3/24/03

Memorandum of Meeting

Date: March 24, 2003

Place: Harvey W. Wiley Federal Building, College Park, MD
Room 1A001

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 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)
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)
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
Artemis Simopoulos, M.D., The Center for Genetics, Nutrition and Health

This meeting was held at the request of representatives from the California Walnut Commission (CWC) to discuss FDA's tentative conclusions in a letter dated February 25, 2003, in response to a health claim petition submitted on behalf of the CWC. This petition asked FDA to 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.

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FDA and CWC representatives discussed several issues at this meeting including: 1) the scientific evidence in support of a health claim about walnuts *per se* vs. a broader-based health claim that would encompass other nuts; 2) the scientific evidence for the amount of walnuts necessary to achieve the claimed effect; 3) First Amendment issues; and 4) issues related to the wording of a health claim and the need for qualifying statements. No decisions were made on any of these issues.

The meeting closed with a discussion about next steps. An FDA representative noted that it was previously agreed that FDA would respond to the CWC petition by March 28, 2003. A CWC representative indicated that they would like to submit additional data by March 26, 2003. The FDA representative noted that a new time frame would need to be set with the submission of additional data, and that an FDA representative would follow-up by March 28th to set up a new time frame for FDA to respond to this petition.

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

cc: FDA meeting participants