

# FDA HEALTH CLAIM AND QUALIFIED HEALTH CLAIM GUIDELINES

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***From Guidance for Industry: A Food Labeling Guide (Appendix C: Health Claims and Appendix D: Qualified Health Claims)***

## Appendix C: Health Claims

**Requirements for Health Claims Made in Labeling**

| Approved Claims  | Requirements for the Food   | Claim Requirements   | Model Claim, Statements  |
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| <p>Calcium and Osteoporosis and calcium, vitamin D, and osteoporosis</p> <p><i>(21 CFR 101.72)</i></p> | <p>For calcium and osteoporosis claim-high in calcium</p> <p>For calcium, vitamin D and osteoporosis claim-high in calcium and vitamin D -assimilable (Bioavailable)</p> <p>Supplements must disintegrate and dissolve, and</p> <p>Phosphorus content cannot exceed calcium content</p> | <p>Calcium and Osteoporosis: Adequate calcium throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis.</p> <p>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.</p> | <p>The claim makes clear the importance of adequate calcium intake, or when appropriate, adequate calcium and vitamin D intake, throughout life, in healthful diet, are essential to reduce osteoporosis risk. The claim does not imply that adequate calcium intake, or when appropriate, adequate calcium and vitamin D intake, is the only recognized risk factor for the development of osteoporosis.</p> <p>The claim does not attribute any degree of reduction in risk of osteoporosis to maintaining an adequate dietary calcium intake, or when appropriate, an adequate dietary calcium and vitamin D intake, throughout life.</p> |

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| <p>Dietary Fat and Cancer</p> <p>(21 CFR 101.73)</p>   | <p>Low fat<br/>(Fish &amp; game meats: "Extra lean")</p>   | <p><b>Required terms:</b><br/>"Total fat" or "Fat"<br/>"Some types of cancers" or "Some cancers"<br/>Does not specify types of fats or fatty acids that may be related to risk of cancer.</p>   | <p>Development of cancer depends on many factors. A diet low in total fat may reduce the risk of some cancers.</p>   |
| <p>Sodium and Hypertension</p> <p>(21 CFR 101.74)</p>  | <p>Low sodium</p>  | <p><b>Required terms:</b><br/>"Sodium", "High blood pressure"<br/>Includes physician statement (Individuals with high blood pressure should consult their physicians) if claim defines high or normal blood pressure</p>  | <p>Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors.</p>   |
| <p>Dietary Saturated Fat and Cholesterol, and risk of Coronary Heart Disease</p> <p>(21 CFR 101.75)</p>  | <p>Low saturated fat,<br/>Low cholesterol, and<br/>Low fat</p>   | <p><b>Required terms:</b><br/>Saturated fat and cholesterol,<br/>"Coronary heart disease" or heart disease<br/>Includes physician statement (individuals with elevated blood total--or LDL--cholesterol should consult their physicians) if claim defines high or normal blood total--and LDL--cholesterol.</p>   | <p>While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease.</p>  |
| <p>Fiber-Containing Grain Products, Fruits, and Vegetables and Cancer</p> <p>(21 CFR 101.76)</p>   | <p>A grain product, fruit, or vegetable that contains dietary fiber;<br/>Low fat, and<br/>Good source of dietary fiber (without fortification)</p>   | <p><b>Required terms:</b><br/>"Fiber", "Dietary fiber", or "Total dietary fiber"<br/>"Some types of cancer" or "Some cancers"<br/>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, a disease associated with many factors.</p>  |
| <p>Fruits, Vegetables and Grain Products that contain Fiber, particularly Soluble Fiber, and Risk of V Coronary Heart Disease</p> <p>(21 CFR 101.77)</p> | <p>A fruit, vegetable, or grain product that contains fiber;<br/>Low saturated fat,<br/>Low cholesterol,<br/>Low fat,<br/>At least 0.6 grams of soluble fiber per RACC (without fortification), and,<br/>Soluble fiber content provided on label</p> | <p><b>Required terms:</b><br/>"Fiber", "Dietary fiber", "Some types of dietary fiber", "Some dietary fibers", or "Some fibers"<br/>"Saturated fat" and "Cholesterol"<br/>"Heart disease" or "Coronary heart disease"<br/>Includes physician statement ("Individuals with elevated blood total--or LDL--cholesterol should consult their physicians") if claim defines high or normal blood total--and LDL--cholesterol.</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.</p> |

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| <p>Fruits and Vegetables and Cancer</p> <p>(21 CFR 101.78)</p>                                | <p>A fruit or vegetable, Low fat, and 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, or</li> <li>Dietary fiber</li> </ul>  | <p><b>Required terms:</b></p> <p>"Fiber", "Dietary fiber", or "Total dietary fiber";</p> <p>"Total fat" or "Fat",</p> <p>"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."</p> <p>Characterizes specific food as a "Good source" of one or more of the following: Dietary fiber, Vitamin A, or Vitamin C.</p> <p>Does not specify types of fats or fatty acids or 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, a disease associated with many factors. Broccoli is high in vitamin A and C, and it is a good source of dietary fiber.</p> |
| <p>Folate and Neural Tube Defects</p> <p>(21 CFR 101.79)</p>                                  | <p>"Good source" of folate (at least 40 mcg folate per serving)</p> <p>Dietary supplements, or foods in conventional food form that are naturally good sources of folate (i.e., only non-fortified food in conventional food form)</p> <p>The claim shall not be made on products that contain more than 100% of the RDI for vitamin A as retinol or preformed vitamin A or vitamin D</p> <p>Dietary supplements shall meet USP standards for disintegration and dissolution or otherwise bioavailable</p> <p>Amount of folate required in Nutrition Label</p> | <p><b>Required terms:</b></p> <p>Terms that specify the relationship (e.g., women who are capable of becoming pregnant and who consume adequate amounts of folate) "Folate", "folic acid", "folacin", "folate a B vitamin", "folic acid, a B vitamin," "folacin, a B vitamin," "neural tube defects", "birth defects, spinal bifida, or anencephaly", "birth defects of the brain or spinal cord -- anencephaly or spinal bifida", "spinal bifida or anencephaly, birth defects of the brain or spinal cord".</p> <p>Must also include information on the multifactorial nature of neural tube defects, and the safe upper limit of daily intake.</p> | <p>Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord defect.</p>   |
| <p>Dietary Noncariogenic Carbohydrate Sweeteners and Dental Caries</p> <p>(21 CFR 101.80)</p> | <p>Sugar free, and</p> <p>When a fermentable carbohydrate is present, the food must not lower plaque pH below 5.7.</p> <p><b>Eligible substances</b></p> <p>1) The following sugar alcohols: xylitol, sorbitol, mannitol, maltitol, isomalt, lactitol, hydrogenated starch hydrolysates, hydrogenated glucose syrups, erythritol, or a combination of these.</p> <p>2) The following sugar: D-tagatose</p>   | <p><b>Required terms:</b></p> <p>"does not promote," "may reduce the risk of," "useful [or is useful] in not promoting" or "expressly [or is expressly] for not promoting" dental caries;</p> <p>"dental caries" or "tooth decay."</p> <p>"sugar alcohol" or "sugar alcohols" or the name or names of the sugar alcohols; or D-tagatose, or sucralose</p> <p>Note: D-tagatose may be identified as "tagatose"</p>   | <p><b>Full claim:</b> Frequent between-meal consumption of foods high in sugars and starches promotes tooth decay. The sugar alcohols in [name of food] do not promote tooth decay.</p> <p><b>Shortened claim (on small packages only):</b> Does not promote tooth decay.</p>                             |

