



Food and Drug Administration  
Washington, DC

JUL 14 2003

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Mr. D. J. Soetaert  
President  
International Tree Nut Council  
Nutrition Research and Education Foundation  
2413 Anza Avenue  
Davis, CA 95616

RE: Health Claim Petition – Nuts and Coronary Heart Disease  
(Docket No. 02P-0505)

Dear Mr. Soetaert:

This letter is to notify you of our decision with regard to the health claim petition you submitted on August 28, 2002, on behalf of the International Tree Nut Council Nutrition Research and Education Foundation. This petition requests that the Food and Drug Administration (FDA) authorize a health claim about the relationship between the consumption of nuts and reduced risk of coronary heart disease (CHD) on the label or in the labeling of whole or chopped nuts and certain nut-containing products. Your petition identifies peanuts and nine tree nuts (i.e., almonds, Brazil nuts, cashew nuts, hazelnuts, macadamia nuts, pecans, pine nuts, pistachio nuts, and walnuts) as appropriate for your requested health claim. Specifically, your petition requests that FDA authorize the following two model health claims for these nuts and certain nut-containing products:

- 1) "Diets containing one ounce of nuts per day can reduce your risk of heart disease."
- 2) "Eating a diet that includes one ounce of nuts daily can reduce your risk of heart disease."

FDA filed the petition for comprehensive review on December 6, 2002, in accordance with section 403(r)(4)(A)(i) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 343(r)(4)(A)(i)). The initial deadline for FDA's response was March 6, 2003. After mutual agreement, the deadline for the agency's response was extended to April 20, 2003, and finally to July 17, 2003.

Based on our review of the scientific evidence, we conclude that there is not significant scientific agreement that consumption of nuts may reduce the risk of CHD. Consequently, we cannot authorize a health claim by regulation pursuant to section 403(r)(3)(B)(i) of the Act (21 U.S.C. § 343(r)(3)(B)(i)) and 21 C.F.R. § 101.14(c).

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ANS

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However, we conclude that there is a sufficient basis for a qualified health claim about nuts and reduced risk of CHD. Therefore, FDA has decided to consider the exercise of its enforcement discretion with regard to the following qualified health claim and disclosure statement, where applicable, on the label or in the labeling of certain nuts cited in your petition and nut-containing products as presented below:

“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.]”

In the above claim, use of the bracketed phrase that refers to the name of a specific nut is optional. Also, as further discussed in this letter, the bracketed disclosure statement about fat content is applicable to “whole or chopped nuts” but not to “nut-containing products.” When applicable, this disclosure statement is to be placed immediately adjacent to and directly beneath the claim, with no intervening material and no brackets, in the same size, typeface, and contrast as the claim itself (21 C.F.R. §§ 101.14(e)(3) and 101.13(h)).

For purposes of the qualified health claim above, the following definitions are intended to distinguish between (1) products that are essentially only nuts, and (2) products that contain nuts and significant amounts of other ingredients.

- 1) “Whole or chopped nuts” are whole or chopped nuts that are raw, blanched, roasted, salted, and/or lightly coated and/or flavored, but any fat or carbohydrate added in the coating or flavoring of a whole or chopped nut should meet the definition of an insignificant amount in 21 C.F.R. § 101.9(f)(1).
- 2) “Nut-containing products” are all other nut-containing foods that do not meet the definition of “whole or chopped nuts” above. These include the many products in the food supply that contain nuts in varying amounts in combination with significant amounts of other ingredients.

Generally, qualified health claims for whole or chopped nuts and nut-containing products are subject to all applicable statutory and regulatory requirements under the Act. However, there are certain exceptions to the requirements for health claims that the agency would consider as part of its enforcement discretion. Such exceptions would include compliance with the requirement that a health claim meet the significant scientific agreement standard and the requirement that the claim be made in accordance with an authorizing regulation. In addition, there are exceptions specific to each category of products described above that the agency would also consider as part of its enforcement discretion. These exceptions are identified below according to product categories.

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Additional Enforcement Discretion Factors for Whole or Chopped Nuts

*Disqualifying Nutrient Levels.* Although the nuts cited in your petition exceed the total fat disqualifying levels for health claims in 21 C.F.R. § 101.14 (a)(4), FDA believes that an appropriately qualified claim about consumption of most nuts would assist consumers in maintaining healthy dietary practices, provided that the label bears a disclosure statement that complies with 21 C.F.R. § 101.13(h) (i.e., "See nutrition information for fat content."). However, for the types of nuts cited in your petition that exceed the saturated fat disqualifying levels (i.e., Brazil nuts, macadamia nuts, cashew nuts, and some varieties of pine nuts), FDA believes that such a claim and disclosure statement would not assist consumers in maintaining healthy dietary practices. Thus, FDA does not intend to consider exercising its enforcement discretion for these types of nuts.

*Nutrient Contribution Requirement.* Although walnuts do not meet the minimum 10 percent nutrient contribution requirement in 21 C.F.R. § 101.14(e)(6), FDA intends to consider exercising enforcement discretion as to this requirement because the levels of protein and dietary fiber in walnuts are very close to the 10% level. For example, walnuts contain about 9 percent of the Daily Value per reference amount customarily consumed (RACC) for protein and about 8 percent of the Daily Value per RACC for dietary fiber.

Additional Enforcement Discretion Factors for Nut-Containing Products


*Nut(s) and Nutrient Content.* FDA will consider exercising enforcement discretion for nut-containing products when (1) the product contains at least 11 grams of one or more of the type of whole or chopped nuts cited in your petition per RACC that do not exceed saturated fat disqualifying levels (which is based on a determination that this would be the minimum amount necessary to obtain the daily effective dose of 1.5 ounces per day from 4 servings of nut-containing products); and (2) the product meets the definition of a "low saturated fat" food in 21 C.F.R. § 101.62(c)(2) and a "low cholesterol" food in 21 C.F.R. § 101.62(d)(2).

Pursuant to this letter, we will immediately begin considering the exercise of our enforcement discretion for the above-referenced qualified health claim and disclosure statement, when applicable, on the label or in the labeling of the whole or chopped nuts and nut-containing products identified in this letter. We will be posting this letter on our website or otherwise providing guidance to the public regarding our advice in this letter.

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Within 60 days of the date of this letter, we plan to issue another letter explaining our decision on your petition in more detail.

Sincerely Yours,

  
for Christine L. Taylor, Ph.D.

Director  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition