



# **Silliker Nutrient and Health Claims U.S. Regulatory Guide**

With Technical Content by  
Food Consulting Company



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# Silliker Nutrient and Health Claims U.S. Regulatory Guide

Label claims and statements can draw attention to products and increase product sales, but developing compliant claims can be tricky. This guidebook was developed to help product developers become familiar with the various types of label claims and statements available and recognize which is best suited to a product's nutritional attributes and marketing objectives.

**Nutrient Content Claims** describe directly or by implication the level of a nutrient or dietary substance in a serving.

**Statements of Fact** can be made on labels as long as they do not make a nutrient content claim or health claim or other claim that requires specific FDA authorization.

**Health Claims** characterize the ability of a nutrient or functional component to reduce the risk of disease or a health-related condition.

**Structure/Function Claims** describe the role of a nutrient or functional component in affecting or maintaining normal body structure or function or general well-being.

**Dietary Guidance Statements** typically explain the relationship between a group of foods (such as fruits and vegetables or whole grains) and health.

Regardless of the type of label claim or statement chosen, all labeling must be truthful and not misleading.



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## Conventional Food vs. Dietary Supplement

Early in the product development process, manufacturers will want to determine if the product will be regulated as a conventional food or as a dietary supplement. This determination carries many ramifications for formulation, labeling, and marketing (i.e., allowable/restricted ingredients, possible label claims). Conventional foods are labeled with Nutrition Facts while dietary supplements are labeled with Supplement Facts.

A dietary supplement is a product taken by mouth that contains a “dietary ingredient” intended to supplement the diet; “dietary ingredients” include: vitamins, minerals, herbs/botanicals, amino acids, enzymes, organ tissues, glandulars, metabolites, extracts or concentrates. Dietary supplements have many forms: tablets, capsules, softgels, gelpcaps, liquids, and powders. They can also be in the form of a bar, and in this case information on the label must not represent the product as a conventional food or a sole item of a meal or diet. Regardless of the form, every supplement must be labeled as a dietary supplement.

### Label Claims and Statements for Conventional Foods and Dietary Supplements

Type of Label Claim or Statement	Allowed on Conventional Foods?	Allowed on Dietary Supplements?
Nutrient Content Claims	Yes, as pre-approved by FDA except on labels for products intended for infants and toddlers.	Yes, as pre-approved by FDA except on labels for products intended for infants and toddlers. Certain claims can be made only on products with over 40 calories per serving.
Statements of Fact	Yes	Yes
Health Claims		
SSA* Health Claims	Yes, as pre-approved by FDA.	Yes, as pre-approved by FDA. Use requires specific FDA notification.
FDAMA** Health Claims	Yes, requires FDA authorization via notification from a stakeholder.	No
Qualified Health Claims	Yes, requires a petition to FDA.	Yes, requires a petition to FDA.
Structure/Function Claims	Yes, except on USDA-regulated foods.	Yes. Use requires specific FDA notification and label “disclaimer.”
Dietary Guidance Statements	Yes	No

\* SSA – Significant Scientific Agreement

\*\* FDAMA – FDA Modernization Act



## Disclosure Statement Requirements

FDA and USDA have established specific regulations to help ensure that label claims and statements are not misleading to consumers.

When claims are made about a product's nutrition or health benefits, a **disclosure statement** is required if one or more of the four nutrients shown in the chart below exceed threshold levels for the product's reference amount<sup>1</sup> or labeled serving size if larger, or per 50g for small servings<sup>2</sup>. The disclosure statement must be placed adjacent to the claim without intervening material and generally in a type size at least as large as the Net Contents statement, but never less than half of the size of the claim. See example in shaded box below which calls the consumer's attention to the Nutrition Facts.

### Disclosure Statement Threshold Levels

Nutrient	Individual Foods <sup>3</sup> (includes small servings)	Main Dishes <sup>4</sup>	Meals <sup>5</sup>
Total Fat	13.0g	19.5g	26.0g
Saturated Fat	4.0g	6.0g	8.0g
Cholesterol	60 mg	90 mg	120 mg
Sodium	480 mg	720 mg	960 mg

### Definitions

<sup>1</sup> **Reference Amounts** are Reference Amounts Customarily Consumed per eating occasion (RACC).

