredient), and reduced risk of a disease or health-related condition.		
<i>Authorized Health Claims</i>	FDA authorizes health claims for foods and dietary supplements that are based on an extensive review of the scientific literature using the significant scientific agreement standard to determine whether the substance/disease relationship is well established.	FDA issues a regulation authorizing health claims, typically in response to a health claim petition.	“Diets low in saturated fat, cholesterol, and total fat may reduce the risk of heart disease. Heart disease is dependent on many factors including diet, a family history of the disease, elevated blood LDL-cholesterol levels, and physical inactivity.”
<i>Qualified Health Claims (QHC)</i>	Health claims that are supported by scientific evidence, but do not meet the rigorous “significant scientific agreement” standard required for an authorized health claim. QHCs include qualifying language to convey the limits on the level of scientific evidence supporting the claim or to prevent the claim from being misleading in other ways.	If FDA finds credible evidence supporting the claim and the claim can be qualified to prevent it from misleading consumers, the agency issues a letter of enforcement discretion, typically in response to a qualified health claim petition.	“Scientific evidence suggests but does not prove that eating 1.5 ounces per day of most nuts [such as name of specific nut] as part of a diet low in saturated fat and cholesterol may reduce the risk of heart disease. [See nutrition information for fat content.]”
<i>Food and Drug Administration Modernization Act Health Claim</i>	Health claims based on an authoritative statement of the National Academy of Sciences or a scientific body of the U.S. government with responsibility for public health protection or nutrition research.	Submitted as a health claim notification to FDA. Such claims may be used 120 days after submission to FDA, unless otherwise notified by FDA.	“Diets containing foods that are a good source of potassium and that are low in sodium may reduce the risk of high blood pressure and stroke.”

¹ This chart provides a broad overview of types of claims, and examples are for illustrative purposes to help facilitate discussion during the breakout session. Please refer to the relevant authorizing regulations for regulatory requirements for use of label claims.

Claim Type	Description	Regulatory Process	Example
Other Nutrition-Related Labeling Statements	Statements that do not contain the basic elements of an authorized claim. For example, dietary guidance statements focus on general dietary patterns, practices, and recommendations that promote health.	Does not require premarket review or authorization by FDA. Must be truthful and not misleading.	"Eat broccoli as part of a nutritious diet."
Nutrient Content Claims	FDA authorized claims that characterize the level of a nutrient in a food. They describe the level of a nutrient in the product, using terms such as free, high, and low, or they compare the level of a nutrient in a food to that of another food, using terms such as more, reduced, and lite. "Healthy" is an implied <i>nutrient content claim</i> that can be used if the food meets certain <i>nutrient</i> conditions.	FDA issues a regulation authorizing the claim, typically in response to a petition.	"Low sodium" "Good source of calcium"
Structure/Function Claims	Describe the role of a nutrient or dietary ingredient intended to affect the normal structure or function of the human body, or characterize how a nutrient or dietary ingredient acts to maintain such structure or function. Structure/function claims for conventional foods focus on effects derived from nutritive value, while structure/function claims for dietary supplements may focus on non-nutritive as well as nutritive effects.	Conventional food manufacturers are not required to notify FDA about their structure/function claims. The Dietary Supplement Health and Education Act of 1994 established special regulatory requirements and procedures for using structure/function claims on dietary supplements, including submitting a notification of the claim to FDA no later than 30 days after marketing the dietary supplement with the claim; and use of a disclaimer that FDA has not evaluated the claim.	"Calcium builds strong bones" "Fiber maintains bowel regularity"

Attachment 2: Prioritization Factors for Reviewing Qualified Health Claims Petitions²

To maximize the public health benefit of FDA's claims review process, FDA intends to prioritize on a case-by-case basis all complete petitions according to several factors, including:

- Whether the food or dietary supplement that is the subject of the petition is likely to have a significant impact on a serious or life-threatening illness;
- The strength of the evidence;
- Whether consumer research has been provided to show the claim is not misleading;
- Whether the substance of the claim has undergone an FDA safety review (i.e., is an authorized food additive, has been GRAS (generally recognized as safe) affirmed, listed, or has received a letter of "no objection" to a GRAS notification);
- Whether the substance that is the subject of the claim has been adequately characterized so that the relevance of available studies can be evaluated;
- Whether the disease is defined and evaluated in accordance with generally accepted criteria established by a recognized body of qualified experts; and
- Whether there is prior review of the evidence or the claim by a recognized body of qualified experts.

² FDA's Interim Procedures for Qualified Health Claims 2003 Guidance,
<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm053832.htm>