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|   | <p>3) The following non-nutritive sweetener:sucralose</p>  | <p>When the substance that is the subject of the claim is a noncariogenic sugar (i.e., D-tagatose) the claim shall identify the substance as a sugar that, unlike other sugars, does not promote the development of dental caries.</p> <p>Includes statement that frequent between meal consumption of foods high in sugars and starches can promote tooth decay.</p> <p>Packages with less than 15 square inches of surface area available for labeling may use a shortened claim.</p>  |   |
| <p>Soluble Fiber from Certain Foods and Risk of Coronary Heart Disease<br/><br/>(21 CFR 101.81)</p> | <p>Low saturated fat<br/>Low cholesterol<br/>Low fat, and<br/>The food product must include one or more of the following whole oat or barley foods: 1) oat bran, 2) rolled oats, 3) whole oat flour, 4) whole grain barley or dry milled barley, and the whole oat or barley foods must contain at least 0.75 g of soluble fiber per RACC of the food product; or<br/>Oatrim that contains at least 0.75 g of beta-glucan soluble per RACC of the food product; or<br/>Psyllium husk that contains at least 1.7 g of soluble fiber per RACC of food product.</p> <p><b>Eligible Sources of Soluble Fiber</b><br/>Beta-glucan soluble fiber from the following whole oat and barley sources:</p> <ol style="list-style-type: none"> <li>1) Oat bran</li> <li>2) Rolled Oats</li> <li>3) Whole Oat Flour</li> <li>4) Oatrim</li> <li>5) Whole Grain Barley and Dry Milled Barley</li> <li>6) Barley Beta Fiber</li> <li>7) Soluble fiber from psyllium husk with purity of no less than 95%</li> </ol> | <p><b>Required terms:</b><br/>"Heart disease" or "coronary heart disease."<br/>"Saturated fat" and "cholesterol."<br/>In specifying the substance the claim uses the term "soluble fiber" qualified by the name of the eligible source of the soluble fiber, which is either whole oat or barley or psyllium seed husk.<br/>Claim specifies the daily dietary intake of the soluble fiber source necessary to reduce the risk of CHD<br/>Claim specifies the amount of soluble fiber in one serving of the product.</p> <p><b>Additional Required Label Statement</b><br/>Foods bearing a psyllium seed husk health claim must also bear a label statement concerning the need to consume them with adequate amounts of fluids; e.g., "NOTICE: This food should be eaten with at least a full glass of liquid. Eating this product without enough liquid may cause choking. Do not eat this product if your have difficulty in swallowing."<br/>(21 CFR 101.17(f))</p> | <p>Soluble fiber from foods such as [name of soluble fiber source, and, if desired, name of food product], as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of food product] supplies __ grams of the [necessary daily dietary intake for the benefit] soluble fiber from [name of soluble fiber source] necessary per day to have this effect.</p> |

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|  | The amount of soluble fiber per RACC must be declared in nutrition label.   |   |   |
| Soy Protein and Risk of Coronary Heart Disease<br><br>(21 CFR 101.82)                | At least 6.25 g soy protein per RACC<br>Low saturated fat,<br>Low cholesterol, and<br>Low fat (except that foods made from whole soybeans that contain no fat in addition to that inherent in the whole soybean are exempt from the "low fat" requirement)  | <b>Required terms:</b><br>"Heart disease" or "coronary heart disease"<br>"Soy protein"<br>"Saturated fat" and "cholesterol"<br>Claim specifies daily dietary intake levels of soy protein associated with reduced risk<br>Claim specifies amount of soy protein in a serving of food  | (1) 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. A serving of [name of food] supplies ___ grams of soy protein.<br>(2) Diets low in saturated fat and cholesterol that include 25 grams of soy protein a day may reduce the risk of heart disease. One serving of [name of food] provides ___ grams of soy protein.   |
| Plant Sterol/stanol esters and Risk of Coronary Heart Disease<br><br>(21 CFR 101.83) | At least 0.65 g plant sterol esters per RACC of spreads and salad dressings, or<br>At least 1.7 g plant stanol esters per RACC of spreads, salad dressings, snack bars, and dietary supplements.<br>Low saturated fat,<br>Low cholesterol, and<br>Spreads and salad dressings that exceed 13 g fat per 50 g must bear the statement "see nutrition information for fat content"<br>Salad dressings are exempted from the minimum 10% DV nutrient requirement (see General Criteria below) | <b>Required terms:</b><br>"May" or "might" reduce the risk of CHD<br>"Heart disease" or "coronary heart disease"<br>"Plant sterol esters" or "plant stanol esters"; except "vegetable oil" may replace the term "plant" if vegetable oil is the sole source of the sterol/stanol ester<br>Claim specifies plant sterol/stanol esters are part of a diet low in saturated fat and cholesterol.<br>Claim does not attribute any degree of CHD risk reduction.<br>Claim specifies the daily dietary intake of plant sterol or stanol esters necessary to reduce CHD risk, and the amount provided per serving.<br>Claim specifies that plant sterol or stanol esters should be consumed with two different meals each day. | (1) Foods containing at least 0.65 gram per of vegetable oil sterol esters, eaten twice a day with meals for a daily total intake of least 1.3 grams, 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 ___ grams of vegetable oil sterol esters.<br>(2) Diets low in saturated fat and cholesterol that include two servings of foods that provide a daily total of at least 3.4 grams of plant stanol esters in two meals may reduce the risk of heart disease. A serving of [name of food] supplies ___ grams of plant stanol esters. |

