

HEALTH CLAIMS ...

- ... are pre-authorized by FDA
- ... characterize the ability of the nutrient or functional component to **reduce the risk** of disease or a health-related condition (they are not about treating, curing or mitigating any disease)
- ... 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)
- ... cannot be used on products that exceed disqualifying levels for total fat, saturated fat, cholesterol or sodium
- ... can be used only on foods that contain, without fortification, 10% or more Daily Value for Vitamin A, Vitamin C, calcium, iron, protein or fiber
- ... must use tightly-controlled wording as set forth in the Code of Federal Regulations

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. Model claim examples† are shown below.

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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.

†Adapted from U.S. Code of Federal Regulations



FDAMA CLAIMS (based on the FDA Modernization Act of 1997) can be used only for conventional foods and cannot be used on dietary supplements at this time. FDA authorizes the use of an FDAMA claim as a result of the notification from a stakeholder. The notification must include wording for a proposed claim that is based on an “authoritative statement” (of significant scientific agreement) from a scientific body of the U.S. Government or the National Academy of Sciences.

To date, only five health claims have been authorized for use under the FDA Modernization Act.

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| <ol style="list-style-type: none"> 1. Whole Grains & Risk of Heart Disease and Certain Cancers (authorized via authoritative statement from National Academies of Science) 2. Potassium & Risk of High Blood Pressure and Stroke (authorized via authoritative statement from National Academies of Science) 3. Fluoride & Risk of Dental Caries (authorized via authoritative statement from multiple sources including U.S. Surgeon General) | <ol style="list-style-type: none"> 4. Saturated Fat, Cholesterol and Trans Fat & Risk of Heart Disease (authorized via authoritative statement from 2005 Dietary Guidelines for Americans) 5. Substitution of Saturated Fat with Unsaturated Fatty Acids & Risk of Heart Disease (authorized via authoritative statement from National Academies of Science) |
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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 the label meets all requirements stated in the letter. In general, many product developers find that these claims have limited usability because of the required wording.

At this time there are 25 authorized qualified health claims (letters of enforcement discretion), 15 claim denials, and one withdrawn claim. The 25 authorized qualified health claims fit into one of the 16 substance/disease relationships shown below.

Cancer

- Antioxidant Vitamins & Certain Cancers
- Calcium & Colon/Rectal Cancer and Recurrent Colon/Rectal Polyps
- Green Tea & Certain Cancers
- Selenium & Certain Cancers
- Tomatoes & Certain Cancers

Cognitive Function

- Phosphatidylserine & Cognitive Dysfunction and Dementia

Diabetes

- Chromium Picolinate & Insulin Resistance and Type 2 Diabetes

Neural Tube Defects

- Folic Acid & Neural Tube Defects

Cardiovascular Disease

- Certain B Vitamins & Vascular Disease
- Nuts & Coronary Heart Disease
- Walnuts & Coronary Heart Disease
- Omega-3 Fatty Acids & Coronary Heart Disease
- Unsaturated Fatty Acids from Canola Oil & Coronary Heart Disease
- Corn Oil & Heart Health
- Monounsaturated Fatty Acids from Olive Oil & Coronary Heart Disease

Hypertension

- Calcium & Hypertension, Pregnancy-Induced Hypertension and Preeclampsia



* 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.