



ALMONDS
BRAZILS
CASHEWS
HAZELNUTS
MACADAMIAS
PECANS
PINE NUTS
PISTACHIOS
WALNUTS

8/18/03

August 18, 2003

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Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20749

REFERENCE: Docket 02P-0505

Dear Dr. Taylor:

Thank you for your letter of July 14th regarding a qualified health claim for nuts. The International Tree Nut Council Nutrition Research & Education Foundation (INC NREF) would like to commend your office for its swift response to the consumer research that was presented at our July 7th meeting. We believe that the qualifier, "suggests but does not prove," is much more consumer-friendly than language that uses the word "inconclusive". We appreciate the agency's willingness to work with us to craft a claim that more effectively communicates the cardioprotective properties of nuts to American consumers.

Your letter states that the agency will provide additional detail on your response to our petition within 60 days. The purpose of this letter is to provide comments on the existing qualified claim for your consideration during this period.

It is requested that FDA clarify that whole or chopped nut mixes that contain nut types cited in the petition that exceed the saturated fat disqualifying level (i.e. Brazil nuts, macadamia nuts, cashew nuts and some varieties of pine nuts), will qualify for the health claim provided they meet the definition of whole or chopped nuts and otherwise do not exceed the disqualifying level for saturated fat. Many mixed nut products currently in the marketplace contain such nuts, but do not exceed the saturated fat disqualifier level. We believe the scientific information summarized in our petition supports the appropriateness of such products to bear the claim. In addition, use of the claim on the label or in labeling of such products will provide consumers with additional options to incorporate nuts into a heart-healthy diet.

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It is also requested that FDA consider slightly altering its criteria with respect to enforcement discretion for nut-containing products. The current criteria require that such products contain at least 11 grams of nuts and meet the definition of a "low cholesterol" food in 21 C.F.R. § 101.62(d)(2) and a "low-saturated fat" food in 21 C.F.R. § 101.62(c)(2). We believe that the latter condition is unnecessary. Eleven grams of nuts that do not exceed the saturated fat disqualifier level contain 0.42 – 0.85 grams of saturated fat. As a result, the non-nut ingredients in such foods would be required to be virtually saturated fat free for the product to be eligible to bear the claim. INC NREF believes application of the definition for "low cholesterol" is sufficient to ensure that such products would not contribute excessive amounts of saturated fat because this definition limits both cholesterol and saturated fat. According to 21 C.F.R. § 101.62(d)(2)(ii)(B), "low-cholesterol" foods must contain 2 grams or less of saturated fatty acids per reference amount customarily consumed (RACC). The application of this criterion would provide manufactures with a small amount of additional flexibility with respect to the non-nut ingredients that could be used, or allow such products to contain more than 11 grams of nuts per RACC.

Finally, INC NREF is concerned about certain media reports characterizing nuts that are not included in the claim as possible contributors to CHD. We believe this characterization is incorrect. Such nuts were included in the observational studies that show nut consumers in the upper quintile had a 30-50% lower incidence of CHD than those in the lowest quintile, and one of these nuts (Macadamias) have been shown to lower T-C and LDL-C in two controlled clinical trials (Curb *et.al.*, 2000; Garg *et.al.*, 2003) despite the fact that it exceeds the saturated fat disqualifier level.

We respectfully request that FDA acknowledge that there is no evidence to suggest that the nuts not included in the qualified claim increase the risk of CHD in its forthcoming correspondence.

Once again, INC NREF appreciates FDA's very rapid response to the consumer research we provided. We also look forward to working with the agency in the future to pursue an unqualified claim, which we believe is supported by rapidly accumulating data.

Sincerely,

Doug Youngdahl
Chair

INC Nutrition Research & Education Foundation



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Garg, M.L., Blake, R.J. and Wills, R.B.H. 2003. Macadamia nut consumption lowers plasma total and LDL cholesterol levels in hypercholesterolemic men. J. Nutr. 133:2003.