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

| Approved Claims | Food Requirements | Claim Requirements | Model Claim |
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| Whole Grain Foods and Risk of Heart Disease and Certain Cancers<br>(Docket No. 1999P-2209)              | Contains 51 percent or more whole grain ingredients by weight per RACC, and<br>Dietary fiber content at least:<br>3.0 g per RACC of 55 g<br>2.8 g per RACC of 50 g<br>2.5 g per RACC of 45 g<br>1.7 g per RACC of 35 g<br>Low fat  | <b>Required wording of the claim:</b><br>"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." | NA         |
| Potassium and the Risk of High Blood Pressure and Stroke<br>(Docket No. 2000Q-1582)                     | Good source of potassium<br>Low sodium<br>Low total fat<br>Low saturated fat<br>Low cholesterol  | <b>Required wording for the claim:</b><br>"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."                     | NA         |
| Fluoridated Water and Reduced Risk of Dental Caries<br>(Docket No. 2006Q-0418)                          | Bottled water meeting the standards of identity and quality set forth in 21 CFR 165.110<br>Meet all general requirements for health claims in 21 CFR 101.14) with the exception of the minimum nutrient contribution (21 CFR 101.14(e)(6)),<br>Total Fluoride: >0.6 to 1.0 mg/L<br>Excluding bottled water products specifically marketed for use by infants | <b>Required wording for the claim:</b><br>"Drinking fluoridated water may reduce the risk of [dental caries or tooth decay]"   | NA         |
| Saturated Fat, Cholesterol, and Trans Fat, and Reduced Risk of Heart Disease<br>(Docket No. 2006Q-0458) | Low saturated fat<br>Low cholesterol<br>Bear quantitative trans fat labeling<br>Contain less than 0.5 g trans fat per RACC<br>Contain less than 6.5 g total fat  | <b>Required wording for the claim:</b><br>"Diets low in saturated fat and cholesterol, and as low as possible in <i>trans</i> fat, may reduce the risk of heart disease."                                    | NA         |

## Appendix D: Qualified Health Claims

FDA will exercise enforcement discretion for qualified health claims when the claim meets all general requirements of 21 CFR 101.14, except for the requirements that the claim meet the significant scientific agreement standard and that the claim be made in accordance with an authorizing regulation. Other factors that FDA will consider in exercising enforcement discretion are listed in the following qualified health claim table.

| Qualified Health Claims  | Eligible Foods   | Factors for Exercising Enforcement Discretion   | Claim Statements   |
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| <p><b>0.8 mg Folic Acid &amp; Neural Tube Birth Defects</b><br/> <i>Docket No. 1991N-100H</i><br/>           10/10/2000 enforcement discretion letter<br/>           04/03/2001 clarification letter<br/>           Note: there also is a folic acid/neural tube defect health claim authorized by regulation (see 21 CFR 101.79).</p> | <p>Dietary supplements containing folic acid</p>                         | <p>The disclaimer (i.e., FDA does not endorse this claim...) is placed immediately adjacent to and directly beneath the claim (i.e., 0.8 mg folic acid ...), with no intervening material, in the same size, typeface, and contrast as the claim.</p>   | <p>0.8 mg folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form. FDA does not endorse this claim. Public health authorities recommend that women consume 0.4 mg folic acid daily from fortified foods or dietary supplements or both to reduce the risk of neural tube defects.</p>                                     |
| <p><b>B Vitamins &amp; Vascular Disease</b><br/> <i>Docket No. 1999P-3029</i> 11/28/2000 enforcement discretion letter<br/>           05/15/2001 clarification letter</p>  | <p>Dietary supplements containing vitamin B6, B12, and/or folic acid</p> | <p>The disclaimer (i.e., FDA evaluated the above claim...) must be immediately adjacent to and directly beneath the first claim (i.e., As part of a well-balanced diet...) with no intervening material that separates the claim from the disclaimer, and the second sentence must be in the same size, type face and contrast as the first sentence.</p> <p>Products that contain more than 100 percent of the Daily Value (DV) of folic acid (400 micrograms), when labeled for use by adults and children 4 or more years of age, must identify the safe upper limit of daily intake with respect to the DV. The folic acid safe upper limit of daily intake value of 1,000 micrograms (1 mg) may be included in parentheses.</p> <p>The claim does not suggest a level of vitamins B6, B12, and/or folic acid as being useful in achieving the claimed effect.</p> <p>Dietary supplements containing folic acid must meet the United States Pharmacopeia (USP) standards for disintegration and dissolution, except that if there are no applicable USP standards, the folate in the dietary supplement shall be shown to be bioavailable under the conditions of use stated on the product</p> | <p>As part of a well-balanced diet that is low in saturated fat and cholesterol, Folic Acid, Vitamin B6 and Vitamin B12 may reduce the risk of vascular disease. FDA evaluated the above claim and found that, while it is known that diets low in saturated fat and cholesterol reduce the risk of heart disease and other vascular diseases, the evidence in support of the above claim is inconclusive.</p> |

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| <p><b>Selenium &amp; Cancer</b><br/> Docket No. 2002P-0457 02/21/2003 enforcement discretion letter<br/> 04/28/2003 clarification letter</p> | Dietary supplements containing selenium                       | <p>The disclaimer (i.e., Some scientific evidence suggests...) is placed immediately adjacent to and directly beneath the claim (i.e., Selenium may reduce the risk), with no intervening material, in the same size, typeface, and contrast as the claim itself</p> <p>The supplement does not recommend or suggest in its labeling, or under ordinary conditions of use, a daily intake exceeding the Tolerable Upper Intake Level established by the National Academy of Sciences/Institute of Medicine for selenium (400 micrograms per day).</p> <p>Paragraph 101.14(d)(2)(vii) requires that the dietary supplement bearing the claim meet the nutrient content claim definition for high (i.e., 20% or more of the daily value (DV) per RACC). 20% DV for selenium is 14 micrograms.</p> | <p>(1) Selenium may reduce the risk of certain cancers. Some scientific evidence suggests that consumption of selenium may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive. or,</p> <p>(2) Selenium may produce anticarcinogenic effects in the body. Some scientific evidence suggests that consumption of selenium may produce anticarcinogenic effects in the body. However, FDA has determined that this evidence is limited and not conclusive.</p>   |
| <p><b>Antioxidant Vitamins &amp; Cancer</b><br/> Docket No. 1991N-0101 04/01/2003 enforcement discretion letter</p>                          | Dietary supplements containing vitamin E and/or vitamin C     | <p>The disclaimer (i.e., ...evidence is limited and not conclusive) is placed immediately adjacent to and below the claim, with no intervening material, in the same size, typeface, and contrast as the claim itself.</p> <p>The supplement does not recommend or suggest in its labeling, or under ordinary conditions of use, a daily intake exceeding the Tolerable Upper Intake Levels established by the Institute of Medicine for vitamin C (2000 mg per day) or for vitamin E (1000 mg per day).</p> <p>Paragraph 101.14(d)(2)(vii) requires that the food bearing the claim meet the nutrient content claim definition for high (i.e., 20% or more of the daily value (DV) per RACC). 20% DV for vitamin C is 12 mg; 20% DV for vitamin E is 6 IU.</p>                                 | <p>(1) Some scientific evidence suggests that consumption of antioxidant vitamins may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive. or,</p> <p>(2) Some scientific evidence suggests that consumption of antioxidant vitamins may reduce the risk of certain forms of cancer. However, FDA does not endorse this claim because this evidence is limited and not conclusive. or,</p> <p>(3) FDA has determined that although some scientific evidence suggests that consumption of antioxidant vitamins may reduce the risk of certain forms of cancer, this evidence is limited and not conclusive.</p> |
| <p><b>Phosphatidylserine &amp; Cognitive Dysfunction and Dementia</b></p>  | Dietary supplements containing soy-derived phosphatidylserine | <p>The disclaimer (i.e., Very limited and preliminary scientific research...) is placed immediately adjacent to and directly beneath the claim (i.e.,</p>   | <p>(1) Consumption of phosphatidylserine may reduce the risk of dementia in the elderly. Very</p>   |



