Public Health Service



SEP 13 2002

Food and Drug Administration College Park, MD 20740

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Mr. D. J. Soetaert
President
International Tree Nut Council
Nutrition Research and Education Foundation
2413 Anza Avenue
Davis, CA 95616

RE: Health Claim Petition - Nuts and Coronary Heart Disease.

Dear Mr. Soeraert:

This letter acknowledges receipt on August 28, 2002 by the Food and Drug Administration (FDA) of the petition you submitted pursuant to Section 403(r)(5)(D) of the Federal Food, Drug and Cosmetic Act (FFD&C Act) (21 U.S.C. § 343(r)(5)(D)). The petition requests FDA authorization of health claims on the labels and in labeling of nuts and eligible nut-containing foods for the relationship between nuts and reduction in the risk of coronary heart disease.

This petition is undergoing initial FDA review. In accordance with Section 403(r)(4)(A)(i) of the FFD&C Act and 21 CFR 101.70(j)(2), within 100 days of receipt of your petition, you will be notified of FDA's decision to either file the petition for comprehensive review, or to deny the petition. A denial may be by FDA action within the initial 100-day period, which ends on December 6, 2002, or by operation of law.

Please feel free to contact me at 301-436-1450 if you have questions concerning this petition.

Sincerely yours,

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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

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