12. 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*
0.8 mg Folic Acid & Neural Tube Birth Defects *Docket No. 1991N-100H* 10/10/2000 enforcement discretion letter 04/03/2001 clarification letter Note: there also is a folic acid/ neural tube defect health claim authorized by regulation (see *21 CFR 101.79)*.	Dietary supplements containing folic acid	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.	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.

Qualified Health Claims	*Eligible Foods*	*Factors for Exercising Enforcement Discretion*	*Claim Statements*
B Vitamins & Vascular Disease *Docket No. 1999P-3029* 11/28/2000 enforcement discretion letter 05/15/2001 clarification letter	Dietary supplements containing vitamin B6, B12, and/or folic acid	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. 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. The claim does not suggest a level of vitamins B6, B12, and/or folic acid as being useful in achieving the claimed effect. 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 label.	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.

Qualified Health Claims	*Eligible Foods*	*Factors for Exercising Enforcement Discretion*	*Claim Statements*
Selenium & Cancer *Docket No. 2002P-0457* 02/21/2003 enforcement discretion letter 04/28/2003 clarification letter	Dietary supplements containing selenium	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. 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 micro-grams per day). 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.	(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, (2) Selenium may produce anti-carcinogenic 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.

Qualified Health Claims	*Eligible Foods*	*Factors for Exercising Enforcement Discretion*	*Claim Statements*
Antioxidant Vitamins & Cancer *Docket No. 1991N-0101* 04/01/2003 enforcement discretion letter	Dietary supplements containing vitamin E and/ or vitamin C	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. 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). 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.	(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, (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, (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.
Phosphatidylserine & Cognitive Dysfunction and Dementia *Docket No. 2002P-0413* 02/24/2003 enforcement discretion letter 05/13/2003 clarification letter 11/24/2004 updated letter	Dietary supplements containing soy-derived phosphatidylserine	The disclaimer (i.e., Very limited and preliminary scientific research...) is placed immediately adjacent to and directly beneath the claim (i.e., Phosphatidylserine may reduce...), with no intervening material, in the same size, typeface, and contrast as the claim itself. The claim does not suggest a level of phosphatidylserine as being useful in achieving the claimed effect. The soy-derived phosphatidylserine used is of very high purity.	(1) Consumption of phosphatidylserine may reduce the risk of dementia in the elderly. Very 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.

Qualified Health Claims	*Eligible Foods*	*Factors for Exercising Enforcement Discretion*	*Claim Statements*
Nuts & Heart Disease *Docket No. 2002P-0505* 07/14/2003 enforcement discretion letter	(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. (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. (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.	Whole or chopped nuts Whole or chopped nuts do not need to comply with the total fat disqualifying level in 21 CFR 101.14(a)(4). 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. 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. 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). ***Nut-containing products*** 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. 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). Nut-containing products bearing the claim must comply with the 21 CFR 101.62(c)(2) definition of a low saturated fat food and the 21 CFR 101.62(d)(2) definition of a low cholesterol food. Nut-containing products bearing the claim must comply with the 21 CFR 101.14(e)(6) 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.	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.] 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.

Qualified Health Claims	*Eligible Foods*	*Factors for Exercising Enforcement Discretion*	*Claim Statements*
Walnuts & Heart Disease *Docket No. 2002P-029* 03/09/2004 enforcement discretion letter	Whole or chopped walnuts	Walnuts do not need to comply with the total fat disqualifying level in 21 CFR 101.14(a)(4). 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. 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.	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. 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.

Qualified Health Claims	*Eligible Foods*	*Factors for Exercising Enforcement Discretion*	*Claim Statements*
Omega-3 Fatty Acids & Coronary Heart Disease *Docket No. 2003Q-0401* 09/08/2004 enforcement discretion letter - Wellness Petition 09/08/2004 enforcement discretion letter - Martek Petition	Conventional foods and dietary supplements that contain EPA and DHA omega-3 fatty acids.	Dietary supplements should not recommend or suggest in their labeling a daily intake exceeding 2 grams of EPA and DHA ***Total fat content*** 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 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 ≤ 30 g or ≤ 2 tbsp). (See *"Qualified Health Claims Subject to Enforcement Discretion, Omega-3 Fatty Acids and Coronary Heart Disease" and the enforcement discretion letter for Omega-3 Fatty Acids and Coronary Heart Disease)* 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.	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.] Note: Dietary supplements may declare the amount of EPA and DHA per serving in "Supplement Facts," instead of making the declaration in the claim.

