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Kathleen C. Ellwood, Ph.D.  
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Office of Nutritional Products, Labeling and Dietary Supplements  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
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**REFERENCE: Docket 02P-0505**

Dear Dr. Ellwood:

The purpose of this letter is to express my support for a health claim petition entitled, "Authorization of a Health Claim for Nuts and Coronary Heart Disease" submitted for your consideration by the International Tree Nut Council Nutrition Research and Education Foundation (INC NREF). This petition would authorize almonds, Brazil nuts, cashew nuts, hazelnuts, macadamia nuts, pecans, pine nuts, pistachio nuts and walnuts (or certain foods containing them) to bear the claim, "Diets containing one ounce of nuts per day can reduce your risk of heart disease."

A considerable body of literature shows that nuts (and other sources of "healthy" fats) can have a beneficial effect on the incidence of coronary heart disease (CHD) in the United States. Much of the evidence that has led to this conclusion was summarized in my previous letter to FDA<sup>1</sup> supporting a health claim petition by the California Walnut Commission. This evidence was also summarized in a recent review paper (Kris-Etherton *et al.*, 2001). In short, at least four major prospective epidemiologic studies have shown that people who regularly consume nuts experience a 30 to 50% reduction in CHD morbidity and mortality. Importantly, this finding has been consistently observed in many different population groups. In addition, approximately 20 controlled studies have shown that inclusion of nuts in a diet that is low in saturated fat and cholesterol for at least three weeks lowers the concentration of serum total- and/or LDL-cholesterol normo- and/or moderately hypercholesterolemic individuals. These data are applicable not only for walnuts, but for tree nuts and peanuts as a group.

<sup>1</sup> Letter to the Office of Nutritional Products, Labeling and Dietary Supplements from Dr. Penny Kris-Etherton, September 16, 2002.

There is abundant evidence reporting that moderate-fat diets rich in unsaturated fatty acids (and low in saturated fatty acids) are viable alternatives to the traditional low-fat, high carbohydrate diets designed to manage the risk of CHD. In fact, a number of groups have made dietary recommendations that are consistent with including nuts in a heart-healthy diet that is moderate in total fat (American Heart Association Dietary Recommendations, 2000; National Cholesterol Education Program, ATP III, 2001; Dietary Reference Intakes for Macronutrients, 2002; American Diabetes Association, 2003). Nuts are excellent sources of mono- and/or polyunsaturated fatty acids.

In summary, the evidence that nuts can reduce the risk of CHD is compelling. Unfortunately, many consumers and health professionals are concerned about consuming nuts because they are high in total fat, which is perceived as being unhealthy. An FDA-authorized health claim would be extremely helpful in dispelling this misconception and would provide the foundation for education programs designed to help consumers incorporate nuts into a nutritious, heart-healthy diet.

The use of a qualified health claim, as recently described by FDA, might undermine the credibility of the important public health opportunity described above. The strength of the science supporting a health claim for nuts, as a group, is certainly as strong as unqualified CHD-related health claims previously authorized. Consequently, I believe an unqualified claim is most appropriate for nuts.

In conclusion, I believe FDA should move swiftly to authorize an unqualified health claim for nuts as proposed by the INC NREF petition. I think the burden of scientific evidence is sufficient to warrant this. Thus, I believe that if nuts are widely included in a heart-healthy diet there could be a reduction in the prevalence of CHD in the United States.

Sincerely,

A handwritten signature in cursive script, reading "Penny Kris-Etherton".

Penny Kris-Etherton, Ph.D., R.D.  
Distinguished Professor of Nutrition  
Department of Nutritional Sciences  
Penn State University

Literature cited:

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