<sup>2</sup> **Small Servings** are those with reference amounts of 30 grams or less or 2 Tbsp or less.

<sup>3</sup> **Individual Foods** are those with reference amounts of more than 30 grams or more than 2 Tbsp.

<sup>4</sup> **Main Dishes** are products that weigh at least 6 oz per serving, contain not less than 40 grams each of at least two different foods from at least two specified food groups, and are represented as main dishes.

<sup>5</sup> **Meals** are products that weigh at least 10 oz per serving, contain not less than 40 grams each of at least three different foods from at least two specified food groups, and are represented as meals.

### Example for a disclosure statement for a product low in sodium but high in fat:

**LOW SODIUM**  
SEE NUTRITION PANEL  
FOR FAT CONTENT

The use of disclosure statements is discussed further in the Nutrient Content Claims and Statements of Fact sections.



## NUTRIENT CONTENT CLAIMS ...

- ... describe directly or by implication the level of a nutrient or dietary substance in a serving
- ... are limited to those authorized by FDA regulation; generally this is limited to nutrients that are mandatory or voluntary in the Nutrition Facts and that have an FDA-established Daily Value
- ... are used on labels without review by FDA but must comply with all FDA definitions and regulations
- ... placed on labels for USDA-regulated products must always be submitted for USDA approval
- ... can be made for both conventional foods and dietary supplements
- ... are not allowed on products for infants and toddlers
- ... must be accompanied by the following disclosure when fat, cholesterol, saturated fat, or sodium threshold levels are exceeded: **SEE NUTRITION PANEL FOR <NAME OF NUTRIENT> CONTENT.**

**Nutrients that qualify** for nutrient content claims include: total calories, total fat, saturated fat, cholesterol, sodium, potassium, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, iron, vitamin D, vitamin E, vitamin K, thiamin, riboflavin, niacin, vitamin B6, folate, vitamin B12, biotin, pantothenic acid, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, choline, and ALA & DHA omega-3 fatty acids.

Note: Even though there is no Daily Value for Choline or ALA & DHA Omega-3's and these nutrients are not mandatory or voluntary for Nutrition Facts reporting (and cannot be included in Nutrition Facts), they are allowable per specific FDA notification. Choline claims are allowable per FDA's notification under FDAMA; ALA & DHA Omega-3 claims are allowable per the "Martek Notification."

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**ABSOLUTE NUTRIENT CONTENT CLAIMS** are direct statements about the level of a nutrient in the product.

- **Free:** means a product's reference amount and labeled serving contains an insignificant amount of: total fat, saturated fat, cholesterol, sodium, sugars, or calories. (Insignificant is defined as an amount that may be rounded to zero, per FDA rounding rules). Synonyms include "zero," "no," "without," "trivial source of," "negligible source of," and "dietarily insignificant source of." "Non-fat" is a synonym for fat-free.
- **Low:** means a product could be eaten frequently without exceeding the guidelines for: total fat, saturated fat, cholesterol, sodium, or calories. Synonyms include "little," "few (for calories)," "contains a small amount of," and "low source of." The term Very Low is also defined, but only with respect to sodium levels.

### Notes about "free" and "low" claims:

- » When using "free" or "low" on a product that has not been specifically processed or altered to qualify for the claim, the manufacturer must indicate that the food inherently qualifies for the claim (e.g., peanut butter, a cholesterol free food).
- » FDA has not defined nutrient content claims for trans fat, therefore it is not permissible to use the words "free" or "low" (or their synonyms) to describe trans fat levels (e.g., trans fat free, no trans fat, and zero trans fat are unauthorized nutrient content claims; however 0g trans fat per serving is allowed as a statement of fact).