(Continued)

Qualified Health Claims	*Eligible Foods*	*Factors for Exercising Enforcement Discretion*	*Claim Statements*
		Conventional foods 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 ≤ 30 g or ≤ 2 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. ***Saturated fat content*** Dietary supplements must meet the criterion for low saturated fat with regard to the saturated fat content (≤ 1 g per RACC) but not with regard to the no more than 15 percent calories from saturated fat criterion. 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 ≤ 30 g or ≤ 2 tbsp). Conventional foods other than fish must meet the criteria for low saturated fat (≤ 1 g per RACC and no more than 15 percent of calories from saturated fat for individual foods, ≤ 1 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 saturated fat" criteria *(21 CFR 101.62(c)(2))*. The CFR number should be *(21 CFR 101.62(c)(3))*. ***Cholesterol content*** 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 (≤ 20 mg per 50g).	

(Continued)

Qualified Health Claims	*Eligible Foods*	*Factors for Exercising Enforcement Discretion*	*Claim Statements*
		Fish must meet the extra lean criterion with regard to cholesterol content (< 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. ***Conventional foods*** 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. ***Sodium*** All conventional foods and dietary supplements must meet the sodium disqualifying level (≤ 480 mg per RACC and per 50 g if RACC is ≤ 30 g or ≤ 2 tbsp for individual foods, ≤ 960 mg per label serving size for meal products, ≤ 720 mg per label serving size for main dish products). ***The 10 percent minimum nutrient requirement*** 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))*.	

Qualified Health Claims	*Eligible Foods*	*Factors for Exercising Enforcement Discretion*	*Claim Statements*
Monounsaturated Fatty Acids From Olive Oil and Coronary Heart Disease *Docket No. 2003Q-0559* 11/01/2004 enforcement discretion letter	All products that are essentially pure olive oil and labeled as such (see * for definitions) Dressings for salads (i.e. salad dressings) that contain 6 g or more olive oil per Reference Amount Customarily Consumed (RACC), are low in cholesterol *(21 CFR 101.62(d)(2))*, and do not contain more than 4 g of saturated fat per 50 g. Vegetable oil spreads that contain 6 g or more olive oil per RACC, are low in cholesterol *(21 CFR 101.62(d)(2))*and do not contain more than 4 g of saturated fat per RACC. Olive oil-containing foods that contain 6 g or more olive oil per RACC, are low in cholesterol *(21 CFR 101.62(d)(2))*, contain at least 10% of either vitamin A, vitamin C, iron, calcium, protein or dietary fiber.	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)*. 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 olive oil, vegetable oil spreads, and shortenings. 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 olive oil, dressings for salads, and shortenings. 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. 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 the same size, typeface, and contrast as the claim itself. 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).	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 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. 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. *(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. (2) Vegetable oil spread means margarine *(21 CFR 166.110)* and margarine-like products. (3) "dressings for salads" means dressings for salads formulated to contain olive oil. (4) "shortenings" means vegetable oil shortenings, formulated to contain olive oil. (5) Olive oil-containing foods means foods, such as sauces or baked goods, excluding olive oil, vegetable oil spreads, dressings for salads, and shortenings.

(Continued)

Qualified Health Claims	*Eligible Foods*	*Factors for Exercising Enforcement Discretion*	*Claim Statements*
	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. Shortenings that contain 6 g or more olive oil per RACC and are low in cholesterol *(21 CFR 101.62 (d)(2))* and do not contain more than 4 g of saturated fat per RACC. Meal products *(21 CFR 101.13 (l))* or Main dish products *(21 CFR 101.13(m))* are not eligible for the claim.		

