

## Requirements For Health Claims Made in Labeling

Approved Claims	Requirements for the Food	Claim Requirements	Model Claim Statements
<b>Calcium and Osteoporosis</b>	For calcium and osteoporosis claim - high in calcium	The claim makes clear the importance of adequate calcium intake throughout life in a healthful diet to reduce osteoporosis risk. It does not imply that calcium intake is the only recognized risk factor for osteoporosis.	Calcium and Osteoporosis: Adequate calcium throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis. (21 CFR 101.72)
<b>Calcium, Vitamin D, and Osteoporosis</b>	For calcium, vitamin D and osteoporosis claim - high in calcium and vitamin D	The claim does not attribute any degree of reduction in osteoporosis risk to maintaining adequate calcium and vitamin D intake throughout life. It must be assimilable (bioavailable). Supplements must disintegrate and dissolve. Phosphorus content cannot exceed calcium content.	Calcium, vitamin D and osteoporosis: Adequate calcium and vitamin D, as part of a well balanced diet, along with physical activity, may reduce the risk of osteoporosis.

**Source:** Appendix C & D of The Official FDA Food Labeling Guide

(<https://www.fda.gov/files/food/published/Food-Labeling-Guide-%28PDF%29.pdf>)

<p><b>Dietary Fat and Cancer</b></p>	<p>Low fat (Fish &amp; game meats: "Extra lean")</p>	<p><b>Required terms:</b></p> <p>"Total fat" or "Fat"</p> <p>Development of cancer depends on many factors. The claim does not specify types of fats or fatty acids related to cancer risk.</p>	<p>Some types of cancers may be reduced by a diet low in fat. (21 CFR 101.73)</p>
<p><b>Sodium and Hypertension</b></p>	<p>Low sodium</p>	<p><b>Required terms:</b></p> <p>"Sodium", "High blood pressure"</p> <p>Includes a physician consult statement if defining high or normal blood pressure. (21 CFR 101.74)</p>	<p>Diets low in sodium may reduce the risk of high blood pressure.</p>
<p><b>Dietary Saturated Fat and Coronary Heart Disease</b></p>	<p>Low saturated fat</p> <p>Low cholesterol</p> <p>Low fat</p>	<p><b>Required terms:</b></p> <p>"Coronary heart disease" or "heart disease"</p> <p>Includes physician consult statement if defining high or normal cholesterol levels. (21 CFR 101.75)</p>	<p>While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk.</p>

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<p><b>Fiber-Containing Grain Products, Fruits, and Vegetables and Cancer</b></p>	<p>A grain product, fruit, or vegetable that contains dietary fiber;</p> <p>Low fat</p> <p>Good source of dietary fiber (without fortification)</p>	<p><b>Required terms:</b></p> <p>“Fiber”, “Dietary fiber”, or “Total dietary fiber”</p> <p>“Some types of cancer” or “Some cancers”</p> <p>Does not specify types of dietary fiber that may be related to risk of cancer.</p>	<p>Low-fat diets rich in fiber-containing grain products, fruits, and vegetables may reduce the risk of some types of cancer.</p>
<p><b>Fruits, Vegetables and Grain Products that contain Fiber, particularly Soluble Fiber, and Risk of Coronary Heart Disease</b></p>	<p>A fruit/vegetable/grain product that contains fiber; Low saturated fat, Low cholesterol, Low fat, at least 0.6 grams of soluble fiber per RACC (without fortification), and soluble fiber content provided on label</p>	<p><b>Required terms:</b></p> <p>“Fiber”, “Dietary fiber”, “Some types of dietary fiber”, “Some dietary fibers”, or “Some fibers”, “Saturated fat” and “Cholesterol”, “Heart disease” or “Coronary heart disease”</p>	<p>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. (21 CFR 101.77)</p>