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| <p>Docket No. 2002P-0413 02/24/2003 enforcement discretion letter 05/13/2003 clarification letter 11/24/2004 updated letter</p> |   | <p>Phosphatidylserine may reduce...), with no intervening material, in the same size, typeface, and contrast as the claim itself.</p> <p>The claim does not suggest a level of phosphatidylserine as being useful in achieving the claimed effect.</p> <p>The soy-derived phosphatidylserine used is of very high purity.</p>  | <p>limited and preliminary scientific research suggests that phosphatidylserine may reduce the risk of dementia in the elderly. FDA concludes that there is little scientific evidence supporting this claim. or, (2) Consumption of phosphatidylserine may reduce the risk of cognitive dysfunction in the elderly. Very limited and preliminary scientific research suggests that phosphatidylserine may reduce the risk of cognitive dysfunction in the elderly. FDA concludes that there is little scientific evidence supporting this claim.</p> |
| <p><b>Nuts &amp; Heart Disease</b><br/>Docket No. 2002P-0505 07/14/2003 enforcement discretion letter</p>                       | <p>(1) Whole or chopped nuts listed below that are raw, blanched, roasted, salted, and/or lightly coated and/or flavored; any fat or carbohydrate added in the coating or flavoring must meet the 21 CFR 101.9(f)(1) definition of an insignificant amount.</p> <p>(2) Nut-containing products other than whole or chopped nuts that contain at least 11 g of one or more of the nuts listed below per RACC.</p> <p>(3) Types of nuts eligible for this claim are restricted to almonds, hazelnuts, peanuts, pecans, some pine nuts, pistachio nuts, and walnuts. Types of nuts on which the health claim may be based is restricted to those nuts that were specifically included in the health claim petition, but that do not exceed 4 g saturated fat per 50 g of nuts.</p> | <p><b>Whole or chopped nuts</b></p> <p>Whole or chopped nuts do not need to comply with the total fat disqualifying level in 21 CFR 101.14(a)(4).</p> <p>Only walnuts do not need to comply with the requirement in § 101.14(e)(6) that the food contain a minimum of 10 percent of the Daily Value per RACC of vitamin A, vitamin C, iron, calcium, protein, or dietary fiber.</p> <p>Where the claim is used on whole or chopped nuts, the disclosure statement (see nutrition information...) must be placed immediately adjacent to and directly beneath the claim, with no intervening material, in the same size, typeface, and contrast as the claim itself.</p> <p>Nuts bearing the claim must comply with the 21 CFR 101.14(a)(4) saturated fat disqualifying level (4 g saturated fat per 50 g nuts).</p> <p><b>Nut-containing products</b></p> <p>Nut-containing products bearing the claim must comply with all the 21 CFR 101.14(a)(4) disqualifying levels which are 13 g total fat, 4 g saturated fat, 60 mg of cholesterol, and 480 mg of sodium per RACC.</p> <p>The claim applies only to types of nuts that do not exceed the 21 CFR 101.14(a)(4) disqualifying nutrient level for saturated fat (4 g saturated fat per 50 g nuts).</p> | <p>Scientific evidence suggests but does not prove that eating 1.5 ounces per day of most nuts [such as name of specific nut] as part of a diet low in saturated fat and cholesterol may reduce the risk of heart disease. [See nutrition information for fat content.]</p> <p>Note: The bracketed phrase naming a specific nut is optional. The bracketed fat content disclosure statement is applicable to a claim made for whole or chopped nuts, but not a claim made for nut-containing products.</p>  |

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|  |   | <p>Nut-containing products bearing the claim must comply with the <i>21 CFR 101.62(c)(2)</i> definition of a low saturated fat food and the <i>21 CFR 101.62(d)(2)</i> definition of a low cholesterol food.</p> <p>Nut-containing products bearing the claim must comply with the <i>21 CFR 101.14(e)(6)</i> requirement that the food contain a minimum of 10 percent of the Daily Value per RACC of vitamin A, vitamin C, iron, calcium, protein, or dietary fiber prior to any nutrient addition.</p>  |  |
| <p><b>Walnuts &amp; Heart Disease</b><br/> Docket No. 2002P-029 03/09/2004<br/> enforcement discretion letter</p>  | <p>Whole or chopped walnuts</p>   | <p>Walnuts do not need to comply with the total fat disqualifying level in <i>21 CFR 101.14(a)(4)</i>.</p> <p>Walnuts do not need to comply with the requirement in § 101.14(e)(6) that the food contain a minimum of 10 percent of the Daily Value per RACC of vitamin A, vitamin C, iron, calcium, protein, or dietary fiber.</p> <p>The disclosure statement about total fat content (i.e., See nutrition information for fat content) is placed immediately following the claim, with no intervening material, in the same size, typeface, and contrast as the claim itself.</p> | <p>Supportive but not conclusive research shows that eating 1.5 ounces per day of walnuts, as part of a low saturated fat and low cholesterol diet and not resulting in increased caloric intake, may reduce the risk of coronary heart disease. See nutrition information for fat [and calorie] content.</p> <p>Notes: The bracketed phrase "and calorie" is optional in that FDA does not intend for the presence or absence of such phrase to be a factor in whether it considers enforcement discretion for the use of the qualified health claim. FDA considered this additional information beneficial to consumers to heighten their awareness of the caloric contribution from walnuts and encourages companies to include it in product labeling.</p> |
| <p><b>Omega-3 Fatty Acids &amp; Coronary Heart Disease</b><br/> Docket No. 2003Q-0401 09/08/2004<br/> enforcement discretion letter - Wellness Petition 09/08/2004 enforcement discretion letter - Martek Petition</p> | <p>Conventional foods and dietary supplements that contain EPA and DHA omega-3 fatty acids.</p> | <p>Dietary supplements should not recommend or suggest in their labeling a daily intake exceeding 2 grams of EPA and DHA</p> <p><b>Total fat content</b></p> <p>Dietary supplements that weigh 5 g or less per RACC (RACC for dietary supplement is labeled serving size) are exempted from the total fat disqualifying level, but if dietary supplements that weigh 5 g or less per RACC exceed the total fat disqualifying level (13.0 g per 50 g) the disclosure statement (i.e., "See nutrition information for total fat</p>  | <p>Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. One serving of [Name of the food] provides [ ] gram of EPA and DHA omega-3 fatty acids. [See nutrition information for total fat, saturated fat, and cholesterol content.]</p> <p>Note: Dietary supplements may</p>   |

