



SEP 7 2002

Penny Kris-Etherton, Ph.D., R.D.
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College of Health and Human Development
The Pennsylvania State University
S 126 Henderson Building
University Park, PA 16802-6504

Dear Dr. Kris-Etherton:

This letter is in response to your letter dated September 16, 2002, in which you support the health claim petition submitted by the California Walnut Commission.

We appreciate your interest in the issues raised in the health claim petition. We have forwarded your letter to the Dockets Management Branch (HFA-305) for inclusion in the administrative record under Docket No. 02P-0292. Your letter will be considered by the agency in its deliberations on what action to take on the California Walnut Commission's health claim petition.

Sincerely,

James E. Hoadley, Ph.D.
Team Leader for Nutrition Labeling and Programs
Division of Nutrition Science and Policy
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

02P-0292

C10/ANS



September 16, 2002

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-800)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Harvey W. Wiley Federal Building
5100 Paint Branch Parkway
College Park, MD 20740-3835

Re: Letter of support for a Health Claim Petition – Docket # 02P-0292: Diets Including Walnuts can Reduce the Risk of Heart Disease

To Whom it May Concern:

I am writing to support the Health Claim Petition (Docket # 02P-0292) submitted by the California Walnut Commission requesting that FDA approve “for use in the labeling of foods comprising whole and chopped walnuts, health claims communicating that diets including walnuts can reduce the risk of coronary heart disease”. I believe that the epidemiologic data clearly show that a strong and consistent association exists between nut consumption and decreased risk of coronary heart disease (CHD). Results of several reports from four major population studies (the Seventh-Day Adventist Study, the Iowa Women’s Study, the Nurses’ Health Study and the Physicians’ Health Study) conducted in the United States have consistently reported a protective association between nut consumption and risk of CHD. The findings indicate that nut consumption is associated with a 30 to 50% decreased risk of coronary heart disease morbidity and mortality in all population groups studied. Moreover, the studies reported a dose-response relationship between nut consumption and decreased risk of CHD. It is noteworthy that the findings reported are impressively consistent among the different populations studied.

Clinical studies are the “gold” standard for establishing cause and effect relationships. To date, there have been a number of clinical studies with walnuts that have utilized various experimental designs and different subject populations, including both healthy and high-risk populations. These studies all consistently demonstrated that inclusion of walnuts in a diet low in saturated fat and cholesterol lowered total and LDL cholesterol levels and, thus, risk for CHD. In studies that reported a baseline LDL cholesterol or that had an appropriate control group, LDL cholesterol was decreased by 8 to 16% in subjects consuming the walnut experimental diet. This would be expected to result in a 12 to 24% reduction in CHD risk.

In addition to the strength of evidence demonstrating a beneficial effect of nuts and walnuts on CHD risk, these foods are a rich source of macronutrients and micronutrients that have reported cardioprotective effects. For example, of all nuts,

walnuts are uniquely high in polyunsaturated fatty acids, both the n-6 fatty acid, linoleic acid, and the n-3 fatty acid, alpha-linolenic acid, both of which have been shown to reduce risk of cardiovascular disease. Two recently released reports, the DRI Report for Macronutrients from the Food and Nutrition Board of the National Academies and the National Cholesterol Education Program Third Adult Treatment Panel Report (ATP III), have advised that total fat intake be 20 to 35% of calories and 25 to 35% of calories, respectively. Moreover, both recommend a diet low in saturated fat, *trans* fat and cholesterol to reduce risk of cardiovascular disease. The remaining fat calories should come from unsaturated fatty acids, with 5 to 10% of total calories from n-6 polyunsaturated fatty acids (DRI Report) and up to 10% of total calories from polyunsaturated fatty acids (ATP III), respectively. With respect to alpha-linolenic acid, the DRI Report recommends 0.6 to 1.2% of calories. Thus, the recommended ratio of n-6:n-3 fatty acids is 5 to 10:1. This ratio in walnuts (4:1) closely approximates the recommended ratio and, importantly, illustrates that walnuts can be an ideal food source for achieving the recommended levels of n-6 and n-3 polyunsaturated fatty acids. It is important to emphasize that walnuts are one of a few commonly used foods that are a rich source of alpha-linolenic acid.

Walnuts are an excellent source of vitamin E, and a good source of dietary fiber, folic acid, vitamin B-6, niacin, magnesium, copper, zinc and potassium, all of which have been shown to reduce CHD risk. As might be expected from the micronutrient profile of nuts, studies have shown that nut consumers have a healthier diet (i.e., improved nutrient density) than non-nut consumers. In addition, there is no evidence that nut consumption is associated with increased body weight and, specifically, overweight and obesity.

In summary, the scientific evidence demonstrating health benefits of walnuts is strong and consistent. The available evidence indicates that walnuts can be incorporated in a healthy diet that reduces risk of CHD. It is evident that there is growing support for incorporating nuts into a heart-healthy diet that decreases LDL cholesterol. In fact, the American Heart Association Dietary Guidelines 2000 specifically recommend substituting unsaturated fats from nuts and other foods for saturated fat to reduce LDL cholesterol levels. I think it is important for consumers to know that nuts and walnuts are a healthy food, which they might not appreciate presently. An FDA Health Claim for walnuts would reinforce this health message and encourage walnut consumption. Thus, I am most supportive of the Health Claim Petition FDA presently is reviewing and believe it can encourage a healthful dietary pattern that includes walnuts and, consequently, decrease risk of CHD in the United States.

Sincerely,



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