Label Claims for Conventional Foods and Dietary Supplements

Among the claims that can be used on food and dietary supplement labels are three categories of claims that are defined by statute and/or FDA regulations: health claims, nutrient content claims, and structure/function claims.

Health Claims

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. There are three ways in which FDA exercises its oversight in determining which health claims may be used on a label or in labeling for a conventional food or dietary supplement: 1) the 1990 Nutrition Labeling and Education Act (NLEA) provides for FDA to issue regulations authorizing health claims for foods and dietary supplements after reviewing and evaluating the scientific evidence, either in response to a health claim petition or on its own initiative; 2) the 1997 Food and Drug Administration Modernization Act (FDAMA) provides for 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; such claims may be used 120 days after a health claim notification has been submitted to FDA, unless the agency has informed the notifier that the notification does not include all the required information; and 3) as described in FDA’s guidance entitled Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements, the agency reviews petitions for qualified health claims where the quality and strength of the scientific evidence falls below that required for FDA to issue an authorizing regulation. If FDA finds that the evidence supporting the proposed claim is credible and the claim can be qualified to prevent it from misleading consumers, the agency issues a letter of enforcement discretion specifying the qualifying language that should accompany the claim and describing the circumstances under which it intends to exercise enforcement discretion for use of the claim in food labeling. The differences between these three methods of oversight for health claims are summarized below. Appendix C of The Food Labeling Guide contains a summary of those health claims that have been approved for use on food and dietary supplement labels. A Food Labeling Guide - Appendix C: Health Claims.

A "health claim" by definition has two essential components: (1) a substance (whether a food, food component, or dietary ingredient) and (2) a disease or health-related condition. A statement lacking either one of these components does not meet the regulatory definition of a health claim. For example, statements that address a role of dietary patterns or of general categories of foods (e.g., fruits and vegetables) in maintaining good health are considered to be dietary guidance rather than health claims. Dietary guidance statements used on food labels must be truthful and non-misleading. Statements that address a role of a specific substance in maintaining normal healthy structures or functions of the body are considered to be structure/function claims; see Structure/Function Claims. Unlike health claims, dietary guidance statements and structure/function claims are not subject to premarket review and authorization by FDA.

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NLEA Authorized Health Claims. The Nutrition Labeling and Education Act of 1990 (NLEA) provides for the use in food labeling of health claims that characterize a relationship between a food, a food component, or dietary ingredient and risk of a disease (for example, "adequate calcium throughout life may reduce the risk of osteoporosis"), provided the claims meet certain criteria and are authorized by an FDA regulation. FDA authorizes these types of health claims based on an extensive review of the scientific literature, generally as a result of the submission of a health claim petition, using the significant scientific agreement standard to determine whether the substance/disease relationship is well established.

Health Claims Based on Authoritative Statements. The Food and Drug Administration Modernization Act of 1997 (FDAMA) provides a second way for the use of a health claim in food labeling to be authorized. Under FDAMA, a new health claim can be authorized by submitting a notification to FDA of a claim based on an "authoritative statement" from certain scientific bodies of the U.S. Government or the National Academy of Sciences. FDA has issued guidance on how a firm can submit such a notification and make use of authoritative statement-based health claims. This guidance can be found at: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body. FDAMA does not include dietary supplements in the provisions for health claims based on authoritative statements. Consequently, this method of oversight for health claims cannot be used for dietary supplements at this time. Examples of health claims based on authoritative statements may also be found at: A Food Labeling Guide - Appendix C: Health Claims.

Qualified Health Claims. FDA's Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements describes the agency’s process for considering petitions for the use of a qualified health claim in food labeling. When there is emerging evidence for a relationship between a food substance (a food, food component, or dietary ingredient) and reduced risk of a disease or health-related condition, but the evidence is not well enough established to meet the significant scientific agreement standard required for FDA to issue an authorizing regulation, the qualified health claim petition process provides a mechanism to request that FDA review the scientific evidence and exercise enforcement discretion to permit the use of the qualified claim in food labeling. If, after evaluating the quality and strength of the totality of the scientific evidence, FDA finds that credible evidence supports the claim, the agency issues a letter outlining the circumstances under which it intends to consider the exercise of enforcement discretion for use of the claim in food labeling. Qualifying language is included as part of the claim to indicate that the evidence supporting the claim is limited. Although FDA's letters of enforcement discretion are issued to the petitioner requesting the qualified health claim, the qualified claims are available for use on any food or dietary supplement product meeting the enforcement discretion conditions specified in the letter. FDA has issued guidance on interim procedures for qualified health claims (see Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements) and on the scientific criteria the agency uses in conducting health claim evaluations (see Evidence-Based Review System for the Scientific Evaluation of Health Claims). Qualified health claim petitions that are submitted to FDA will be available for public review and comment. A listing of
petitions open for public comment is at the FDA Dockets Management website. A summary of the qualified health claims authorized by FDA may be found at: Qualified Health Claims Subject to Enforcement Discretion. For more information see Qualified Health Claims.