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|  |  | <p>content") must be placed immediately adjacent to the health claim. Dietary supplements that weigh more than 5 g per RACC must not exceed the total fat disqualifying level (13.0 g per RACC and per 50 g if RACC is <math>\leq 30</math> g or <math>\leq 2</math> tbsp). (See "<i>Qualified Health Claims Subject to Enforcement Discretion, Omega-3 Fatty Acids and Coronary Heart Disease</i>" and the enforcement discretion letter for Omega-3 Fatty Acids and Coronary Heart Disease)</p> <p>Fish (i.e., "products that are essentially all fish") may not exceed 16.0 g total fat per RACC. Fish with a total fat content greater than 13.0 g per RACC must include "See nutrition information for total fat content" with the health claim. The "products that are essentially all fish" include fish without any added ingredients and fish with a small amount of added fat or carbohydrate that meets the definition of an insignificant amount in 21 CFR 101.9(f)(1). Examples of these products are raw fish, boiled fish, and broiled fish.</p> <p><b>Conventional foods</b> other than fish may not exceed the total fat disqualifying levels. For individual foods, the total fat disqualifying level is 13.0 g per RACC and per 50 g if RACC is <math>\leq 30</math> g or <math>\leq 2</math> tbsp. The total fat disqualifying level is 26.0 g per label serving size for meal products and 19.5 g per label serving size for main dish products.</p> <p><b>Saturated fat content</b></p> <p>Dietary supplements must meet the criterion for low saturated fat with regard to the saturated fat content (<math>\leq 1</math> g per RACC) but not with regard to the no more than 15 percent calories from saturated fat criterion.</p> <p>Fish may not exceed the saturated fat disqualifying level of 4.0 g per RACC (or 4.0 g per 50 g if RACC is <math>\leq 30</math> g or <math>\leq 2</math> tbsp).</p> <p>Conventional foods other than fish must meet the criteria for low saturated fat (<math>\leq 1</math> g per RACC and no more than 15 percent of calories from saturated fat for individual foods, <math>\leq 1</math> g per 100 g and less than 10 percent calories from saturated fat for meal products and main dish products). There is an error in the enforcement discretion letters in the section of "low saturated fat," stating that meal products and main dishes meet all criteria specified for the "low</p> | <p>declare the amount of EPA and DHA per serving in "Supplement Facts," instead of making the declaration in the claim.</p> |
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|  |   | <p>saturated fat" criteria (21 CFR 101.62(c)(2)). The CFR number should be (21 CFR 101.62(c)(3)).</p> <p><b>Cholesterol content</b></p> <p>Dietary supplements that weigh 5 g or less per RACC are exempt from the cholesterol disqualifying level (60 mg per 50 g), but those that exceed the cholesterol disqualifying level must include "See nutrition information for cholesterol content" with the qualified health claim. Dietary supplements that weigh more than 5 g per RACC must meet the criterion for low cholesterol (<math>\leq</math> 20 mg per 50g).</p> <p>Fish must meet the extra lean criterion with regard to cholesterol content (&lt; 95 mg per RACC and per 100 g, whichever is greatest), but not with regard to saturated fat content. Fish with cholesterol content greater than 60 mg per RACC must include "See nutrition information for cholesterol content" with the qualified health claim.</p> <p><b>Conventional foods</b> other than fish must meet the low cholesterol criterion (21 CFR 101.62(d)(2)). See 21 CFR 101.62(d)(2) for the low cholesterol criterion specific for individual foods, meal products, and main dish products.</p> <p><b>Sodium</b></p> <p>All conventional foods and dietary supplements must meet the sodium disqualifying level (<math>\leq</math> 480 mg per RACC and per 50 g if RACC is <math>\leq</math> 30 g or <math>\leq</math> 2 tbsp for individual foods, <math>\leq</math> 960 mg per label serving size for meal products, <math>\leq</math> 720 mg per label serving size for main dish products).</p> <p><b>The 10 percent minimum nutrient requirement</b></p> <p>All conventional foods must meet the 10 percent minimum nutrient requirement (Vitamin A 500 IU, Vitamin C 6 mg, Iron 1.8 mg, Calcium 100 mg, Protein 5 g, Fiber 2.5 g per RACC), prior to any nutrient addition. The 10 percent minimum nutrient requirement does not apply to dietary supplements (21 CFR 101.14(e)(6)).</p> |   |
| <p><b>Monounsaturated Fatty Acids From Olive Oil and Coronary Heart Disease</b><br/>Docket No. 2003Q-0559 11/01/2004</p> | <p>All products that are essentially pure olive oil and labeled as such (see * for definitions)</p> <p>Dressings for salads (i.e. salad dressings) that contain 6 g or more</p> | <p>Olive oil, vegetable oil spreads, dressings for salads, shortenings and olive-oil containing foods do not need to comply with the total fat disqualifying level in 21 CFR 101.14(a)(4).</p>   | <p>Limited and not conclusive scientific evidence suggests that eating about 2 tablespoons (23 grams) of olive oil daily may reduce the risk of coronary heart disease due to the</p> |