Qualified Health Claims	*Eligible Foods*	*Factors for Exercising Enforcement Discretion*	*Claim Statements*
Green Tea & Cancer *Docket No. FDA-2004-Q-0427* 02/24/2011 enforcement discretion letter	Green tea and conventional foods and dietary supplements that contain green tea	Green tea does not exceed the disqualifying nutrient levels for total fat, saturated fat, cholesterol, and sodium specified in *21 CFR 101.14(a)(4)*. FDA intends to consider the exercise of its enforcement discretion for qualified health claims for 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 *21 CFR 101.14(e)(6)*. FDA does not intend to consider the exercise of its enforcement discretion for green tea-containing foods that do not meet the requirements of *21 CFR 101.14(e)(6)*.	(1) Green tea may reduce the risk of breast or prostate cancer although the FDA has concluded that there is very little scientific evidence for this claim. (2) Green tea may reduce the risk of breast or prostate cancer. FDA has concluded that there is very little scientific evidence for this claim.
Chromium Picolinate & Diabetes *Docket No. 2004Q-0144* 08/25/2005 enforcement discretion letter	Dietary supplements containing chromium	Dietary supplement containing chromium must meet or exceed the requirement for a "high" level of chromium as defined in *21 CFR 101.54(b)* (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.

Qualified Health Claims	*Eligible Foods*	*Factors for Exercising Enforcement Discretion*	*Claim Statements*
Calcium and Colon/Rectal Cancer & Calcium and Recurrent Colon/ Rectal Polyps *Docket No. 2004Q-0097* 10/12/2005 enforcement discretion letter	Dietary supplements containing calcium	The dietary supplement must meet or exceed the requirement for a "high" level of calcium as defined in *21 CFR 101.54(b)* (i.e., 200 mg or more calcium per RACC) 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))*.	***Colon/Rectal Cancer:*** 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. ***Recurrent Colon Polyps:*** 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.
Calcium & Hypertension, Pregnancy-Induced Hypertension, and Preeclampsia *Docket No. 2004Q-0098* 10/12/2005 enforcement discretion letter	Dietary supplements containing calcium	The dietary supplement must meet or exceed the requirement for a "high" level of calcium as defined in *21 CFR 101.54(b)* (i.e., 200 mg or more calcium per RACC) 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))*.	***Hypertension:*** Some scientific evidence suggests that calcium supplements may reduce the risk of hypertension. However, FDA has determined that the evidence is inconsistent and not conclusive. ***Pregnancy-Induced Hypertension:*** 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. ***Preeclampsia:*** 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.

Qualified Health Claims	*Eligible Foods*	*Factors for Exercising Enforcement Discretion*	*Claim Statements*
Tomatoes and/or Tomato Sauce & Prostate, Ovarian, Gastric, and Pancreatic Cancers *Docket No. 2004Q-0201* 11/08/2005 enforcement discretion letter - American Longevity Petition 11/08/2005 enforcement discretion letter - Lycopene Heath Claim Coalition Petition	(1) Cooked, Raw, Dried, or Canned Tomatoes (2) Tomato Sauces that contain at least 8.37 percent salt-free tomato solids		***Tomatoes and/or Tomato Sauce and Prostate Cancer:*** 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. ***Tomato Sauce and Ovarian Cancer:*** 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 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. ***Tomatoes and Gastric Cancer:*** 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. ***Tomatoes and Pancreatic Cancer:*** 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.

Qualified Health Claims	*Eligible Foods*	*Factors for Exercising Enforcement Discretion*	*Claim Statements*
Unsaturated Fatty Acids from Canola Oil and Reduced Risk of Coronary Heart Disease *Docket No. 2006Q-0091* 10/06/2006 enforcement discretion letter	Canola oil (see * for definitions) 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))*. Vegetable oil spreads and canola oil-containing foods must also meet the 10% minimum nutrient content requirement *(21 CFR 101.14(e)(6))*.	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)*. 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 not apply to canola oil, dressings for salads, and shortenings. 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.	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. For purposes of this qualified health claim: (1) "Canola oil" means products that are essentially pure canola oil and are labeled as such. (2) "Vegetable oil spread" means margarine *(21 CFR 166.110)* and margarine-like products, formulated to contain canola oil. (3) "Dressings for salads" means dressings for salads formulated to contain canola oil. (4) "Shortenings" means vegetable oil shortenings, formulated to contain canola oil. (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.

