

4/16/03

**INC Nutrition Research and Education Foundation**

April 16, 2003

Dr. Kathleen Ellwood  
Director, Division of Nutrition Programs and Labeling  
FDA, Center for Food Safety and Applied Nutrition  
Office of Nutritional Products, Labeling and Dietary Supplements  
HFS-830  
5100 Paint Branch Parkway  
College Park, MD 20740

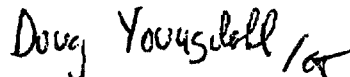
**RE: Docket 02P-0505**

Dear Dr. Ellwood:

This letter is to formally agree to a 90-day extension of the deadline for consideration of our petition entitled, "Authorization of a health claim for nuts and coronary heart disease" that was filed with your office on August 28, 2002. The original date stipulated in your letter to the International Tree Nut Council was March 6, 2003. This date was extended to April 18, as acknowledged by our letter to you of March 6. We now agree to extend the deadline to July 17, 2003.

We appreciate your careful consideration of our petition and look forward to working with the Agency during the next 90 days to move toward authorization of this important new claim.

Sincerely,



Doug Youngdahl  
Chairman

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**Memorandum of Meeting**

**Date:** March 27, 2003  
**Place:** Harvey W. Wiley Federal Building, College Park, MD  
Room 4C075  
**Subject:** Health Claim Petition- International Tree Nut Council  
Nutrition Research and Education Foundation  
(Docket No. 02P-0505)

**Participants:**

**Food and Drug Administration**  
**Center for Food Safety and Applied Nutrition**

Office of Nutritional Products, Labeling and Dietary Supplements

Christine Taylor, Ph.D., Director (HFS-800)  
Joanne Lupton, Ph.D., Visiting Scientist (HFS-800)  
Shellee Anderson, M.S., Food Technologist (HFS-800)  
Kathleen Ellwood, Ph.D., Director, Division of Nutrition Labeling and Programs  
(HFS-830)  
Nancy Crane, M.P.H, R.D., Expert Regulatory Review Scientist, Division of  
Nutrition Labeling and Programs (HFS-830)

Office of Science

Elizabeth Yetley, Ph.D., Lead Scientist for Nutrition (HFS-006)

Office of the Commissioner

Office of the Chief Counsel

Michael Landa, Esq., Deputy Chief Counsel (GCF-1)  
Heather Banuelos, Esq., General Attorney (GCF-1)

**International Tree Nut Council Nutrition Research and Education Foundation**

Guy Johnson, Ph.D., Johnson Nutrition Solutions  
Maureen Ternus, Nutrition Coordinator, M.S., R.D., International Tree Nut  
Council Nutrition Research and Education Foundation  
Richard Walden, President, Farmers Investment Company

The meeting was held at the invitation of FDA to discuss the agency's tentative conclusions in a letter dated March 14, 2003, in response to a health claim petition submitted on behalf of the International Tree Nut Council Nutrition Research and Education Foundation (INCNREF). This petition requested that FDA authorize a health claim about the relationship between the consumption of nuts and the reduction of risk of coronary heart disease on the label or in the labeling of certain whole or chopped nuts (i.e, peanuts and nine tree nuts) and certain nut-containing products.

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FDA and INCNREF representatives discussed several issues at this meeting including: 1) FDA's tentative conclusion that the current scientific evidence supports a qualified health claim for nuts, but not a health claim with significant scientific agreement; 2) the applicability of the claim to some but not all nuts; and 3) the relatively high levels of nuts used in the studies to achieve the claimed effect, and potential adverse effects.

INCNREF representatives stated that they still wanted to pursue a health claim with significant scientific agreement and asked if FDA would review the study design prior to their conducting further research. FDA responded (1) that they could continue to pursue a health claim with significant scientific agreement and that the agency would review the science, and (2) that the agency would work with them on a study design as circumstances allow, recognizing FDA's very limited resources and staffing.

INCNREF representatives also proposed conducting consumer research with respect to the wording of a qualified health claim for nuts.

Shellee Anderson, M.S.

cc: FDA meeting participants