- » FDA has not defined nutrient content claims for carbohydrate, therefore it is not permissible to use the words “free” or “low” (or their synonyms) to describe carbohydrate levels (e.g., no carbs, carb free, and low carb are unauthorized nutrient content claims; however Xg carb per serving is allowed as a statement of fact as long as it is simply a repeat of information from the Nutrition Facts and does not imply a level).
  - » FDA has not provided a definition for “low sugar,” therefore this claim cannot be used; however, manufacturers can use “sugar free,” “reduced sugar,” and “no added sugar” claims as long as food also qualifies as a low calorie food or includes the “not a low calorie food” disclaimer.
  - » If a claim is made about fatty acids or cholesterol, then polyunsaturated fat and monounsaturated fat must be included in the Nutrition Facts (or Supplement Facts) unless the product is fat free; additionally, specific disclosure about total fat and cholesterol levels must be included directly next to the claim when certain threshold levels are exceeded.
  - » For dietary supplements: claims for total fat, saturated fat, and cholesterol can be made only if the product is greater than 40 calories per serving, and claims for calories can be made only when a similar product exists that contains over 40 calories per serving.
- **Lean:** may be used to describe meat, poultry, seafood, and game meat and means less than 10g fat, 4.5g or less saturated fat, and less than 95mg cholesterol per reference amount or per 100 grams (whichever is larger). Criteria are different for mixed foods, meals, and main dishes.
  - **Extra Lean:** may be used to describe meat, poultry, seafood, and game meat and means less than 5g fat, less than 2g saturated fat, and less than 95mg cholesterol per reference amount or per 100 grams (whichever is larger). Criteria are different for mixed foods, meals, and main dishes.
  - **Good Source:** means the reference amount of a product contains 10 to 19% of the Daily Value of a particular nutrient (i.e., fiber, protein, or a vitamin or mineral). Synonyms include “contains” and “provides.”
  - **High:** means the reference amount of a product contains 20% or more of the Daily Value for a particular nutrient (i.e., fiber, protein, or a vitamin or mineral). Synonyms include “excellent source” and “rich in.”

**Notes about “good source” and “high” claims:**

- » “Good source” and “high” cannot be used to describe nutrients and functional components without an FDA-established Daily Value (i.e., cannot be used to describe carotenoids, flavonoids, etc.).
  - » The term “antioxidant” can be used in a claim as long as the antioxidant is named, it has an FDA-established Daily Value, and its level qualifies for the “good source” or “high” claim (i.e., high in antioxidant vitamin C).
  - » If a fiber claim is made and the food does not qualify as a low fat food, then the fiber claim must be accompanied by a disclaimer that discloses the level of total fat per labeled serving.
  - » If a protein claim is made, then the Nutrition Facts (or Supplement Facts) must include the % Daily Value from protein based on the protein-digestibility corrected amino acid score (PDCAAS).
- **High Potency:** means the vitamin or mineral is present in a product at 100% or more of the RDI per reference amount and must identify the nutrient in the claim (e.g., high potency vitamin C). “High Potency” can also be used to describe a conventional food or dietary supplement when the product contains 100% or more RDI for at least two-thirds of vitamins and minerals with Daily Values present in the product at 2% or more (e.g., high potency multivitamin/mineral supplement).