Qualified Health Claims	*Eligible Foods*	*Factors for Exercising Enforcement Discretion*	*Claim Statements*
Corn Oil and Corn Oil-Containing Products and a Reduced Risk of Heart Disease *Docket No. 2006P-0243* 3/26/2007 enforcement discretion letter	Corn oil (see * for definitions) for definitions) 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. 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. 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*	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)*. 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. 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. 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. 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 the same size, typeface, and contrast as the claim itself. 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).	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. (1) "corn oil" means products that are essentially pure corn oil and are labeled as such (2) "vegetable oil blends" means a blend of two or more vegetable oils formulated to contain corn oil (3) "vegetable oil spread" means margarine *(21 CFR 166.110)* and margarine-like products formulated to contain corn oil (4) "dressings for salads" means dressings for salads formulated to contain corn oil (5) "shortenings" means vegetable oil shortenings formulated to contain corn oil (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.

(Continued)

Qualified Health Claims	*Eligible Foods*	*Factors for Exercising Enforcement Discretion*	*Claim Statements*
	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. Corn oil-containing foods 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. 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.		

Qualified Health Claims	*Eligible Foods*	*Factors for Exercising Enforcement Discretion*	*Claim Statements*
Selenium & Cancer *Docket No. FDA-2008-Q-0323* 06/19/2009 enforcement discretion letter Summary of settlement in Alliance for Natural Health vs. Sebelius	Dietary supplements containing selenium	The qualified health claim 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. 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. Paragraph *101.14(d)(2)(vii)* requires that the dietary supplement bearing claim meet the nutrient content clai definition for high (i.e., 20% or more of the daily value (DV) per RACC). 20% DV for selenium is 14 micrograms.	***Bladder Cancer*** "One study suggests 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." ***Colorectal Cancers*** "Selenium may reduce the risk of colorectal cancer. Scientific evidence concerning this claim is inconclusive. Based on its review, FDA does not agree that selenium may reduce the risk of colorectal cancer." "Selenium may reduce the risk of colon and rectal cancer. Scientific evidence concerning this claim is inconclusive. Based on its review, FDA does not agree that selenium may reduce the risk of colon and rectal cancer." ***Colon Cancer*** "Selenium may reduce the risk of colon cancer. Scientific evidence concerning this claim is inconclusive. Based on its review, FDA does not agree that selenium may reduce the risk of colon cancer." ***Prostate Cancer*** "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." "Selenium may reduce the risk of prostate cancer. Scientific evidence concerning this claim is inconclusive. Based on its review, FDA does not agree that selenium may reduce the risk of prostate cancer." ***Several Cancers*** "Selenium may reduce the risk of bladder, colon, prostate, rectal and thyroid cancers. Based on its review, FDA does not agree that selenium may reduce the risk of these cancers."

Qualified Health Claims	*Eligible Foods*	*Factors for Exercising Enforcement Discretion*	*Claim Statements*
			Thyroid Cancer "One weak, small study sugggests that selenium intake may reduce the risk of thyroid cancer. Based on this study, FDA concludes that it is highly uncertain that selenium supplements reduce the risk of thyroid cancer."
Antioxidant Vitamins & Cancer *Docket No. FDA-2008-Q-0299* 06/19/2009 enforcement discretion letter Summary of settlement in Alliance for Natural Health vs. Sebelius	Dietary supplements containing vitamin E *and*/or vitamin C	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. 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*.	***Vitamin C*** ***Gastric (Stomach) Cancer*** "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 supplements reduce the risk of gastric cancer." "Vitamin C may reduce the risk of gastric cancer although the FDA has concluded that there is very little scientific evidence for this claim." "Vitamin C may reduce the risk of gastric cancer. FDA has concluded that there is very little scientific evidence for this claim." ***Vitamin E*** ***Bladder Cancer*** "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." "Vitamin E may reduce the risk of bladder cancer although the FDA has concluded that there is very little scientific evidence for this claim." "Vitamin E may reduce the risk of bladder cancer. FDA has concluded that there is very little scientific evidence for this claim."

