

Memorandum of Meeting

Date: October 14, 2003

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Place: Harvey W. Wiley Federal Building, College Park, MD
Room 4E029

Subject: Smart Balance Plus 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 Programs and Labeling
(HFS-830)

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

Shellee Anderson, M.S., Acting Team Leader, Regulations and Review Team
(HFS-830)

Paula Trumbo, Ph.D., Team Leader, Science Review Team (HFS-830)

Wanda Kelker, Branch Chief, Compliance and Enforcement Branch (HFS-820)

Visitors

Robert M. Harris, GFA Brands, Inc.

Martin Hahn, Esq., Hogan and Hartson, L.L.P.

K. C. Hayes, DVM, Ph.D., Brandeis University

This meeting was held at the request of Mr. Hahn on behalf of Mr. Harris to present FDA with information concerning the effect of fatty acid ratio on LDL cholesterol. They stated that their product was formulated with a favorable fatty acid ratio but did not meet the saturated fat requirements in the interim final rule. They asked how to proceed with their comments and whether a qualified health claim petition would be the best way.

FDA representatives indicated that anything the visitors submitted, including a qualified health claim petition, would be considered a comment on the phytosterol rulemaking at this time.

Shellee Anderson

cc: FDA meeting participants

HFA-305 (Docket Nos. 00P-1275 and 00P-1276)

00P-1275

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