### Nutrient Content Claim Definitions for “Free and Low”

Nutrient	Claim	Definition
Calories	Free	Less than 5 calories per serving
	Low	40 calories or less per serving Main dish/meal product: 120 calories or less per 100 grams
Total Fat	Free	Less than 0.5g fat per serving, and includes no ingredients that contain fat (unless asterisked in the ingredient statement and footnoted “*adds a trivial amount of fat”)
	Low	3g or less fat per serving Main dish/meal product: 3g or less fat per 100 grams, and not more than 30% of calories from fat
Saturated Fat	Free	Less than 0.5g saturated fat and less than 0.5g trans fat per serving, and includes no ingredients that contain saturated fat (unless asterisked in the ingredient statement and footnoted “*adds a trivial amount of saturated fat”)
	Low	1g or less saturated fat per serving, and not more than 15% of calories from saturated fat Main dish/meal product: 1g or less saturated fat per 100 grams, and less than 10% of calories from saturated fat
Cholesterol	Free	Less than 2mg cholesterol and 2g or less saturated fat per serving, and includes no ingredients that contain cholesterol (unless asterisked in the ingredient statement and footnoted “*adds a trivial amount of cholesterol”)
	Low	20mg or less cholesterol and 2g or less saturated fat per serving Main dish/meal product: 20mg or less cholesterol and 2g or less saturated fat per 100 grams
Sodium	Free	Less than 5mg sodium per serving, and contains no sodium chloride (table salt) or other ingredient that contains sodium (unless asterisked in the ingredient statement and footnoted “*adds a trivial amount of sodium”)
	Very Low	35mg or less sodium per serving Main dish/meal product: 35mg or less sodium per 100 grams
	Low	140mg or less sodium per serving Main dish/meal product: 140mg or less sodium per 100 grams

*“Per serving” means per reference amount or per labeled serving, whichever is larger. However, if a product has a small serving size (i.e., reference amount of 30 grams or less or 2 Tbsp or less), then the nutrient levels for the claim must be met on a 50 gram basis.*



**RELATIVE NUTRIENT CONTENT CLAIMS** compare the level of nutrients of one product to another.

- **More:** means that the reference amount of a product, whether altered or not, contains at least 10% more of the Daily Value of a nutrient than the reference product. This definition also applies to “fortified,” “enriched,” “added,” and “plus” claims but, unlike “more,” these terms can only be used to describe foods that have been altered.
- **Less:** means that the reference amount of a product, whether altered or not, contains 25% less of a nutrient than the reference product. This definition also applies to “fewer,” which can be used to describe calories.
- **Reduced:** means that the reference amount of a nutritionally-altered product contains 25% less of a nutrient than the reference product. This definition also applies to “lower.”
- **Light:** means that the reference amount of a nutritionally-altered product contains 50% less fat or 1/3 fewer calories than the reference product.

**Notes about “light” claims:**

- » For products with greater than 50% calories from fat, the claim must be met on the basis of 50% less fat (not 1/3 fewer calories). For products with less than 50% calories from fat, the claim can be met on either the calorie or fat basis.
- » A “light” claim is not allowed on products when the reference product is low calorie (40 calories or less) or low fat (3g fat or less), unless the sodium of such a product is reduced by 50%.

FDA has specified **reference products** that may be used as a basis of comparison for each of the four relative claims above. For “more,” “less,” and “reduced,” the reference product can be the company’s regular brand, a competing regular brand, or a representative value for a broad base of products of that type. For “more” and “less,” the reference product may also be a similar product in the same product category (e.g., pretzels with 25% less fat than potato chips). For “light,” the reference product must be similar and the reference value must be a representative value for a broad base of products of that type. Relative claims trigger many disclosure and footnote requirements.

- The identity of the reference product and the percent/fractional difference for nutrient/s that are the subject of the claim between the two comparison products must be declared adjacent to the claim. Example: half the calories and 60% less fat than [name of reference product].
- Quantitative information comparing level of nutrients (i.e., calories and fat, or sodium) in the product and reference product must be disclosed, either adjacent to the claim or on the information panel. Example: light soy sauce 500mg sodium per serving; regular soy sauce 1000mg sodium per serving.
- The following disclosure is required when total fat, cholesterol, saturated fat, or sodium threshold levels are exceeded: **SEE NUTRITION PANEL FOR <NAME OF NUTRIENT> CONTENT.**



