

**Memorandum of Meeting**

**Date:** July 25, 2003 5 38 8 '03 SEP -4 P1:55  
**Place:** Harvey W. Wiley Federal Building, College Park, MD  
Room 3B047  
**Subject:** Health Claim Petition- Omega-3 Fatty Acids and Coronary Heart  
Disease

**Participants:**

**Food and Drug Administration/Center for Food Safety and Applied Nutrition**  
Office of Nutritional Products, Labeling and Dietary Supplements  
Kathleen Ellwood, Ph.D., Director, Division of Nutrition Labeling and Programs  
(HFS-830)  
Shellee Anderson, M.S., Acting Team Leader, Regulations and Review Team  
(HFS-830)  
Paula Trumbo, Ph.D., Acting Team Leader, Science Review Team (HFS-830)

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

Office of the Commissioner  
Office of the Chief Counsel  
Gloria Overholser, Esq., Associate Chief Counsel for Foods (GCF-1)

**Emord and Associates, P.C.**  
Jonathan W. Emord, Esq.  
Andrea Ferrenz, Esq.

This meeting was held at the request of Mr. Emord and Ms. Ferrenz to discuss the petition that their office submitted, on behalf of Wellness Lifestyles and Life Extension Foundation Buyers Club, Inc., for an amended health claim about omega-3 fatty acids and coronary heart disease on conventional food and dietary supplements. Mr. Emord stated that his client believed that the claim has significant scientific agreement. However, if FDA only allows a qualified claim, Mr. Emord stated that his client would be agreeable to the use of a disclaimer incorporated into the wording of the claim, in lieu of a claim statement followed by a separate disclaimer statement.

FDA representatives indicated that they did not believe that the agency would object to a qualified health claim with the qualified language embedded into the wording of the claim. Mr. Emord briefly discussed some of the scientific evidence related to the petitioned claim.

Shellee Anderson

2003Q-0401

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