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| <p>enforcement discretion letter</p>  | <p>olive oil per Reference Amount Customarily Consumed (RACC), are low in cholesterol (<i>21 CFR 101.62(d)(2)</i>), and do not contain more than 4 g of saturated fat per 50 g.</p> <p>Vegetable oil spreads that contain 6 g or more olive oil per RACC, are low in cholesterol (<i>21 CFR 101.62(d)(2)</i>) and do not contain more than 4 g of saturated fat per RACC.</p> <p>Olive oil-containing foods that contain 6 g or more olive oil per RACC, are low in cholesterol (<i>21 CFR 101.62(d)(2)</i>), contain at least 10% of either vitamin A, vitamin C, iron, calcium, protein or dietary fiber. If the RACC of the olive oil-containing food is greater than 30 g the food cannot contain more than 4 g of saturated fat per RACC and if the RACC of the olive oil-containing food is 30 g or less the food cannot contain more than 4 g of saturated fat per 50 g.</p> <p>Shortenings that contain 6 g or more olive oil per RACC and are low in cholesterol (<i>21 CFR 101.62(d)(2)</i>) and do not contain more than 4 g of saturated fat per RACC.</p> <p>Meal products (<i>21 CFR 101.13(l)</i>) or Main dish products (<i>21 CFR 101.13(m)</i>) are not eligible for the claim.</p> | <p>The requirement that the food comply with the 50 gram-criterion of the saturated fat disqualifying level (<i>21 CFR 101.14(e)(3)</i>) does not apply to olive oil, vegetable oil spreads, and shortenings.</p> <p>The requirement that the food contain a minimum of 10 percent of the Daily Value per RACC of at one of the following: vitamin A, vitamin C, iron, calcium, protein, or dietary fiber per RACC (<i>21 CFR 101.14(e)(6)</i>) does not apply to olive oil, dressings for salads, and shortenings.</p> <p>When the total fat disqualifying level is exceeded in vegetable oil spreads, dressings for salads, shortenings, or olive-oil containing foods the disclosure statement (i.e., See nutrition information for saturated fat content) must be placed immediately following the claim, with no intervening material, in the same size, typeface, and contrast as the claim itself.</p> <p>When the food does not meet the definition of low saturated fat (<i>21 CFR 101.62(c)(2)</i>) the disclosure statement (i.e., See nutrition information for saturated fat content) must be placed immediately following the claim, with no intervening material, in the same size, typeface, and contrast as the claim itself.</p> <p>If both of the above two conditions are met the disclosure statements for total fat and saturated fat can be combined (i.e., See nutrition information for total and saturated fat content).</p> | <p>monounsaturated fat in olive oil. To achieve this possible benefit, olive oil is to replace a similar amount of saturated fat and not increase the total number of calories you eat in a day. One serving of this product contains [x] grams of olive oil.</p> <p>Note: The last sentence of the claim "One serving of this product contains [x] grams of olive oil." is optional when the claim is used on the label or in the labeling of olive oil.</p> <p>* (1) Olive oil means virgin olive oil, or blends of virgin olive oil and refined olive oil; where virgin olive oil is the oil resulting from the first pressing of olives and is suitable for human consumption without further processing and refined olive oil is the oil obtained from subsequent pressings and which is suitable for human consumption by refining processes which neutralize the acidity or remove particulate matter.</p> <p>(2) Vegetable oil spread means margarine (<i>21 CFR 166.110</i>) and margarine-like products.</p> <p>(3) "dressings for salads" means dressings for salads formulated to contain olive oil.</p> <p>(4) "shortenings" means vegetable oil shortenings, formulated to contain olive oil.</p> <p>(5) Olive oil-containing foods means foods, such as sauces or baked goods, excluding olive oil, vegetable oil spreads, dressings for salads, and shortenings.</p> |
| <p><b>Green Tea &amp; Cancer</b><br/>Docket No. 2004Q-0083 06/30/2005<br/>enforcement discretion letter</p> | <p>Green tea and conventional foods and dietary supplements that contain green tea</p>  | <p>Green tea does not exceed the disqualifying nutrient levels for total fat, saturated fat, cholesterol, and sodium specified in <i>21 CFR 101.14(a)(4)</i>.</p> <p>FDA intends to consider the exercise of its enforcement discretion for qualified health claims for</p>  | <p>(1) Two studies do not show that drinking green tea reduces the risk of breast cancer in women, but one weaker, more limited study suggests that drinking green tea may reduce</p>  |

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|  |   | <p>green tea and breast cancer and for green tea and prostate cancer to be used on the label or in the labeling of green tea-containing foods when the food does not exceed any of the disqualifying nutrient levels for fat, saturated fat, cholesterol, and sodium. FDA intends to consider the exercise of its enforcement discretion for green tea that does not meet the 10% minimum nutrient content requirement in <i>21 CFR 101.14(e)(6)</i>.</p> <p>FDA does not intend to consider the exercise of its enforcement discretion for green tea-containing foods that do not meet the requirements of <i>21 CFR 101.14(e)(6)</i>.</p>                                    | <p>this risk. Based on these studies, FDA concludes that it is highly unlikely that green tea reduces the risk of breast cancer. or,</p> <p>(2) One weak and limited study does not show that drinking green tea reduces the risk of prostate cancer, but another weak and limited study suggests that drinking green tea may reduce this risk. Based on these studies, FDA concludes that it is highly unlikely that green tea reduces the risk of prostate cancer.</p> |
| <p><b>Chromium Picolinate &amp; Diabetes</b><br/>Docket No. 2004Q-0144 08/25/2005<br/>enforcement discretion letter</p>  | Dietary supplements containing chromium | Dietary supplement containing chromium must meet or exceed the requirement for a "high" level of chromium as defined in <i>21 CFR 101.54(b)</i> (i.e., 24 mg or more per RACC under the current regulation) for FDA to exercise enforcement discretion.  | One small study suggests that chromium picolinate may reduce the risk of insulin resistance, and therefore possibly may reduce the risk of type 2 diabetes. FDA concludes, however, that the existence of such a relationship between chromium picolinate and either insulin resistance or type 2 diabetes is highly uncertain.  |
| <p><b>Calcium and Colon/Rectal Cancer &amp; Calcium and Recurrent Colon/Rectal Polyps</b><br/>Docket No. 2004Q-0097 10/12/2005<br/>enforcement discretion letter</p> | Dietary supplements containing calcium  | <p>The dietary supplement must meet or exceed the requirement for a "high" level of calcium as defined in <i>21 CFR 101.54(b)</i> (i.e., 200 mg or more calcium per RACC)</p> <p>The calcium content of the dietary supplement must be assimilable (i.e., bioavailable) (<i>21 CFR 101.72(c)(ii)(B)</i>), and meet the United States Pharmacopeia (U.S.P.) standards for disintegration and dissolution applicable to their component calcium salts. For dietary supplements for which no U.S.P. standards exist, the dietary supplement must exhibit appropriate assimilability under the conditions of use stated on the product label (<i>21 CFR 101.72(c)(ii)(C)</i>).</p> | <p><b>Colon/Rectal Cancer:</b><br/>Some evidence suggests that calcium supplements may reduce the risk of colon/rectal cancer, however, FDA has determined that this evidence is limited and not conclusive.</p> <p><b>Recurrent Colon Polyps:</b><br/>Very limited and preliminary evidence suggests that calcium supplements may reduce the risk of colon/rectal polyps. FDA concludes that there is little scientific evidence to support this claim.</p>             |
| <p><b>Calcium &amp; Hypertension, Pregnancy-Induced Hypertension, and Preeclampsia</b><br/>Docket No. 2004Q-</p>   | Dietary supplements containing calcium  | The dietary supplement must meet or exceed the requirement for a "high" level of calcium as defined in <i>21 CFR 101.54(b)</i> (i.e., 200 mg or more calcium per RACC)   | <p><b>Hypertension:</b><br/>Some scientific evidence suggests that calcium supplements may reduce the risk of hypertension. However, FDA has determined that</p>   |

