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February 18, 2003

Dr. Kathleen C. Ellwood
Acting Director
Division of Nutrition Science and Policy
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20749

ATTENTION: Docket 02P-0505

Dear Dr. Ellwood:

The purpose of this letter is to express my enthusiastic support for a health claim petition on the ability of nuts to reduce the risk of coronary heart disease (CHD). Specifically, I would like to recommend that FDA act swiftly to grant a petition submitted by the International Tree Nut Nutrition Research and Education Foundation (INC NREF) that would authorize such a claim for tree nuts and peanuts as a group.

I conducted one of the initial clinical trials that demonstrated feeding nuts could have a beneficial effect on serum lipids¹. We demonstrated that including walnuts in a low-fat (AHA Step 1) diet resulted in reduced serum cholesterol, LDL-C and the ratio of LDL-C to HDL-C in normocholesterolemic men compared to the Step 1 diet without walnuts.

Since this early study, the hypocholesterolemic effect of a wide range of tree nuts and peanuts has been demonstrated in both normocholesterolemic and moderately hypercholesterolemic individuals.

Furthermore, observational studies have consistently shown that people who eat nuts experience less heart disease than people who rarely eat nuts. In fact, a recent assessment of the available epidemiologic data² led to the conclusion that nut consumption is also inversely related to all-cause mortality, which suggests increased longevity.

I recently wrote your office³ to express my support of a health claim specifically for walnuts. I would now like to add my endorsement for a health claim for all nuts, as a group, because the science is also compelling. Considering nuts as a group allows one to apply the epidemiologic data to the claim since the dietary data collected by these studies was for mixed nuts. In addition, more than a dozen clinical trials with nuts other than walnuts have confirmed their hypocholesterolemic effect.

¹ Sabaté, J. et al. Effects of walnuts on serum lipid levels and blood pressure in normal men. *New Eng. J. Med.* 328:603 (1993).

² Sabaté, J. Nut consumption, vegetarian diets, ischemic heart disease risk, and all-cause mortality: evidence from epidemiologic studies. *Am. J. Clin. Nutr.* 70(suppl):500S (1999).

³ Sabaté, J. Letter to Michael A. Adams, Ph.D. September 10, 2002.

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Although nuts are concentrated sources of energy, they do not appear to contribute to weight gain when consumed as part of a balanced diet. It may be that the satiating properties of nuts protect against over consumption, or there may be other physiological factors involved.

I believe that a health claim for nuts would be valuable because many consumers are unaware of their protective properties. In addition, nuts are a well-liked food, and providing information on their healthful attributes may provide the population with an actionable strategy to help manage CHD risk.

I strongly urge that FDA act as quickly as possible to authorize the health claim proposed by the INC NREF.

Sincerely,

A handwritten signature in black ink, appearing to read 'Joan Sabaté', with a large, stylized flourish extending from the end of the signature.

Joan Sabaté, MD, DrPH
Professor and Chair,
Department of Nutrition
Professor, Department of Epidemiology
Loma Linda University, School of Public Health