



**Memorandum**

Date September 17, 2003  
From Jillonne Kevala  
To Guy Johnson, Nutrition Solutions  
Subject Memorandum of Electronic Mail, Subject: Olive Oil Petition

Hello Guy,

I left a message on your phone concerning some references our Science Review team would like to evaluate, I also tried your cell number but was not able to contact you. In order for our Science Review team to determine the quality and significance of these studies, will you fax (301) 436-2639 or (301) 436-2623 or mail the articles, to the address below, which are listed in the enclosed attachment.

Thanks  
Jillonne Kevala

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

**Relevant References not included in the olive oil petition**

**References from the Tables that were not included in the petition**

Barbagallo, C.M., Cefalu, A.B., Gallo, S., Rizzo, M., Noto, D., Cavera, G., Camemi, A.R., Marino, G., Caldarella, R., Notarbartolo, A., Averna, M.R. Effects of Mediterranean diet on lipid levels and cardiovascular risk in renal transplant recipients. *Nephron* 1999; 82:199-204.

Berry EM, Eisenberg S, Friedlander Y et al. Effects of diet rich in monounsaturated fatty acids on plasma fatty acids on lipoproteins – the Jerusalem Nutrition Study. II Monounsaturated fat vs carbohydrates. *Am J Clin Nutr* 1992; 56:394-403.

Donnelly SM, Ali MAM, Churchill, DN. Effect of n-3 fatty acids from fish oil on hemostasis, blood pressure and lipid profile of dialysis patients. *J Am Soc Nephrol* 1992; 2: 1634-1639.

2003Q-0559

LET 2

Dreon, D.M., Vranizan, K.M., Krauss, R.M., Austin, M.A., Wood, P.D. The effect of polyunsaturated fat vs monounsaturated fat on plasma lipoproteins. *J Am Med Assoc* 1990; 263:2462-2466.

Flaten, H., Hostmark, A.T., Kierulf, P., Lystad, E., Trygg, K., Bjerkedal, T., Osland, A. Fish-oil concentrate: effects on variables related to cardiovascular disease. *Am J Clin Nutr* 1990; 52: 300-6.

Gimeno E, Fitó M, Lamuela-Raventós RM, Castellote AI, Covas M, Farré M, de la Torre-Boronat MC, López-Sabater MC. Effect of ingestion of virgin olive oil on human low-density lipoprotein composition. *Eur J Clin Nutr* 2002; 56:114-120.

Goldberg J, O'Mara K. Metabolic and anthropometric changes in obese subjects from an unrestricted calorie, high monounsaturated fat, very low carbohydrate diet. *J Clinical Ligand Assay* 2000; 23:97-103.

De Lorgeril, M., Salen, P., Martin, J-L., Mamelle, N., Monjaud, I., Touboul, P., Delaye, J. Effect of a Mediterranean type of diet on the rate of cardiovascular complications in patients with coronary artery disease. Insights into the cardioprotective effect of certain nutrients. *J Am Coll Cardiol* 1996; 28:1103-8.

Lovejoy JC, Most MM, Lefevre M, Greenways FL, Rood JC. Effect of diets enriched in almonds on insulin action and serum lipids in adults with normal glucose tolerance or type 2 diabetes. *Am J Clin Nutr* 2002; 276:1000-6.

Madigan C, Ryan M, Owens D, Collins P, Tomkin GH. Dietary unsaturated fatty acids in type 2 diabetes. *Diabetes Care* 2000; 23:1472-1477.

Mori TA, Vandongen R, Mahanian F, Douglas A. Plasma lipid levels and platelet and neutrophil function in patients with vascular disease following fish oil and olive oil supplementation. *Metabolism* 1992; 41:1059-1067.

Olszewski AJ, McCully KS. Fish oil decreases serum homocysteine in hyperlipemic men. *Coronary Artery Disease* 1993; 4:53-60.

Ramirez-Tortosa C, Lopez-Pedrosa JM, Suarez A, Ros E, Mataix J, Gil A. Olive oil- and fish oil-enriched diets modify plasma lipids and susceptibility of LDL to oxidative modification in free-living male patients with peripheral vascular disease: the Spanish Nutrition Study. *Br J Nutr* 1999; 82:31-9.

Reis, G.J., Boucher, T.M., Sipperly, M.E., Silverman, D.I., McCabe, C.H., Baim, D.S., Sacks, F.M., Grossman, W., Pasternak, R.C. Randomized trial of fish oil for prevention of restenosis after coronary angioplasty. *Lancet* 1989; 177-181.

Rivellese AA, Maffettone A, Vessby B, Uusitupa M, Hermansen K, Berglund L, Louheranta A, Meyer BL, Riccardi G. Effects of dietary saturated, monounsaturated and n-3 fatty acids on fasting

lipoproteins, LDL size and post-prandial lipid metabolism in healthy subjects. *Atherosclerosis* 2003;167:149-58.

Sacks, F.M, Stone, P.H., Gibson, M.C., Silverman, D.I., Rosner, B. and Pasternak, R.C. Controlled trial of fish oil for regression of human coronary atherosclerosis. *J Am Coll Cardiol* 1995; 25 1492-1498.