Qualified Health Claims	*Eligible Foods*	*Factors for Exercising Enforcement Discretion*	*Claim Statements*
			Colorectal Cancer "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 showed no reduction of risk. Based on these studies, FDA concludes that it is highly unlikely that vitamin E supplements reduce the risk of colorectal cancer." "Vitamin E may reduce the risk of colorectal cancer although the FDA has concluded that there is very little scientific evidence for this claim." "Vitamin E may reduce the risk of colorectal cancer. FDA has concluded that there is very little scientific evidence for this claim." ***Renal Cell Cancer*** "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." "Vitamin E may reduce the risk of renal cancer although the FDA has concluded that there is very little scientific evidence for this claim." "Vitamin E may reduce the risk of renal cancer. FDA has concluded that there is very little scientific evidence for this claim."
100% Whey-Protein Partially Hydrolyzed Infant Formula & Atopic Dermatitis Docket No. FDA-2009-Q-0301 05/24/2011 enforcement discretion letter	100% Whey-Protein Partially Hydrolyzed Infant Formula	The following language is placed immediately adjacent to and directly beneath the claim: "Partially hydrolyzed formulas **should not be fed to infants who are allergic to milk or to infants with existing milk allergy symptoms.** If you suspect your baby is already allergic to milk, or if your baby is on a special formula for the treatment of allergy, your baby's care and feeding choices should be under a doctor's supervision."	(1) "Very little scientific evidence suggests that, for healthy infants who are not exclusively breastfed and who have a family history of allergy, feeding a 100 % Whey-Protein Partially Hydrolyzed infant formula from birth up to 4 months of age instead of a formula containing intact cow's milk proteins may reduce the risk of developing atopic dermatitis throughout the 1st year of life and up to 3 years of age." *(Continued)*

Qualified Health Claims	*Eligible Foods*	*Factors for Exercising Enforcement Discretion*	*Claim Statements*
			(2) "Little scientific evidence suggests that, for healthy infants who are not exclusively breastfed and who have a family history of allergy, feeding a 100 % Whey-Protein Partially Hydrolyzed infant formula from birth up to 4 months of age instead of a formula containing intact cow's milk proteins may reduce the risk of developing atopic dermatitis throughout the 1st year of life." (3) "For healthy infants who are not exclusively breastfed and who have a family history of allergy, feeding a 100% Whey-Protein Partially Hydrolyzed infant formula from birth up to 4 months of age instead of a formula containing intact cow's milk proteins may reduce the risk of developing atopic dermatitis throughout the 1st year of life and up to 3 years of age. FDA has concluded that the relationship between 100% Whey-Protein Partially Hydrolyzed infant formulas and the reduced risk of atopic dermatitis is uncertain, because there is very little scientific evidence for the relationship." (4) "For healthy infants who are not exclusively breastfed and who have a family history of allergy, feeding a 100% Whey-Protein Partially Hydrolyzed infant formula from birth up to 4 months of age instead of a formula containing intact cow's milk proteins may reduce the risk of developing atopic dermatitis throughout the 1st year of life. FDA has concluded that the relationship between 100% Whey-Protein Partially Hydrolyzed infant formulas and the reduced risk of atopic dermatitis is uncertain, because there is little scientific evidence for the relationship."

* *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 alphatocopherol in food, fortified food or multivitamin = 0.67 X IU of the RRR-α-tocopherol or = 0.45 X IU of the all rac-α-tocopherol) (IOM, 2000, Chapter 6).*