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| <p>0098 10/12/2005<br/>enforcement discretion<br/>letter</p>  |  | <p>The calcium content of the dietary supplement must be assimilable (i.e., bioavailable) (21 CFR 101.72(c)(ii)(B)), and meet the United States Pharmacopeia (U.S.P.) standards for disintegration and dissolution applicable to their component calcium salts. For dietary supplements for which no U.S.P. standards exist, the dietary supplement must exhibit appropriate assimilability under the conditions of use stated on the product label (21 CFR 101.72(c)(ii)(C)).</p> | <p>the evidence is inconsistent and not conclusive.</p> <p><b>Pregnancy-Induced Hypertension:</b><br/>Four studies, including a large clinical trial, do not show that calcium supplements reduce the risk of pregnancy-induced hypertension during pregnancy. However, three other studies suggest that calcium supplements may reduce the risk. Based on these studies, FDA concludes that it is highly unlikely that calcium supplements reduce the risk of pregnancy-induced hypertension.</p> <p><b>Preeclampsia:</b><br/>Three studies, including a large clinical trial, do not show that calcium supplements reduce the risk of preeclampsia during pregnancy. However, two other studies suggest that calcium supplements may reduce the risk. Based on these studies, FDA concludes that it is highly unlikely that calcium supplements reduce the risk of preeclampsia.</p> |
| <p><b>Tomatoes and/or Tomato Sauce &amp; Prostate, Ovarian, Gastric, and Pancreatic Cancers</b><br/>Docket No. 2004Q-0201 11/08/2005<br/>enforcement discretion<br/>letter - American Longevity<br/>Petition 11/08/2005<br/>enforcement discretion<br/>letter - Lycopene Heath<br/>Claim Coalition Petition</p> | <p>(1) Cooked, Raw, Dried, or Canned Tomatoes<br/>(2) Tomato Sauces that contain at least 8.37 percent salt-free tomato solids</p> |  | <p><b>Tomatoes and/or Tomato Sauce and Prostate Cancer:</b><br/>Very limited and preliminary scientific research suggests that eating one-half to one cup of tomatoes and/or tomato sauce a week may reduce the risk of prostate cancer. FDA concludes that there is little scientific evidence supporting this claim.</p> <p><b>Tomato Sauce and Ovarian Cancer:</b><br/>One study suggests that consumption of tomato sauce two times per week may reduce the risk of ovarian cancer; while this same study shows that consumption of</p>  |

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|   |   |  | <p>tomatoes or tomato juice had no effect on ovarian cancer risk. FDA concludes that it is highly uncertain that tomato sauce reduces the risk of ovarian cancer.</p> <p><b>Tomatoes and Gastric Cancer:</b><br/>Four studies did not show that tomato intake reduces the risk of gastric cancer, but three studies suggest that tomato intake may reduce this risk. Based on these studies, FDA concludes that it is unlikely that tomatoes reduce the risk of gastric cancer.</p> <p><b>Tomatoes and Pancreatic Cancer:</b><br/>One study suggests that consuming tomatoes does not reduce the risk of pancreatic cancer, but one weaker, more limited study suggests that consuming tomatoes may reduce this risk. Based on these studies, FDA concludes that it is highly unlikely that tomatoes reduce the risk of pancreatic cancer.</p> |
| <p><b>Unsaturated Fatty Acids from Canola Oil and Reduced Risk of Coronary Heart Disease</b><br/>Docket No. 2006Q-0091 10/06/2006 enforcement discretion letter</p> | <p>Canola oil (see * for definitions)<br/>Vegetable oil spreads, dressings for salads, shortenings, and canola oil-containing foods that contain 4.75 g or more of canola oil per RACC, are low in saturated fat (21 CFR 101.62(c)(2)), are low in cholesterol(21 CFR 101.62(d)(2)), and meet the saturated fat, cholesterol, and sodium disqualifying levels (21 CFR 101.14(a)(4)).<br/>Vegetable oil spreads and canola oil-containing foods must also meet the 10% minimum nutrient content requirement (21 CFR 101.14(e)(6)).</p> | <p>Canola oil, vegetable oil spreads, dressings for salads, shortenings and canola-oil containing foods do not need to comply with the total fat disqualifying level in 21 CFR 101.14(a)(4).<br/>The requirement that the food contain a minimum of 10 percent of the Daily Value per RACC of at one of the following: vitamin A, vitamin C, iron, calcium, protein, or dietary fiber per RACC (21 CFR 101.14(e)(6)) does not apply to canola oil, dressings for salads, and shortenings.<br/>When the total fat disqualifying level is exceeded in vegetable oil spreads, dressings for salads, shortenings, or canola-oil containing foods, the disclosure statement (i.e., See nutrition information for total fat content) must be placed immediately following the claim, with no intervening material, in the same size, typeface, and contrast as the claim itself.</p> | <p>Limited and not conclusive scientific evidence suggests that eating about 1 1/2 tablespoons (19 grams) of canola oil daily may reduce the risk of coronary heart disease due to the unsaturated fat content in canola oil. To achieve this possible benefit, canola oil is to replace a similar amount of saturated fat and not increase the total number of calories you eat in a day. One serving of this product contains [x] grams of canola oil.<br/>For the purposes of this qualified health claim:<br/>(1) "Canola oil" means products that are essentially pure canola oil and are labeled as such.<br/>(2) "Vegetable oil spread" means margarine (21 CFR 166.110) and</p>  |



