

Qualified Claims About Cardiovascular Disease Risk

Nuts & Heart Disease

Docket No. 02P-0505

07/14/2003 [enforcement discretion letter](#)

Claim Statement

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.]

Notes: 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.

Eligible Foods

- (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 § 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.

Factors

Whole or chopped nuts

The claim meets all 21 CFR 101.14 general health claim requirements, except for: (1) the requirement that the claim meet the significant scientific agreement standard and be made in accordance with an authorizing regulation; (2) the § 101.14(a)(4) requirement that the food comply with the total fat disqualifying level; and (3) for walnuts only, the § 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.

For chopped nuts, the disclosure statement (see nutrition label) 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 § 101.14(a)(4) saturated fat disqualifying level (4 g saturated fat per 50 g nuts).

Nut-containing products

The claim meets all 21 CFR 101.14 general health claim requirements, *except* for the requirement that the claim meet the significant scientific agreement standard and be made in accordance with an authorizing regulation

Nut-containing products bearing the claim must comply with all the § 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 § 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 § 101.62(c)(2) definition of a *low saturated fat food* and the § 101.62(d)(2) definition of a *low cholesterol food*.

Nut-containing products bearing the claim must comply with the § 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.

Walnuts & Heart Disease

Docket No. 02P-0292
03/09/2004 [enforcement discretion letter](#)

Claim Statement

- (1) 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.
 - Note: 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

ed this additional information might be beneficial to
en their awareness of the caloric contribution from
walnuts and encourages companies to include it in product labeling.

Eligible Foods

Whole or chopped walnuts

Factors

The claim meets the general requirements for health claims in 21 CFR 101.14, *except* for the requirement that: (1) the evidence for the claim meet the significant scientific agreement standard; (2) the claim be made in accordance with an authorizing regulation; (3) the food not exceed the disqualifying level for total fat; and (4) the food provide at least 10 percent of the Daily Value of vitamin A, vitamin C, iron, calcium, protein, or dietary fiber per reference amount customarily consumed.

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.

NOTE: 1.5 OUNCES OF PEANUTS = 6 POINTS VALUES ; 1.5 OUNCES OF HAZELNUTS = 7 POINTS VALUES