**Nutrient Content Claims**

The Nutrition Labeling and Education Act of 1990 (NLEA) permits the use of label claims that characterize the level of a nutrient in a food (i.e., nutrient content claims) if they have been authorized by FDA and are made in accordance with FDA's authorizing regulations. Nutrient content claims 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*. An accurate quantitative statement (e.g., 200 mg of sodium) that does not otherwise "characterize" the nutrient level may be used to describe the amount of a nutrient present. However, a statement such as "only 200 mg of sodium" characterizes the level of sodium by implying that it is low. Therefore, the food would have to meet the nutritional criteria for a “low” nutrient content claim or carry a disclosure statement that it does not qualify for the claim (e.g., “not a low sodium food”). Most nutrient content claim regulations apply only to those nutrients that have an established Daily Value: A Food Labeling Guide - VII. Nutrition Labeling. The requirements that govern the use of nutrient content claims help ensure that descriptive terms, such as *high or low*, are used consistently for all types of food products and are thus meaningful to consumers. *Healthy* is an implied nutrient content claim that characterizes a food as having "healthy" levels of total fat, saturated fat, cholesterol and sodium, as defined in the regulation authorizing use of the claim. Percentage claims for dietary supplements are another category of nutrient content claims. These claims are used to describe the percentage level of a dietary ingredient in a dietary supplement and may refer to dietary ingredients for which there is no established Daily Value, provided that the claim is accompanied by a statement of the amount of the dietary ingredient per serving. Examples include simple percentage statements such as "40% omega-3 fatty acids, 10 mg per capsule," and comparative percentage claims, e.g., "twice the omega-3 fatty acids per capsule (80 mg) as in 100 mg of menhaden oil (40 mg)." (See 21 CFR 101.13(q)(3)(ii)). A summary of the rules for use of nutrient content claims can be found in Chapter VI of The Food Labeling Guide. Examples of nutrient content claims can be found in Appendices A and B of The Food Labeling Guide: Appendix A: Definitions of Nutrient Content Claims and Appendix B: Additional Requirements for Nutrient Content Claims.

**Structure/Function Claims and Related Dietary Supplement Claims**

Structure/function claims have historically appeared on the labels of conventional foods and dietary supplements as well as drugs. The Dietary Supplement Health and Education Act of 1994 (DSHEA) established some special regulatory requirements and procedures for using structure/function claims and two related types of dietary supplement labeling claims, claims of general well-being and claims related to a nutrient deficiency disease. Structure/function claims may describe the role of a nutrient or dietary ingredient intended to affect the normal structure or function of the human body, for example, "calcium builds strong bones." In addition, they may characterize the means by which a nutrient or
dietary ingredient acts to maintain such structure or function, for example, "fiber maintains bowel regularity," or "antioxidants maintain cell integrity." General well-being claims describe general well-being from consumption of a nutrient or dietary ingredient. Nutrient deficiency disease claims describe a benefit related to a nutrient deficiency disease (like vitamin C and scurvy), but such claims are allowed only if they also say how widespread the disease is in the United States. These three types of claims are not pre-approved by FDA, but the manufacturer must have substantiation that the claim is truthful and not misleading and must submit a notification with the text of the claim to FDA no later than 30 days after marketing the dietary supplement with the claim. If a dietary supplement label includes such a claim, it must state in a "disclaimer" that FDA has not evaluated the claim. The disclaimer must also state that the dietary supplement product is not intended to "diagnose, treat, cure or prevent any disease," because only a drug can legally make such a claim. Structure/function claims may not explicitly or implicitly link the claimed effect of the nutrient or dietary ingredient to a disease or state of health leading to a disease. Further information regarding structure/function claims can be found in FDA's January 9, 2002 Structure/Function Claims Small Entity Compliance Guide.

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. FDA does not require conventional food manufacturers to notify FDA about their structure/function claims, and disclaimers are not required for claims on conventional foods.