## IMPLIED NUTRIENT CONTENT CLAIMS include:

- claims not explicitly stated but implied by association with an ingredient known to contain a particular nutrient or be free of that nutrient. Examples: (1) “good source of oat bran” is an implied fiber claim and is approved for foods that could make a good source of fiber claim, (2) “no tropical oils” is an implied low saturated fat claim and is approved for foods that could make such a claim
- claims that characterize the level of a nutrient as a little or a lot. Examples: (1) “only” implies a little and therefore “only 3g carbohydrate” is not allowed because low carbohydrate claims are not allowed, (2) “packed with antioxidants” implies high in antioxidants. As shown the claim is not allowed because the specific antioxidant is not included. A statement such as “packed with antioxidant vitamins C & E” would be allowed on a product that reports 20% or more Daily Value for those two vitamins within the Nutrition Facts or Supplement Facts
- equivalency claims such as “contains as much [nutrient] as a [food].” This claim can be made if both the reference product and the labeled product are a “good source” of the nutrient on a per serving basis. Example: “contains as much vitamin C as an 8 ounce glass of orange juice” would be allowed when the statement is truthful and not misleading

### Two common implied nutrient content claims:

- **Healthy:** means a food that is low in fat and saturated fat, contains 480mg or less sodium and 60mg or less cholesterol per reference amount or labeled serving (whichever is larger), and provides at least 10% Daily Value per reference amount for one of these nutrients: vitamin A, vitamin C, calcium, iron, protein, or fiber.

#### Notes and exceptions for “healthy” claims:

- » For products with a small serving size, the food must meet the criteria on a 50 gram basis.
  - » For products that qualify as a main dish or meal, the food must meet the criteria above except that it may contain 600mg or less sodium and 90 mg or less cholesterol per labeled serving.
  - » For single ingredient raw meat, poultry, seafood, or game meat, the food must meet the criteria above except that it may contain less than 5g fat, 2g saturated fat, and 95mg cholesterol per reference amount or 100g (whichever is larger). [Note that the criteria for “healthy” in these foods is the same as “extra lean” for fat, saturated fat, and cholesterol.]
  - » Raw fruits and vegetables, canned or frozen single ingredient fruits and vegetables, mixtures of single ingredient raw, canned, or frozen fruits and vegetables, and enriched cereal grain products that conform to certain standards of identity are exempt from the requirement of providing at least 10% Daily Value for vitamin A, vitamin C, calcium, iron, protein, or fiber.
- **Percent Fat Free:** can be stated on foods which meet the low fat or fat free definition. However, 100% fat free can be made only on foods that contain less than 0.5g fat per reference amount or per 100 grams (whichever is larger), and includes no ingredients that contain fat.



## STATEMENTS OF FACT ...

- ... can be made on labels as long as they do not make a nutrient content claim or health claim or other claim that requires specific FDA authorization
- ... are covered by free speech rights
- ... must not characterize the nutrient level by using terms that are defined or implied nutrient content claims (free, zero, no, low, high, good source, only, packed with, etc.)
- ... are allowed on conventional foods and dietary supplements as long as they are truthful and not misleading
- ... may be used to describe an amount of a nutrient or a functional component present in a product which allows manufacturers to inform consumers about the level a nutrient or functional component present when a Daily Value has not been established
- ... taken from the Nutrition Facts panel and repeated elsewhere on the label require the following when total fat, cholesterol, saturated fat, or sodium threshold levels are exceeded:  
**SEE NUTRITION PANEL FOR <NAME OF NUTRIENT> CONTENT**



### EXAMPLES AND EXPLANATIONS:

ALLOWED: 0g trans fat per serving (the numeral 0 is not a defined nutrient content claim)

NOT ALLOWED: zero trans fat/trans fat free/no trans fat (the terms zero, free, and no are defined nutrient content claims; there are no allowable defined nutrient content claims for trans fat at this time)

ALLOWED: 200mg isoflavones per serving (factual statement with no nutrient content claim terms)

NOT ALLOWED: excellent source of isoflavones (the term “excellent source” is a synonym for the nutrient content claim “high” which means 20% or more Daily Value per serving; since FDA has not established a Daily Value for isoflavones, this is an unauthorized nutrient content claim)

ALLOWED: 3g carb per serving (factual statement with no nutrient content claim terms)

NOT ALLOWED: Only 3g carb per serving (the term “only” implies a low level of nutrient and low carbohydrate claims are not allowed)

ALLOWED: 100 Calorie Pack (factual statement with no nutrient content claim terms)

NOT ALLOWED: Only 100 Calories (the term “only” implies a low level of a nutrient and the definition for low calorie is 40 calories or less per serving; this statement requires the addition of a disclaimer “Only 100 calories, not a low calorie food.”)

