



SEP 25 2002

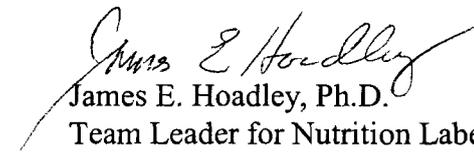
Frank B. Hu, MD, PhD
Associate Professor of Nutrition and Epidemiology
Harvard School of Public Health
Department of Nutrition
665 Huntington Avenue
Boston, Massachusetts 02115

Dear Dr. Hu:

This letter is in response to your letter dated August 24, 2002, to Michael A. Adams, 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

C11/ANS

81946



HARVARD SCHOOL OF PUBLIC HEALTH

Department of Nutrition

SEP 11 2002
RECEIVED

August 24, 2002

Michael A. Adams, PhD
Acting Director, Division of Nutrition Science and Policy
Office of Nutritional Products, Labeling & Dietary Supplements
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

FDA Docket # 02P-0292

Dear Dr. Adams,

I write to support a petition for a health claim to FDA by the walnut industry regarding beneficial effects of walnut consumption on blood lipids and coronary heart disease [FDA Docket # 02P-0292]. As a background, I am an Associate Professor of Nutrition and Epidemiology at Harvard School of Public Health. My main area of research is concerning nutrition and prevention of cardiovascular disease and nutrition, primarily supported by National Institutes of Health. With the funding from NIH, we have studied long-term health effects of nut consumption on coronary heart disease and other chronic diseases in the Nurses' Health Study, an ongoing prospective epidemiologic study of 120,000 female nurses in the US.

Coronary heart disease (CHD) remains leading causes of death in the US, despite decades' decline in coronary mortality. Dietary and lifestyle modifications are considered the most cost-effective way to prevent CHD. It is well accepted that diets that lower serum LDL cholesterol are beneficial for lowering risk of CHD. For this reason, the FDA has approved health claims for oat bran and soy protein, both of which have been shown to lower total and LDL cholesterol. This action can have significant public health implications because increasing consumption of healthy foods not only lowers cardiovascular risk factors but also improves overall dietary quality in general.

The information presented in petition represents a systematic and comprehensive review of scientific evidence on health effects of walnuts. In the past decade, numerous studies have examined the health effects of nut consumption. These studies can be broadly classified into two categories, short-term randomized controlled trials of specific nuts (such as walnuts) on lipid profile and long-term epidemiologic studies of nut consumption (nuts as a group) and risk of CHD. These two types of studies are complementary. So far, at least six randomized trials of walnut consumption and lipids have been conducted in diverse populations, including men and women and older and younger age groups, and Caucasians and Asians. These studies have uniformly and conclusively shown that walnuts, as part of a heart-healthy diet, significantly lower total and LDL cholesterol and LDL to HDL ratio. The magnitude of the lipid-lowering effect is clinically significant (4% to 12% reduction in LDL cholesterol, which can be translated to 12% to 36% reduction in CHD) and it exceeds or at least is

comparable to the effects of oat meal or soy. Several studies have also shown that walnuts reduce Lp(a) and triglycerides, both of which are known to elevate risk of CHD. In these trials, there is no indication that a diet higher in walnuts induces weight gain or increase oxidative stress. Such diets were well accepted by the subjects.

Because it is infeasible to conduct a randomized trial of walnuts on CHD endpoint, data from long-term epidemiologic studies of nut consumption and CHD are imperative in evaluating health benefits of nuts in general. To date, five large prospective cohort studies involving tens thousands of subjects have examined the association between nut consumption and risk of CHD and all have found beneficial effects of nuts. The results are remarkably consistent across different populations, vegetarians and nonvegetarians, men and women, younger and older age groups, whites and blacks, people with and without coronary disease. Although these studies cannot distinguish walnuts from other nuts, they suggest that a diet higher in nuts can have long-term beneficial effects on prevention of CHD. It is worth noting that no long-term prospective data exist to support the benefits of oat bran or soy on incidence of CHD.

It is generally believed that the benefits of nuts on CHD are in part mediated through their effects on lipid profile. Although virtually all nuts are expected to improve lipid profile when they are used to replace refined carbohydrates or meats, walnuts possess somewhat unique nutrient profile compared to other nuts because they contain much larger amount of n-6 (linoleic acid) and n-3 (alpha-linolenic acid) polyunsaturated fatty acids. In epidemiologic studies and clinical trials, both n-6 and n-3 fatty acids have been demonstrated to reduce risk of CHD in healthy subjects or among those with existing coronary disease. In addition to these healthy fatty acids, walnuts as well as other nuts contain substantial amount of other beneficial nutrients including antioxidants, minerals, fiber, and plant protein (especially arginine).

Traditionally, nuts were perceived as an unhealthy food because of their high fat content. However, research in the past decade has conclusively shown that it is the type of fat rather than total amount of fat determines risk of CHD. This notion is reinforced by clinical and epidemiologic studies of nut consumption and CHD risk mentioned above. Incorporating nuts including walnuts into a heart healthy diet without increasing caloric intake can significantly lower risk of CHD and improve overall diet quality. Therefore, I believe that the health claim for walnuts approved by the FDA can have important public health implications.

Sincerely



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