



# HARVARD SCHOOL OF PUBLIC HEALTH

Department of Nutrition

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January 16, 2003

Kathleen C. Ellwood, Ph.D.  
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

**REFERENCE: Docket 02P-0505**

Dear Dr. Ellwood:

The purpose of this letter is to express support for a health claim petition submitted to your office by the International Tree Nut Council Nutrition Research and Education Foundation entitled, "Authorization of a Health Claim for Nuts and Coronary Heart Disease."

My appointment as Associate Professor of Nutrition and Epidemiology at the Harvard School of Public Health has enabled me to conduct considerable research on the cardioprotective effects of nuts in long-term prospective human studies. Much of this research was summarized in a previous letter to FDA<sup>1</sup> in support of a health claim petition for walnuts.

I believe that a generic claim for nuts as a group is warranted because our observational data (including prospective data from the Nurses' Health Study) consistently show that people who frequently eat nuts experience significantly less mortality from coronary heart disease than people who rarely eat nuts. This information was recently reviewed<sup>2</sup>. In addition, as my previous letter noted, numerous randomized controlled intervention trials have shown that many different nuts reduce the concentration of serum total- and/or LDL-cholesterol in normo- and moderately hypercholesterolemic subjects. This effect is undoubtedly related to the fact that nuts are rich sources of mono- and/or polyunsaturated fatty acids that have been shown to be hypocholesterolemic.

Taken together, the considerable body of observational and experimental data showing that nut consumption is cardioprotective provides compelling justification for a health claim for all tree nuts and peanuts.

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<sup>1</sup> Letter from Dr. Frank B. Hu to Michael A. Adams, Ph.D., Center for Food Safety and Applied Nutrition, August 24, 2002.

<sup>2</sup> Hu, F.B and Stampher, M.J. Nut Consumption and Risk of Coronary Heart Disease: A Review of Epidemiologic Evidence. *Curr. Athero Rpts.* 1:205 (1999).

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Although nuts are energy-dense foods, there are considerable data to suggest that they are unlikely to contribute to the obesity problem in the United States and elsewhere. Data from our studies<sup>3</sup> and others<sup>4</sup> have shown that nut intake is inversely associated with body mass index. In addition, McManus *et al.*<sup>5</sup> have shown that nuts, and other foods containing healthy fats, increased adherence to a weight loss diet and helped achieve better results.

In summary, I believe that a health claim for nuts, as a group, could have important public health benefits, and should be authorized. The scientific evidence supporting such a claim is at least as strong as that for oat bran and soy protein, and it may be easier for consumers to regularly eat nuts than these other foods. In addition, because the science for nuts is so strong, there is no need to issue a qualified claim as described in FDA's new guidelines.

Sincerely,

A handwritten signature in black ink that reads "Frank Hu". The signature is written in a cursive, flowing style.

Frank B. Hu, MD, PhD  
Associate Professor of Nutrition and Epidemiology  
Harvard School of Public Health

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<sup>3</sup> Hu, F.B. *et al.* Frequent Nut Consumption and Risk of Coronary Heart Disease in Women: Prospective Cohort Study. *Br. Med. J.* 317:1341 (1998).

<sup>4</sup> Hu, F.B and Stampher, M.J. Nut Consumption and Risk of Coronary Heart Disease: A Review of Epidemiologic Evidence. *Curr. Athero Rpts.* 1:205 (1999).

<sup>5</sup> McManus, K., Antinoro, L. and Sacks, F. A Randomized Controlled Trial of Moderate-Fat, Low-Energy Diet Compared with a Low Fat, Low-Energy Diet for Weight Loss in Overweight Adults. *Int. J. Obesity* 25:1503 (2001).