

6/9/03

Memorandum of Meeting

Date: June 9, 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)

Kathleen Ellwood, Ph.D., Director, Division of Nutrition Labeling and Programs
(HFS-830)

James Hoadley, Ph.D., Special Assistant to the Director, Division of Nutrition
Labeling and Programs (HFS-830)

Paula Trumbo, Ph.D., Supervisory Team Leader, Division of Nutrition Labeling
and Programs (HFS-830)

Craig Rowlands, Ph.D., Regulatory Review Scientist, 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 Scientific Analysis and Support

Steven Bradbard, Ph.D., Leader, Consumer Studies Team
Division of Market Studies (HFS-727)

Brenda Derby, Ph.D., Statistician, Consumer Studies Team
Division of Market Studies (HFS-727)

Office of the Commissioner

Office of the Chief Counsel

Louisa Nickerson, Esq., Associate Chief Counsel for Foods (GCF-1)

Gloria Overholser, Esq., Associate Chief Counsel for Foods (GCF-1)

Heather Banuelos, Esq., Assistant Chief Counsel for Foods (GCF-1)

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

This meeting was held at the request of representatives of the International Tree Nut Council Nutrition Research and Education Foundation (INCNREF). The purpose was to update FDA on quantitative consumer research that INCNREF is conducting in cooperation with Kraft Foods that pertains to a health claim petition submitted on behalf of the 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.

FDA and INCNREF representatives discussed several issues at this meeting including: 1) the alternatives for qualified health claim language that are being tested in this consumer research, 2) a general description of the study that INCNREF is conducting and the sample size; 3) the criteria that INCNREF plans to use to evaluate the qualified health claim language alternatives, and 4) the time frame for communicating the study's findings.

OCC asked whether a protocol or methodology for the petitioner's study has been submitted to the agency for review. INCNREF representatives stated that none has been submitted and that the study is already currently underway.

In addition, FDA and INCNREF representatives discussed procedural issues pertaining to FDA's review of and response to this health claim petition.

An INCNREF representative asked if it would be possible to schedule another meeting with FDA in early July to report on the findings of their consumer research. FDA agreed to this and provided the INCNREF representatives with the name of the person to contact to schedule this meeting.

/s/

Nancy Crane, M.P.H., R.D.

cc: FDA meeting participants