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<p><b>Fruits and Vegetables and Cancer</b></p>	<p>A fruit or vegetable; Low fat, Good source (without fortification) of at least one of the following:</p> <ul style="list-style-type: none"> <li>•Vitamin A</li> <li>•Vitamin C</li> </ul> <p>or</p> <ul style="list-style-type: none"> <li>•Dietary fiber</li> </ul>	<p><b>Required terms:</b></p> <p>“Fiber”, “Dietary fiber”, or “Total dietary fiber”; “Total fat” or “Fat”, “Some types of cancer” or “Some cancers”</p> <p>Characterizes fruits and vegetables as “Foods that are low in fat and may contain Vitamin A, Vitamin C, and dietary fiber”. Does not specify types of fats/fatty acids/types of dietary fiber that may be related to risk of cancer.</p>	<p>Low fat diets rich in fruits and vegetables (foods that are low in fat and may contain dietary fiber, Vitamin A, or Vitamin C) may reduce the risk of some types of cancer. Broccoli is high in vitamin A and C, and it is a good source of dietary fiber. (21 CFR 101.78)</p>
<p><b>Soluble Fiber &amp; Risk of Coronary Heart Disease</b></p>	<p>Low saturated fat, cholesterol, fat</p> <p><b>Must include:</b> oat bran, rolled oats, whole oat flour, whole grain barley, dry milled barley with ≥ 0.75 g soluble fiber/RACC</p> <p>Oatrim with ≥ 0.75 g beta-glucan soluble/RACC</p> <p>Psyllium husk with ≥ 1.7 g soluble fiber/RACC</p> <p><b>Eligible Sources:</b> Oat bran, Rolled Oats, Whole Oat Flour, Oatrim, Whole Grain Barley, Dry Milled Barley,</p>	<p><b>Required terms:</b></p> <p>“Heart disease” or “coronary heart disease”, “Saturated fat”, “cholesterol”</p> <p>Specify “soluble fiber” by eligible source</p> <p>Specify daily intake &amp; amount in serving</p> <p>Declare fiber amount/RACC</p>	<p>Soluble fiber from [fiber source, food product], in a low saturated fat &amp; cholesterol diet, may reduce heart disease risk. A serving of [food product] provides ^ grams of [daily intake] soluble fiber from [fiber source].</p>

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Barley Betafiber, ≥ 95%  
pure psyllium husk

**The FDAMA (FDA Modernization Act) Health Claims (Health Claims Authorized Based on an Authoritative Statement by Federal Scientific Bodies)**

Approved Claims	Requirements for the Food	Claim Requirements	Model Claim Statements
<p><b>Whole Grain Foods and Risk of Heart Disease and Certain Cancers</b></p>	<p>Contains ≥ 51% whole grain ingredients by weight per RACC</p> <p>Dietary fiber content at least:</p> <ul style="list-style-type: none"> <li>• 3.0 g per RACC of 55 g</li> <li>• 2.8 g per RACC of 50 g</li> <li>• 2.5 g per RACC of 45 g</li> <li>• 1.7 g per RACC of 35 g</li> </ul>	<p>Required wording for the claim</p>	<p>“Diets rich in whole grain foods and other plant foods and low in total fat, saturated fat, and cholesterol may reduce the risk of heart disease and some cancers.”</p>
<p><b>Whole Grain Foods with Moderate Fat Content and Risk of Heart Disease</b></p>	<p>Contains ≥ 51% whole grain ingredients by weight per RACC</p> <p>Dietary fiber content at least:</p> <ul style="list-style-type: none"> <li>• 3.0 g per RACC of 55 g</li> </ul>	<p>Required wording for the claim</p>	<p>“Diets rich in whole grain foods and other plant foods, and low in total fat, saturated fat, and cholesterol may help reduce the risk of heart disease.”</p>

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	<ul style="list-style-type: none"> <li>• 2.8 g per RACC of 50 g</li> <li>• 2.5 g per RACC of 45 g</li> <li>• 1.7 g per RACC of 35 g</li> </ul>		
<b>Potassium and the Risk of High Blood Pressure and Stroke</b>	<p>Good source of potassium</p> <p>Low sodium</p> <p>Low total fat</p> <p>Low saturated fat</p> <p>Low cholesterol</p>	Required wording for the claim	“Diets containing foods that are a good source of potassium and that are low in sodium may reduce the risk of high blood pressure and stroke.”
<b>Fluoridated Water and Reduced Risk of Dental Caries</b>	<p>Bottled water meeting standards in 21 CFR 165.110</p> <p>Meet all general health claim requirements in 21 CFR 101.14 except minimum nutrient contribution (21 CFR 101.14(e)(6))</p> <p>Total Fluoride: &gt;0.6 to 1.0 mg/L</p> <p>Excludes bottled water for infants</p>	Required wording for the claim	“Drinking fluoridated water may reduce the risk of [dental caries or tooth decay].”

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<p><b>Saturated Fat, Cholesterol, and Trans Fat, and Reduced Risk of Heart Disease</b></p>	<p>Low saturated fat</p> <p>Low cholesterol</p> <p>Bear quantitative trans fat labeling</p> <p>Contains &lt; 0.5 g trans fat per RACC</p> <p>Contains &lt; 6.5 g total fat</p>	<p>Required wording for the claim</p>	<p>“Diets low in saturated fat and cholesterol, and as low as possible in trans fat, may reduce the risk of heart disease.”</p>
<p><b>Substitution of Saturated Fat in the Diet with Unsaturated Fatty Acids and Reduced Risk of Heart Disease</b></p>	<p>Low fat and low cholesterol</p> <p>Meets all general health claim requirements in 21 CFR 101.14</p>	<p>Required wording for the claim</p>	<p>“Replacing saturated fat with similar amounts of unsaturated fats may reduce the risk of heart disease. To achieve this benefit, total daily calories should not increase.”</p>