ALLOWED: Contains 10mg lutein (factual statement with English use of the word “contains” preceding a quantitative amount)

NOT ALLOWED: Contains lutein (use of the word “contains” without the quantitative amount is a nutrient content claim that means 10% or more Daily Value per serving; since FDA has not established a Daily Value for lutein, this is an unauthorized nutrient content claim)

ALLOWED: Made with oat bran (factual as long as the product contains a significant amount of oat bran in the formulation, generally more than 2% by weight)

NOT ALLOWED: High in oat bran (implies a high level of fiber, which means 20% or more Daily Value per serving; if the product contains less than 20% Daily Value then the claim is not valid)

ALLOWED: Glycemic index of this product is 41 (when based on a clinical trial of the product)

NOT ALLOWED: Low glycemic foods help control diabetes (this is an unauthorized health claim)

## 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](http://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](http://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.*



## STRUCTURE/FUNCTION CLAIMS ...

- ... describe the role of a nutrient or functional component in affecting or maintaining normal body structure or function or general well-being
- ... cannot describe or imply that a nutrient or functional component affects a disease or health-related condition via diagnoses, cure, mitigation, treatment, or prevention (a claim doing this is an unauthorized drug claim)
- ... can be used on FDA-regulated conventional foods and dietary supplements
- ... cannot be used on USDA-regulated products because USDA does not recognize these claims
- ... are not pre-approved by FDA but the manufacturer must have substantiation on file (clinical studies or other research) to show that the claim is truthful and not misleading
- ... 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)
- ... require that the label of a dietary supplement includes the following disclaimer placed adjacent to the statement with no intervening material, or enclosed in a box and linked to the statement with an asterisk or other symbol (labels for conventional foods do not require this disclaimer)

\*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

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### EXAMPLES AND EXPLANATIONS:

ALLOWED: Antioxidants help maintain cell integrity (no mention of disease)

NOT ALLOWED: Antioxidants prevent the onset of cancer (this is an unapproved drug claim)

ALLOWED: Echinacea supports the body's immune system (no mention of disease)

NOT ALLOWED: Echinacea is useful in preventing colds (this is an unapproved drug claim)

ALLOWED: Calcium builds strong bones (no mention of disease)

NOT ALLOWED: Calcium reduces the risk of osteoporosis (this is an unapproved drug claim)

NOTE: A labeler may opt to use the FDA-approved health claim for calcium and osteoporosis (instead of or in addition to a structure/function claim for calcium and bone health) provided that all requirements for use of the health claim are followed. The model health claim for this nutrient/disease relationship "Adequate calcium throughout life, as part of a well-balanced diet, may reduce their risk of osteoporosis later in life." includes reference to a well-balanced diet and adequate calcium throughout life.



## Examples of Allowable Structure/Function Claims\*

Component Category	Component Sub-category	Structure or Function
Vitamins (Water-Soluble)	Vitamin B1 (Thiamin)	may contribute to maintenance of mental function helps regulate metabolism
	Vitamin B2 (Riboflavin)	helps regulate metabolism helps support cell growth
	Vitamin B3 (Niacin)	helps regulate metabolism helps support cell growth
	Vitamin B5 (Pantothenic Acid)	helps regulate metabolism helps regulate hormone synthesis
	Vitamin B6 (Pyridoxine)	may contribute to maintenance of healthy immune function helps regulate metabolism
	Vitamin B9 (Folate/Folic Acid)	supports healthy brain and spinal cord development may contribute to maintenance of heart health
	Vitamin B12 (Cyanocobalamin)	helps regulate metabolism supports blood cell formation may contribute to maintenance of mental function
	Biotin	helps regulate metabolism helps regulate hormone synthesis
	Vitamin C	functions as an antioxidant to neutralize free radicals may contribute to healthy immune function may contribute to maintenance of bone health
Vitamins (Fat-Soluble)	Vitamin A	may contribute to maintenance of healthy vision may contribute to maintenance of healthy immune function may contribute to bone health may contribute to cell integrity
	Vitamin D	helps regulate calcium and phosphorus helps contribute to bone health may contribute to healthy immune function helps support cell growth
	Vitamin E	functions as an antioxidant to neutralize free radicals may contribute to healthy immune function may contribute to maintenance of heart health
	Vitamin K	helps support normal blood clotting
Minerals	Calcium	builds strong bones
	Magnesium	contributes to bone health and healthy immune function
	Potassium	helps maintain a healthy blood pressure level, in combination with a low-sodium diet
	Selenium	neutralizes free radicals and supports a healthy immune system



