

6/3/03 mtg

Memorandum of Meeting

Date: June 3, 2003
Place: Harvey W. Wiley Federal Building, College Park, MD
Room 3B047
Subject: Health Claim Petition- California Walnut Commission
(Docket No. 02P-0292)

Participants:

Food and Drug Administration
Center for Food Safety and Applied Nutrition

Office of the Director

Alan Rulis, Ph.D., Interim Senior Advisor for Applied Nutrition

Office of Nutritional Products, Labeling and Dietary Supplements

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)

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

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

Office of the Commissioner

Office of the Chief Counsel

Michael Landa, Esq., Deputy Chief Counsel (GCF-1)

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

California Walnut Commission

Dennis Balint, Chief Executive Officer, California Walnut Commission

Miriam Guggenheim, Esq., Covington & Burling, Counsel to the California
Walnut Commission

Sarah Taylor, J.D., M.P.H., R.D., Covington & Burling, Counsel to the California
Walnut Commission

Daniel Haley, President, Haley and Associates

Joan Sabaté, M.D., Dr.P.H., Department of Nutrition, Loma Linda University

02P-0292

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This meeting was held at the invitation of FDA to continue discussions about a health claim petition submitted on behalf of the California Walnut Commission (CWC). This petition requested that FDA authorize a health claim about the relationship between the consumption of walnuts and reduced risk of coronary heart disease on the label or in the labeling of whole or chopped walnuts. The CWC representatives requested that this meeting focus on the specific language of the health claim.

FDA and CWC representatives discussed the scientific evidence for a qualified health claim about walnuts versus a broader-based claim that would encompass other nuts. In addition, issues pertaining to the language of the health claim were identified and discussed including: 1) the subject of the health claim and consumer research on the circumstances in which the claim may be misleading; 2) reference to daily amounts necessary to achieve the claimed effect; 3) provision of a total diet context for the claim; 4) the level of evidence for the claim; and 5) the inclusion of a disclosure statement about total fat. FDA and CWC representatives also discussed procedural issues including the possibility of providing a public comment period for the qualified health claim.

CWC representatives requested to meet again with FDA to continue dialogue on these issues, and Dr. Ellwood agreed to contact Ms. Sarah Taylor to arrange this meeting.

/s/

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

cc: FDA meeting participants