**Qualified Health Claims**

Qualified Health Claims	Eligible Foods	Factors for Exercising Enforcement Discretion	Claim Statements
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<p><b>Nuts &amp; Heart Disease</b></p> <p><b>(Docket No. 2002P-0505 07/14/2003)</b></p>	<p>(1) Whole or chopped nuts (raw, blanched, roasted, salted, lightly coated/flavored) with added fat/carb meeting 21 CFR 101.9(f)(1).</p> <p>(2) Nut-containing products with at least 11 g of specific nuts per RACC.</p> <p>(3) Specific nuts: almonds, hazelnuts, peanuts, pecans, some pine nuts, pistachios, walnuts.</p>	<p>Whole/chopped nuts don't need to comply with total fat disqualifying level in 21 CFR 101.14(a)(4). Only walnuts exempt from 10% Daily Value per RACC requirement.</p> <p>Disclosure statement adjacent &amp; below claim in same size/typeface.</p> <p>Nuts with claim must meet 21 CFR 101.14(a)(4) saturated fat level (4 g/50 g nuts).</p> <p>Nut-products with claim must comply with 21 CFR 101.14(a)(4) disqualifying levels, be low in saturated fat/cholesterol, and meet 10% Daily Value per RACC for specific nutrients.</p>	<p>Scientific evidence suggests but doesn't prove that eating 1.5 oz/day of most nuts as part of a low saturated fat/cholesterol diet may reduce heart disease risk. [See nutrition info for fat content.] Note: Specific nut naming is optional. Fat content disclosure for whole/chopped nuts only.</p>
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<p><b>Walnuts &amp; Heart Disease</b></p> <p><b>(Docket No. 2002P-029 03/09/2004)</b></p>	<p>Whole or chopped walnuts</p>	<p>Walnuts exempt from total fat disqualifying level in 21 CFR 101.14(a)(4).</p> <p>Walnuts exempt from 10% Daily Value per RACC requirement for specific nutrients.</p> <p>Disclosure statement about fat content adjacent &amp; following claim in same size/typeface.</p>	<p>Supportive but not conclusive research shows eating 1.5 oz/day of walnuts in a low saturated fat/cholesterol diet, without increasing caloric intake, might reduce coronary heart disease risk. See nutrition info for fat [and calorie] content. Note: “and calorie” phrase is optional. FDA encourages its inclusion for consumer awareness.</p>
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<p><b>Omega-3 Fatty Acids &amp; Coronary Heart Disease</b></p> <p><b>(Docket No. 2003Q-0401)</b></p>	<p>Conventional foods and dietary supplements containing EPA and DHA omega-3 fatty acids.</p>	<p><b>Dietary supplements:</b> Max daily intake recommendation ≤ 2 grams of EPA and DHA.</p> <p><b>Supplements ≤ 5g/RACC:</b> Exempt from total fat disqualifying level; if exceeded, must disclose fat content.</p> <p><b>Supplements &gt; 5g/RACC:</b> Must not exceed total fat disqualifying level.</p> <p><b>Fish:</b> Max total fat ≤ 16.0g/RACC; if &gt; 13.0g, must disclose fat content.</p> <p><b>Other foods:</b> Must not exceed total fat disqualifying levels.</p> <p><b>Saturated fat &amp; cholesterol:</b> Specific criteria for supplements, fish, and other foods.</p> <p><b>Sodium:</b> All foods and supplements must meet sodium disqualifying level.</p> <p><b>10% minimum nutrient requirement:</b> Applies to all conventional foods.</p>	<p>Supportive but not conclusive research shows consumption of EPA and DHA omega-3 fatty acids may reduce coronary heart disease risk. One serving provides [ ] gram of EPA and DHA. See nutrition info for fat, saturated fat, and cholesterol content.</p>
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<p><b>Monounsaturated Fatty Acids From Olive Oil &amp; Coronary Heart Disease</b></p> <p><b>(Docket No. 2003Q-0559)</b></p>	<p>Pure olive oil products</p> <p>Salad dressings with ≥ 6g olive oil/RACC</p> <p>Vegetable oil spreads with ≥ 6g olive oil/RACC</p> <p>Olive oil-containing foods with ≥ 6g olive oil/RACC</p> <p>Shortenings with ≥ 6g olive oil/RACC</p>	<p>Exemption from total fat disqualifying level for certain products.</p> <p>Specific saturated fat requirements based on RACC.</p> <p>Disclosure statements required for certain fat contents.</p> <p>Meal/Main dish products ineligible.</p>	<p>Limited evidence suggests 2 tablespoons daily of olive oil may reduce coronary heart disease risk due to its monounsaturated fat. Replace similar amount of saturated fat without increasing total daily calories. One serving provides [x] grams of olive oil.</p>
<p><b>Tomatoes and/or Tomato Sauce &amp; Prostate, Ovarian, Gastric, and Pancreatic Cancers</b></p> <p><b>(Docket No. 2004Q0201)</b></p>	<p>(1) Cooked, Raw, Dried, or Canned Tomatoes</p> <p>(2) Tomato Sauces with ≥ 8.37% salt-free tomato solids</p>	<p>-</p>	<p><b>Prostate Cancer:</b> Limited research suggests ½ to 1 cup of tomatoes or tomato sauce weekly might reduce risk, but evidence is weak.</p> <p><b>Ovarian Cancer:</b> One study suggests tomato sauce twice weekly might reduce risk, but it's highly uncertain.</p> <p><b>Gastric Cancer:</b> Mixed studies; unlikely tomatoes reduce risk.</p>

