

Regulations for Food and Dietary Supplements Sold in the United States

Regulatory Bodies

[Office of Nutritional Products, Labeling and Dietary Supplements](#)
[Center for Food Safety and Applied Nutrition](#)
[Department of Health and Human Services](#)
[United States Food and Drug Administration](#) (FDA)

Legislation

[Federal Food, Drug and Cosmetic Act](#)
[Food and Drug Modernization Act](#) (FDAMA)
[Code of Federal Regulations](#) (CFR)

Note: Choose the “search or browse options” for rule published under the category of Food and Drugs.

[Nutrition Labeling and Education Act](#) (NLEA)
[Dietary Supplement Health And Education Act Of 1994](#)
[Dietary Supplement and Nonprescription Drug Consumer Protection Act](#)
- regarding serious event reporting

Claim Descriptions

1. Approved Health Claims

Health claims approved by the FDA based on significant scientific agreement (SSA) under the Nutrition Labeling and Education Act (NLEA). There are 12 NLEA-approved health claims in place:

1. Calcium and osteoporosis
2. Sodium and hypertension
3. Dietary fat and cancer
4. Dietary saturated fat and cholesterol and risk of coronary heart disease
5. Fibre-containing grain products, fruits, and vegetables and cancer
6. Fruits, vegetables, and grain products that contain fibre, particularly soluble fibre, and risk of coronary heart disease
7. Fruits and vegetables and cancer
8. Folate (0.4mg/day) and neural tube defects
9. Dietary sugar alcohol and dental caries
10. Soluble fibre from certain foods and risk of coronary heart disease
11. Soy protein and risk of coronary heart disease
12. Plant sterol/stanol esters and risk of coronary heart disease

[FDA Food Labeling Guide – Chapter VIII: Claims](#)

[Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body](#)

[NLEA Authorized Health Claim Chart](#)

2. Qualified Health Claims

Qualified health claims (QHC) may be used when evidence is present for a nutrient/disease relationship but the evidence is not based on significant scientific agreement (SSA). The claims must clearly state that there is limited and not conclusive evidence supporting the claim. The label must not mislead consumers. QHC are based on a sliding scale of scientific evidence and depend on the strength of such evidence. Since QHC are not based on SSA, the label must contain a statement that qualifies the claim. FDA must approve the QHC, an example of which is shown here.

E.g. Supportive but not conclusive research shows that *<amount>* per day of *<food or ingredient>*, as part of a *<diet specifics if necessary>* diet, may reduce the risk of *<specific>* disease.

[FDA Food Labeling Guide – Chapter VIII: Claims](#)

[Guidance for Industry Evidence-Based Review System for the Scientific Evaluation of Health Claims](#)

This guidance document (January 2009) for industry describes the FDA's

- 1) process for evaluating the scientific evidence for a health claim,
- 2) meaning of the significant scientific agreement (SSA) standard in section 403(r)(3) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 343(r)(3)) and 21 CFR 101.14(c), and
- 3) advise on creating credible scientific evidence to support a qualified health claim.

3. Nutrient Content Claims

These claims describe the level of a nutrient or dietary substance in a product using terms such as "good source," "high," or "free." Nutrient content claims may only be made if FDA has a regulation specifying the criteria that a food must meet in order to use the claim (i.e. what quantity per serving is considered a "good source"). Nutrient content claims can only be made for nutrients or dietary substances that have an established daily intake value with a few exceptions.

[FDA Food Labeling Guide – Chapter VIII: Claims](#)

[NLEA Definitions of Nutrient Content Claims](#)

4. Structure/Function Claims

Structure/function claims describe the relationship between the food and general health or stages of life. They cannot relate to a disease or symptoms of diseases.

Examples:

- may claim a benefit related to a nutrient deficiency disease (like vitamin C and scurvy), as long as the statement also tells how widespread such a disease is in the United States.
- may describe the role of a nutrient or dietary ingredient intended to affect a structure or function in humans. (e.g. "calcium builds strong bones")
- may characterize the means by which a nutrient or dietary ingredient acts to maintain such structure or function (e.g. "fiber maintains bowel regularity," or "antioxidants maintain cell integrity,"
- may describe general well-being from consumption of a nutrient or dietary ingredient.

