

HEALTH CLAIMS ...

- ... characterize the ability of the nutrient or functional component to reduce the risk of disease or a health-related condition
- ... use “may” to characterize the relationship between the nutrient and the disease or health-related condition in order to indicate the disease or health-related condition is caused by many factors
- ... can be used for conventional foods and dietary supplements
- ... require that the manufacturer of a dietary supplement submit a notification to FDA no later than 30 days after the product goes to market; the notification must include the text of the claim (conventional foods do not require this notification)
- ... can not be used on products that exceed disqualifying levels for total fat, saturated fat, cholesterol, or sodium
- ... are pre-authorized by FDA and wording for claims is tightly controlled; this includes SSA Claims, FDAMA Claims and Qualified Health Claims

SSA CLAIMS (based on Significant Scientific Agreement) can be used for conventional foods and dietary supplements. FDA authorizes SSA claims based on the Agency’s extensive review of the scientific literature. The Significant Scientific Agreement (SSA) standard* is used to determine that the nutrient/disease relationship is well established. To use an SSA claim, the product must meet all requirements found in 21 CFR 101.72 to 101.83, and must not exceed disqualifying levels of total fat, saturated fat, cholesterol and sodium. Model claim examples are shown below.

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Twelve Allowed SSA Claims

1. Adequate calcium throughout life, as part of a well-balanced diet, may reduce their risk of osteoporosis later in life.
2. Development of cancer depends on many factors. A diet low in total fat may reduce the risk of some cancers.
3. Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors.
4. While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease.
5. Low fat diets rich in fiber-containing grain products, fruits, and vegetables may reduce the risk of some types of cancer, a disease associated with many factors.
6. Diets low in saturated fat and cholesterol and rich in fruits, vegetables, and grain products that contain some types of dietary fiber, particularly soluble fiber, may reduce the risk of heart disease, a disease associated with many factors.
7. Low fat diets rich in fruits and vegetables (foods that are low in fat and may contain dietary fiber, vitamin A, and vitamin C) may reduce the risk of some types of cancer, a disease associated with many factors. [Name of food] is high in vitamins A and C, and it is a good source of dietary fiber.
8. Healthful diets with adequate folate may reduce a woman’s risk of having a child with a brain or spinal cord birth defect.
9. Frequent between-meal consumption of foods high in sugars and starches as between-meal snacks can promote tooth decay. The sugar alcohol [name, optional] used to sweeten this food may reduce the risk of dental caries.
10. Diets low in saturated fat and cholesterol that include [X grams] of soluble fiber per day from [name of soluble fiber source] may reduce the risk of heart disease. One serving of [name of food] provides X grams of this soluble fiber.
11. 25 grams of soy protein a day, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. One serving of [food name] provides X grams of soy protein.
12. Foods containing at least 0.65g per serving of plant sterol esters, eaten twice a day with meals for a daily total intake of at least 1.3 g, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of food] supplies X grams of plant sterol esters.



FDAMA CLAIMS (FDA Modernization Act of 1997) can be used only for conventional foods; they cannot be used for dietary supplements at this time. FDA authorizes this type of claim as a result of the notification from a stakeholder. The notification must include a proposed claim as explained in FDA Guidance for Industry - Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body found at www.cfsan.fda.gov/~dms/hclmguid.html.

To use an FDAMA claim, the product must meet all requirements of the claim and the food must not exceed disqualifying levels of total fat, saturated fat, cholesterol, and sodium. Currently there are five allowed FDAMA claims relating to:

- Fluoride and Dental Caries
- Potassium and High Blood Pressure and Stroke
- Saturated Fat, Cholesterol, and Trans Fat, and Heart Disease
- Substitution of Saturated Fat with Unsaturated Fatty Acids and Heart Disease
- Whole Grain Foods and Heart Disease and Certain Cancers

QUALIFIED HEALTH CLAIMS can be used for conventional foods and dietary supplements. Any interested party may petition FDA to issue a regulation regarding a health claim; see 21 CFR 101.70. FDA evaluates the petition according to the SSA standard.* When the evidence for a substance/disease relationship is credible but does not meet the SSA standard, FDA issues a Letter of Enforcement Discretion to the petitioner; enforcement discretion means that FDA intends not to object to the use of the claim provided that the claim is written exactly as the letter states and that the label meets any other requirements stated in the letter. In general, many labelers find these claims have limited usability because of difficulty with required wording.

At this time there are twenty-four authorized Qualified Health Claims (letters of enforcement discretion). Specific requirements for use are provided at www.cfsan.fda.gov/~dms/lab-qhc.html. The site includes a list of fifteen claim denials and one withdrawn claim. The authorized qualified health claims involve one of the following substance/disease relationships:

- Tomatoes and Certain Cancers
- Calcium and Colon/Rectal Cancer and Colon/Rectal Polyps
- Green Tea and Breast Cancer and Prostate Cancer
- Selenium and Certain Cancers
- Antioxidant Vitamins and Certain Cancers
- Folic Acid, Vitamin B6, and Vitamin B12 and Vascular Disease
- Walnuts and Coronary Heart Disease
- Nuts and Coronary Heart Disease
- Omega-3 Fatty Acids and Coronary Heart Disease
- Corn Oil and Coronary Heart Disease
- Unsaturated Fatty Acids from Canola Oil and Coronary Heart Disease
- Monounsaturated Fatty Acids from Olive Oil and Coronary Heart Disease
- Phosphatidylserine and Cognitive Dysfunction and Dementia
- Chromium Picolinate and Insulin Resistance, Type 2 Diabetes
- Calcium and Hypertension, Pregnancy-Induced Hypertension, and Preeclampsia
- Folic Acid and Neural Tube Defects

* *The SSA standard is intended to be a strong standard that provides a high level of confidence in the validity of the substance/disease relationship; the validity of the relationship is not likely to be reversed by new and evolving science.*