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			<b>Pancreatic Cancer:</b> Mixed studies; highly unlikely tomatoes reduce risk.
<b>Unsaturated Fatty Acids from Canola Oil and Reduced Risk of Coronary Heart Disease</b>  <b>(Docket No. 2006Q0091)</b>	<p>Canola oil</p> <p>Vegetable oil spreads, dressings for salads, shortenings, and canola oil-containing foods with <math>\geq 4.75</math> g canola oil per RACC</p> <p>Low in saturated fat, cholesterol, and meet certain levels for saturated fat, cholesterol, and sodium</p>	<p>Canola oil and certain products don't need to comply with the total fat disqualifying level in 21 CFR 101.14(a)(4).</p> <p>Products exceeding total fat disqualifying level must have a disclosure statement.</p>	<p>Limited evidence suggests about 1 1/2 tbsp of canola oil daily might reduce coronary heart disease risk due to unsaturated fat. To benefit, replace similar amount of saturated fat without increasing total calorie intake. One serving contains [x] grams of canola oil.</p>

Definitions for the qualified health claim:

- “Canola oil” means products that are essentially pure canola oil and are labeled as such.
- “Vegetable oil spread” means margarine (21 CFR 166.110) and margarine-like products, formulated to contain canola oil.
- “Dressings for salads” means dressings for salads formulated to contain canola oil.
- “Shortenings” means vegetable oil shortenings, formulated to contain canola oil.

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- “Canola oil-containing foods” means other foods, like sauces or baked goods, formulated to contain canola oil, excluding canola oil, vegetable oil spreads, dressings for salads, and shortenings.

Qualified Health Claims	Eligible Foods	Factors for Exercising Enforcement Discretion	Claim Statements	Definitions
<p><b>Corn Oil &amp; Reduced Risk of Heart Disease</b></p> <p><b>(Docket No. 2006P0243)</b></p>	<p>Corn oil</p> <p>Oil blends, shortenings, dressings, spreads with specific corn oil content.</p>	<p>Certain products exempt from total fat disqualifying level in 21 CFR 101.14(a)(4).</p> <p>Disclosure needed if exceeding fat level.</p> <p>Specific exemptions for saturated fat and nutrient levels.</p>	<p>About 1 tbsp of corn oil daily might reduce heart disease risk.</p> <p>Replace saturated fat, maintain calorie intake. Serving contains [x] grams.</p>	<ol style="list-style-type: none"> <li>1. “corn oil” = pure labeled corn oil.</li> <li>2. “vegetable oil blends” = blend of oils with corn oil.</li> <li>3. “spread” = margarine with corn oil.</li> <li>4. “dressings” = salad dressings with corn oil.</li> <li>5. “shortenings” = oil shortenings with corn oil.</li> <li>6. “corn oil-containing foods” = foods like sauces/baked goods with corn oil, excluding specific products.</li> </ol>

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**100%  
Whey-Protein  
Partially  
Hydrolyzed Infant  
Formula & Atopic  
Dermatitis**

**(Docket No.  
FDA-2009-Q0301)**

100%  
Whey-Protein  
Partially  
Hydrolyzed  
Infant Formula

"Partially hydrolyzed formulas should not be fed to infants who are allergic to milk or with existing milk allergy symptoms. If suspected, your baby's care should be under a doctor's supervision."

1. "Very little scientific evidence suggests that for infants with a family history of allergy, this formula may reduce the risk of developing atopic dermatitis up to 3 years of age."

2. "Little scientific evidence suggests that this formula may reduce the risk of developing atopic dermatitis throughout the 1st year of life."

3. "This formula may reduce the risk of developing atopic dermatitis up to 3 years of age. FDA finds the relationship uncertain due to very little scientific evidence."

4. "This formula may reduce the risk of developing atopic dermatitis throughout the 1st year of life. FDA finds the relationship uncertain due to little scientific evidence."

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