



SEP 25 2002

Food and Drug Administration
College Park, MD 20740

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Dear Dr. Morris:

This letter is in response to your letter dated September 13, 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.

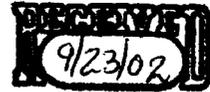
Sincerely,

James E. Hoadley, Ph.D.
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02P-0292

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September 13, 2002

Michael A Adams, 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
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Re: Health Claim Petition for Walnuts to the FDA. Docket # 02P-0292
Dear Dr Adams,

I support the Health Claim Petition 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".

Data from epidemiologic studies, basic pathophysiology, and clinical trials provide a wealth of evidence suggesting that consumption of walnuts will reduce the risk of coronary heart disease(CHD).

Four major studies show a strong association between nut consumption and decreased risk of CHD - the Adventist Study(1), the Iowa Women's Study(2), the Nurses' Health Study(3) and the Physicians' Health Study(4). Nut consumption was associated with a 30 to 50% decreased risk of CHD morbidity and mortality in all these population groups. There was also a dose-response relationship between nut consumption and decreased risk of CHD.

Walnuts have an unusually high content of the n-3 fatty acid, alpha-linolenic acid compared with other nuts (5). In one study the content of this fatty acid was 10-13% by weight(6). Alpha-linolenic acid appears to have cardioprotective effects independent of its effects on LDL-cholesterol. In the 1960s, the diets of the then longest lived populations with the lowest CHD mortality in the world(Crete and Kohama Island, Japan) were noted to have high contents of this fatty acid(7, 8, 9). The putative beneficial effect of alpha-linolenic acid may be partly due to its inhibitory effect on the clotting activity of platelets, and on the inhibition of thrombin(10). There is good reason to believe that alpha-linolenic acid has clinically important effects on inhibiting cardiac arrhythmias in humans, thereby reducing the incidence of sudden death in patients with CHD(11, 12). In rats ventricular fibrillation is reduced by canola oil as much as or even more efficiently than by fish oil, an effect attributed to alpha-linolenic acid - whether directly or as a result of its desaturation and elongation to eicospentaenoic acid and docosahexanoic acid. The latter two omega n-3 fatty acids were felt to be responsible for the 32% reduction in (arrhythmic) cardiac death in the 'diet and reinfarction trial' (DART)(13).

Clinical trials have shown that the addition of walnuts to a diet low in saturated fat and cholesterol lowers total and LDL cholesterol levels(14, 15). The range of decrease of the latter was by 8 to 16% in subjects consuming the walnut supplemented diet. This would be expected to result in a 12 to 24% reduction in CHD risk.

In the Lyon Diet Heart Study, a prospective secondary prevention trial, a Mediterranean diet enriched with alpha linolenic acid had a strikingly beneficial effect on CHD mortality and morbidity compared with a prudent Western-type diet(16)

The recent DRI Report for Macronutrients from the Food and Nutrition Board of the National Academies has recommended that 0.6 to 1.2% of calories should be alpha-linolenic acid with a ratio of n-6:n-3 fatty acids of 5 to 10:1(17) This ratio in walnuts is 4:1 which makes them a readily available source of alpha-linolenic acid.

Additionally, walnuts also contain vitamin E, dietary fiber, folic acid, vitamin B-6, niacin, magnesium, copper, zinc and potassium, all of which have well known health benefits including reduction of CHD.

Obesity and allergic reactions are the potential adverse effects of eating walnuts. Clinical trials and epidemiologic studies do not show an increased prevalence of obesity among walnut consumers. In any case there is a consensus among experts that obesity is caused by an excess of caloric intake compared with caloric expenditure rather than being attributable to any one dietary component.

Allergic reactions to food and medication are not uncommon, but there is no evidence to suggest that reactions to walnuts are more frequent than to other foods.

In summary there is good reason to believe that inclusion of walnuts in the diet offer protection against CHD, and that it is important that this information be disseminated so that the public have the option of incorporating walnuts into their diet. An FDA Health Claim for walnuts would encourage walnut consumption.

Sincerely,



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REFERENCES

- (1) Arch Intern Med 1992 July;152(7):1416-24. A possible protective effect of nut consumption on risk of coronary heart disease. The Adventist Health Study. Fraser GE, Sabate J, Beeson WL, Strahan TM.
- (2) Nutr Metab Cardiovas Dis 2001 Dec;11(6):327-7 Frequent nut intake and risk of death from coronary heart disease and all causes in postmenopausal women: the Iowa Women's Health Study. Ellsworth JL, Kushi, LH, Folsom AR.
- (3) BMJ 1998 Nov 14;317(7169):1341-5 Frequent nut consumption and risk of coronary heart disease in women: prospective cohort study. Hu FB, Stampfer MJ, Manson JE, Rimm EB, Colditz GA, Rosner BA, Speizer FE, Hennekens CH, Willett WC.
- (4) Arch Intern Med 2002 Jun 24; 162(12): 1382-7. Nut consumption and decreased risk of sudden cardiac death in the Physician's Health Study. Albert CM, Gaziano JM, Willett WC, Manson JE.
- (5) Provisional Table on the content of omega-3 fatty acids and other fat components in selected foods. Washington DC:US Department of Agriculture; 1986(Publication HNIS/PT - 103). Exler J, Weihrauch JL.

- (6) Int J Food Sci Nutr 1999. Fatty acid content of New Zealand-grown walnuts(*Juglans regia* L) Zwarts L, Savage GP, McNeil DL.
- (7) Am J clin Nutr 1995;61(Suppl): 1360S-7S. Cretan Mediterranean diet for prevention of coronary heart disease. Renaud S, de Lorgeril M, Delaye J, et al.
- (8) Eur J Clin Nutr 1993;47: 201-08. Serum cholesteryl ester fatty acids and their relation with serum lipids in elderly men in Crete and the Netherlands. Sandker GN, Kromhout D, Aravanis C, et al.
- (9) J Amer Coll 1992; 11: 374-82. Common purslane: a source of omega-3 fatty acids and antioxidants. Simopoulos AP, Norman HA. Gillespy JE, Duke JA.
- (10) Lancet 1983 i: 1169. Small is beautiful: alpha-linolenic acid and eicosapentanoic acid. Renaud S, Nordoy A.
- (11) Am J Cardiol 1992; 69: 879-85. An Indian experiment with nutritional modulation in acute myocardial infarction. Singh RB, Rastogi SS, Verma R, et al.
- (12) J Nutr Health Aging 2001;5(3):179-83. Alpha-linolenic acid and cardiovascular diseases. Lanzmann-Petithory D.
- (13) Lancet 1989;334: 757-61. Effects of changes in fat, fish, and fibre intakes on death and myocardial reinfarction: diet and reinfarction trial(DART). Burr ML, Fehily AM, Filbert JF, et al.
- (14) Arch Intern Med 2000;132:538-546. Substituting Walnuts for Monounsaturated Fat Improves the Serum Lipid Profile of Hhypercholesterolemic Men and Women. A Randomized Crossover Trial. Zambon, Z, Sabate J, Munoz S, et al.
- (15) Am J Clin Nutr 2001 Jul;74(1): 72-9. Effect of walnut consumption on plasma fatty acids and lipoproteins in combined hyperlipidemia. Almario RU, Vonghavaravat V, Wong R, et al.
- (16) Lancet 1994;343: 1454-59. Mediterranean alpha-linolenic acid-rich diet in secondary prevention of coronary heart disease. De Lorgeril M, Renaud S, Mamelle N, et al.
- (17) Dietary Reference Intake Values for macronutrients. Institue of Medicine. 2002 September 5.