Component Category	Component Sub-category	Structure or Function
Carotenoids	Beta carotene	may neutralize free radicals may increase cellular antioxidant defense
	Lutein, Zeaxanthin	may help maintain healthy vision
	Lycopene	may help maintain prostate health
Fatty Acids	ALA, DHA/EPA (Omega-3 fatty acids)	may contribute to maintenance of heart health may contribute to maintenance of mental and visual function
	Conjugated linoleic acid	may contribute to maintenance of desirable body composition may contribute to maintenance of healthy immune function
Flavonoids	Anthocyanins (Cyanidin, Delphinidin, Malvidin)	supports antioxidant defenses may contribute to maintenance of brain function
	Flavanols (Catechins, Epicatechins, Epigallocatechin, Procyanidins)	may contribute to heart health
	Flavanones (Hesperetin, Naringenin)	neutralizes free radicals and supports cellular antioxidant defenses
	Flavonols (Quercetin, Kaempferol, Isorhamnetin, Myricetin)	neutralizes free radicals and supports cellular antioxidant defenses
	Proanthocyanidins	may contribute to urinary tract health and heart health
Isothiocyanates	Sulforaphane	bolsters cellular antioxidant defenses
Phenolic Acids	Caffeic acid, Ferulic acid	may contribute to maintenance of healthy vision may contribute to maintenance of a healthy heart may bolster cellular antioxidant defenses
Prebiotics	Inulin, Fructo-oligosaccharides (FOS), Polydextrose	may improve gastrointestinal health may improve calcium absorption
Probiotics	Yeast, Lactobacilli, Bifidobacteria, and other specific strains of beneficial bacteria	may improve gastrointestinal health and systemic immunity (benefits are strain specific)
Phytoestrogens	Isoflavones (Daidzein, Genistein)	may contribute to maintenance of bone health may contribute to a healthy brain may contribute to healthy immune function for women, may contribute to maintenance of menopausal health
	Lignans	may contribute to maintenance of heart health may contribute to healthy immune function
Sulfides/Thiols	Diallyl sulfide, Allyl methyl trisulfide	may enhance the body's detoxification process may contribute to maintenance of heart health may contribute to a healthy immune function
	Dithiolthiones	may enhance the body's detoxification process may contribute to maintenance of healthy immune function

\* Adapted from "Functional Foods" by International Food Information Council Foundation ([www.ific.org](http://www.ific.org))



## DIETARY GUIDANCE STATEMENTS ...

- ... typically explain the relationship between a group of foods (e.g., fruits and vegetables, whole grains) and health
- ... can mention either a specific nutrient or functional component or a disease or health-related condition (but not both)
- ... can be used on conventional foods only (not dietary supplements)
- ... are not pre-approved by FDA but must be truthful and not misleading
- ... can be based on Dietary Guidelines for Americans, MYPyramid, and other dietary recommendations made by recognized governmental and private health organizations

### EXAMPLES AND EXPLANATIONS:

Fruits and vegetables can protect your health. (This statement mentions groups of food based on the Center for Disease Control and Prevention's Fruits & Veggies - More Matters™ campaign.)

MYPyramid recommends that children ages 6-11 years old eat 1 ½ cups of fruit each day. (This statement is based on USDA's MYPyramid.)



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