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|   |   |  | <p>margarine-like products, formulated to contain canola oil.</p> <p>(3) "Dressings for salads" means dressings for salads formulated to contain canola oil.</p> <p>(4) "Shortenings" means vegetable oil shortenings, formulated to contain canola oil.</p> <p>(5) "Canola oil-containing foods" means all other foods, such as sauces or baked goods, formulated to contain canola oil, excluding canola oil, vegetable oil spreads, dressings for salads, and shortenings.</p>  |
| <p><b>Corn Oil and Corn Oil-Containing Products and a Reduced Risk of Heart Disease</b><br/> Docket No. 2006P-0243<br/> 3/26/2007 enforcement discretion letter</p> | <p>Corn oil (see * for definitions)</p> <p>Vegetable oil blends and shortenings that contain 4 g or more corn oil per RACC, are low in cholesterol (21 CFR 101.62(d)(2)), meet the cholesterol and sodium disqualifying levels (21 CFR 101.14(a)(4)), and do not contain more than 4 g of saturated fat per RACC.</p> <p>Dressings for salads (i.e. salad dressings) that contain 4 g or more corn oil per RACC, are low in cholesterol (21 CFR 101.62(d)(2)), meet the cholesterol and sodium disqualifying levels (21 CFR 101.14(a)(4)), and do not contain more than 4 g of saturated fat per 50 g.</p> <p>Vegetable oil spreads that contain 4 g or more corn oil per RACC, are low in cholesterol (21 CFR 101.62(d)(2)), meet the cholesterol and sodium disqualifying levels (21 CFR 101.14(a)(4)), contain at least 10% of either vitamin A, vitamin C, iron, calcium, protein or dietary fiber, and do not contain more than 4 g of saturated fat per RACC.</p> <p>Corn oil-containing foods that contain</p> | <p>Corn oil, vegetable oil blends, vegetable oil spreads, dressings for salads, shortenings and corn-oil containing foods do not need to comply with the total fat disqualifying level in 21 CFR 101.14(a)(4).</p> <p>The requirement that the food comply with the 50 gram-criterion of the saturated fat disqualifying level (21 CFR 101.14(e)(3)) does not apply to corn oil, vegetable oil blends, vegetable oil spreads, and shortenings.</p> <p>The requirement that the food contain a minimum of 10 percent of the Daily Value per RACC of at one of the following: vitamin A, vitamin C, iron, calcium, protein, or dietary fiber per RACC (21 CFR 101.14(e)(6)) does not apply to corn oil, vegetable oil blends, dressings for salads, and shortenings.</p> <p>When the total fat disqualifying level is exceeded in vegetable oil spreads, dressings for salads, shortenings, or corn-oil containing foods, the disclosure statement (i.e., See nutrition information for total fat content) must be placed immediately following the claim, with no intervening material, in the same size, typeface, and contrast as the claim itself.</p> <p>When the food does not meet the definition of low saturated fat (21 CFR 101.62(c)(2)), the disclosure statement (i.e., See nutrition information for saturated fat content) must be placed immediately following the claim, with no intervening material, in</p> | <p>Very limited and preliminary scientific evidence suggests that eating about 1 tablespoon (16 grams) of corn oil daily may reduce the risk of heart disease due to the unsaturated fat content in corn oil. FDA concludes that there is little scientific evidence supporting this claim. To achieve this possible benefit, corn oil is to replace a similar amount of saturated fat and not increase the total number of calories you eat in a day. One serving of this product contains [x] grams of corn oil.</p> <p>(1) "corn oil" means products that are essentially pure corn oil and are labeled as such</p> <p>(2) "vegetable oil blends" means a blend of two or more vegetable oils formulated to contain corn oil</p> <p>(3) "vegetable oil spread" means margarine (21 CFR 166.110) and margarine-like products formulated to contain corn oil</p> <p>(4) "dressings for salads" means dressings for salads formulated to contain corn oil</p> <p>(5) "shortenings" means vegetable</p> |

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|   | <p>4 g or more corn oil per RACC, are low in cholesterol (21 CFR 101.62(d)(2)), meet the cholesterol and sodium disqualifying levels (21 CFR 101.14(a)(4)), contain at least 10% of either vitamin A, vitamin C, iron, calcium, protein or dietary fiber. If the RACC of the corn oil-containing food is greater than 30 g, the food cannot contain more than 4 g of saturated fat per RACC, and if the RACC of the corn oil-containing food is 30 g or less, the food cannot contain more than 4 g of saturated fat per 50 g.</p> | <p>the same size, typeface, and contrast as the claim itself.</p> <p>If both of the above two conditions are met, the disclosure statements for total fat and saturated fat can be combined (i.e., See nutrition information for total and saturated fat content).</p>  | <p>oil shortenings formulated to contain corn oil</p> <p>(6) "corn oil-containing foods" means all other foods, such as sauces or baked goods, formulated to contain corn oil, excluding corn oil, vegetable oil blends, vegetable oil spreads, dressings for salads, and shortenings.</p>  |
| <p><b>Selenium &amp; Cancer</b><br/>Docket No. FDA-2008-Q-0323<br/>06/19/2009</p>             | <p>Dietary supplements containing selenium</p>   | <p>The qualified health claims about selenium and a reduced risk of bladder cancer can only be used on the label or in labeling of dietary supplements that contain any form of selenium other than selenium sulfide.</p> <p>The qualified health claims about selenium and a reduced risk of prostate cancer or thyroid cancer can only be used on the label or in labeling of dietary supplement that contain selenomethionine.</p> <p>Paragraph 101.14(d)(2)(vii) requires that the dietary supplement bearing claim meet the nutrient content claim definition for high (i.e., 20% or more of the daily value (DV) per RACC). 20% DV for selenium is 14 micrograms.</p> | <p><b>Bladder Cancer</b></p> <p>"One study suggest that selenium intake may reduce the risk of bladder cancer in women. However, one smaller study showed no reduction in risk. Based on these studies, FDA concludes that it is highly uncertain that selenium supplements reduce the risk of bladder cancer in women."</p> <p><b>Prostate Cancer</b></p> <p>"Two weak studies suggest that selenium intake may reduce the risk of prostate cancer. However, four stronger studies and three weak studies showed no reduction in risk. Based on these studies, FDA concludes that it is highly unlikely that selenium supplements reduce the risk of prostate cancer."</p> |
| <p><b>Antioxidant Vitamins &amp; Cancer</b><br/>Docket No. FDA-2008-Q-0299<br/>06/19/2009</p> | <p>Dietary supplements containing vitamin E and/or vitamin C</p>   | <p>The supplement does not recommend or suggest in its labeling, or under ordinary conditions of use, a daily intake of vitamin C above 1000 mg per day or above 670 mg of alpha-tocopherol per day for vitamin E.</p> <p>Paragraph 101.14(d)(2)(vii) requires that the food bearing the claim meet the nutrient content claim definition for high (i.e., 20% or more of the daily</p>  | <p><b>Vitamin C</b></p> <p><b>Gastric (Stomach) Cancer</b></p> <p>"One weak study and one study with inconsistent results suggest that vitamin C supplements may reduce the risk of gastric cancer. Based on these studies, FDA concludes that it is highly uncertain that vitamin C</p>  |

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|  |  | <p>value (DV) per RACC). 20% DV for vitamin C is 12 mg; 20% DV for vitamin E is 6 IU*.</p> | <p>supplements reduce the risk of gastric cancer."<br/> <b>Vitamin E</b><br/> <i>Bladder Cancer</i><br/>         "One small study suggests that vitamin E supplements may reduce the risk of bladder cancer. However, two small studies showed no reduction of risk. Based on these studies, FDA concludes that it is highly unlikely that vitamin E supplements reduce the risk of bladder cancer."<br/> <i>Colorectal Cancer</i><br/>         "Two weak studies and one study with inconsistent results suggest that vitamin E supplements may reduce the risk of colorectal cancer. However, another limited study shower no reduction of risk. Based on these studies, FDA concludes that it is highly unlikely that vitamin E supplements the risk of colorectal cancer."<br/> <i>Renal Cell Cancer</i><br/>         "One weak and limited study suggests that vitamin E supplements may reduce the risk of renal cell cancer. FDA concludes that it is highly uncertain that vitamin E supplements reduce the risk of renal cell cancer."</p> |
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\* Based upon conversion factors identified in the 2000 IOM Report, this equates to about 1500 IU of natural vitamin E or about 2200 IU of synthetic (all racemic) vitamin E. The conversion factors are as follows: (mg of alphotocopherol in food, fortified food or multivitamin = 0.67 X IU of the RRR- $\alpha$ -tocopherol or = 0.45 X IU of the all rac- $\alpha$ -tocopherol) (IOM, 2000, Chapter 6).