The manufacturer is responsible for ensuring the accuracy and truthfulness of these claims as these claims are not approved by FDA.

[FDA Food Labeling Guide – Chapter VIII: Claims](#)

[Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body](#)

[Structure/Function Claims Small Entity Compliance Guide](#)

5. Food Ingredients – Generally Recognized as Safe (GRAS)

Any substance that is intentionally added to food is considered a food additive and is subject to premarket review and approval by FDA. The exemptions are substances “Generally Recognized As Safe (GRAS)” as determined by qualified experts.

The data and information used to establish the safety of a GRAS substance must be generally available (e.g., through publication in the scientific literature) and there must be a basis to conclude there is consensus among qualified experts about the safety of the substance for its intended use.

[How to Submit a GRAS Notice](#)

[Frequently Asked Questions about GRAS](#)

6. Food for Special Dietary Use

(a)(1) The term *special dietary uses*, as applied to food for man, means particular (as distinguished from general) uses of food, as follows:

- (i) Uses for supplying particular dietary needs which exist by reason of a physical, physiological, pathological or other condition, including but not limited to the conditions of diseases, convalescence, pregnancy, lactation, allergic hypersensitivity to food, underweight, and overweight;
- (ii) Uses for supplying particular dietary needs which exist by reason of age, including but not limited to the ages of infancy and childhood;
- (iii) Uses for supplementing or fortifying the ordinary or usual diet with any vitamin, mineral, or other dietary property. Any such particular use of a food is a

special dietary use, regardless of whether such food also purports to be or is represented for general use.

(2) The use of an artificial sweetener in a food, except when specifically and solely used for achieving a physical characteristic in the food which cannot be achieved with sugar or other nutritive sweetener, shall be considered a use for regulation of the intake of calories and available carbohydrate, or for use in the diets of diabetics and is therefore a special dietary use.

Taken from the Electronic Code of Federal Regulations
[21 C.F.R. Part 105—Foods for Special Dietary Use](#)

[Standard for Labelling of and Claims for Prepackaged Foods for Special Dietary Use](#)

7. Dietary Supplements

A dietary supplement is a product taken orally that contains a "dietary ingredient." Dietary Ingredients are one, or any combination, of the following substances:

- a vitamin,
- a mineral,
- an herb or other botanical,
- an amino acid,
- a dietary substance for use by man to supplement the diet by increasing the total dietary intake (e.g., enzymes or tissues from organs or glands), or
- a concentrate, metabolite, constituent or extract.

Definition taken from <http://www.cfsan.fda.gov/~dms/ds-oview.html#what> (Feb 2009)

Dietary supplements may be found in many forms such as tablets, capsules, soft gels, gelcaps, liquids, or powders. They can also be in other forms, such as a bar, but if they are, information on their label must not represent the product as a conventional food or a sole item of a meal or diet.

[Overview of Dietary Supplements](#)

[A Dietary Supplement Labeling Guide](#)

[Labeling of Dietary Supplements](#)

- list of resources and guidance documents pertaining to dietary supplements.

General Food Manufacturing Resources

A Food Labeling Guide

<http://www.cfsan.fda.gov/~dms/2lg-toc.html>

USDA Food Safety and Inspection Service

<http://www.fsis.usda.gov/>

Guidance Documents

Current List of Food and Cosmetic Guidance Documents

<http://www.cfsan.fda.gov/~dms/guidance.html>

Guide to Nutrition Labeling and Education Act (NLEA) Requirements

http://www.fda.gov/ora/inspect_ref/igs/nleatxt.html

Resources

[Food Labeling and Nutrition \(FDA\)](#)

All inclusive site for information regarding labeling regulations, compliance, inspections and more for food sold in the US.

Consumer Health Information for Better Nutrition Initiative

<http://www.fda.gov/oc/nutritioninitiative/whitepaper.html>