Salachas, A., Papadopoulos, C., Sakadamis, G., Styliadis, J., Voudris, V., Oakley, D., Saynor, R. Effects of a low-dose fish oil concentrate on angina, exercise tolerance time, serum triglycerides, and platelet function. *Angiology* 1994; 45: 1023-1031.

Skoldstam, L., Hagfors, L., Johansson, G. An experimental study of a Mediterranean diet intervention for patients with rheumatoid arthritis. *Ann Rheum Dis* 2003; 62:208-14.

Wagner K-H, Tomasch R, Elmadfa I. Impact of diets containing corn oil or olive/sunflower oil mixture on the human plasma and lipoprotein lipid metabolism. *Eur J Nutr* 2001;40:161-7.

Williams CM, Francis-Knapper JA, Webb D, Brookes CA, Zampelas A, Tredger JA, Wright J, Meijer G, Calder PC, Yaqoob P, Roche H, Gibney MJ. Cholesterol reduction using manufactured foods high in monounsaturated fatty acids: A randomized crossover study. *Br J Nutr* 1999; 81:439-446.

Mensink, R.P., Katan, M.B. Effect of monounsaturated fatty acids versus complex carbohydrates on high-density lipoproteins in healthy men and women. *Lancet* 1987; 122-124.

Reis, G.J., Silverman, D.I., Boucher, T.M., Sipperly, M.E., Horowitz, G.L., Sacks, F.M., Pasternak, R.C. Effects of two types of fish oil supplements on serum lipids and plasma phospholipid fatty acids in coronary artery disease. *Am J Cardiol* 1990; 66:1171-1175.

Bairat I, Roy L, Meyer F. Effects of a fish oil supplement on blood pressure and serum lipids in patients treated for coronary artery disease. *Can J Cardiol* 1992;8: 41-46.

de Lorgeril, M., Salen, P., Martin, J., Monjaud, I., Delaye, J. and Mamelle, M. Mediterranean diet, traditional risk factors, and the rate of cardiovascular complications after myocardial infarction final report of the Lyon Diet Heart Study. *Circulation* 1999; 99:779-785.

### **References from the Bibliography that were not included in the petition**

Garg, A., Bantle, J.P., Henry, R.H., Coulston, A.M., Griver, K.A., Ratz, S.K., Brinkley, L., Ida Chen, Y-D., Grundy, S.M., Huet, B.A. and Reaven, G.M. Effects of varying carbohydrate content of diet in patients with Non-Insulin-Dependent Diabetes Mellitus. *J Am Med Assn* 1994; 271:1421.

Ginsberg, H.N., Barr, S.L., Gilbert, A., Karmally, W., Deckelbaum, R., Kaplan, K., Ramakrishnan, R., Holleran, S., Dell, R.B. Reduction of plasma cholesterol levels in normal men on an

American Heart Association Step 1 Diet or a Step 1 diet with added monounsaturated fat. *N Eng J Med* 1990; 322:574.

González, C.A., Pera, G., Quirós, J.R., Lasheras, C., Tormo, M.J., Rodriguez, M., Navarro, C., Martinez, C., Dorronsoro, M., Chirlaque, M.S., Beguiristain, J.M., Barricarte, A., Amiano, P. and Agudo, A. Types of fat intake and body mass index in a Mediterranean country. *Public Health Nutr* 2000; 3(3):329.

Grundy, S.M. Comparison of monounsaturated fatty acids and carbohydrates for lowering plasma cholesterol. *New Eng J Med* 1986; 314:745.

Grundy, S.M., Florentin, L., Nix, D., Whelan, M.F. Comparison of monounsaturated fatty acids and carbohydrates for reducing raised levels of plasma cholesterol in man. *Am J Clin Nutr* 1988; 47: 965.

Grundy SM and Vega GL. Plasma cholesterol responsiveness to saturated fatty acids. *Am J Clin Nutr* 1998; 47:822.

Gumbiner B, Low CC, Reaven PD. Effects of a monounsaturated fatty acid-enriched hypocaloric diet on cardiovascular risk factors in obese patients with type 2 diabetes. *Diabetes Care* 1998; 21:9.

**References not included in Petition that were found on a Pubmed lit search**

Panagiotakos DB, Pitsavos Ch, Chrysohoou Ch, Stefanadis Ch, Toutouzas P. The role of traditional Mediterranean type of diet and lifestyle, in the development of acute coronary syndromes: preliminary results from CARDIO 2000 study. *Cent Eur J Public Health* 2002; 10(1-2):11-5.

Jansen, S., Lopez-Miranda, J., Castro, P., Lopen-Segura, F., Marin, C., Ordovas, J.M., Paz, E., Jimenez-Pereperez, J., Fuentes, F., and Perez-Jimnez, F. *Am J Clin Nutr* 2000; 72:36-41.

Fernandez-Jarne, E., Martinez-Losa, E., Prado-Santamaria, M., Brugarolas-Brufau, C., Serrano-Martinez, M., and Martinez-Gonzalez, M.A. Risk of first non-fatal myocardial infarction negatively associated with olive oil consumption: a case-control study in Spain. *Int J Epi* 2002; 31: 474-480.

Jillonne Kevala Ph.D.

