

Food and Drug Administration College Park, MD 20740

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AUG | \$ 2006

Nancy L. Schnell
Deputy General Counsel
Marketing and Regulatory
Unilever United States, Inc.
700 Sylvan Avenue
Englewood Cliffs, NJ 07632

RE: Health Claim Petition - To amend 21 CFR 101.83, a health claim relating plant sterol/stanol esters and risk of coronary heart disease (CHD). Docket No. 2006P-0316

Dear Ms Schnell:

This letter is in reference to the subject health claim petition, dated May 5 and subsequent submission dated May 10, 2006, and received in the Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition, Food and Drug Administration on May 10, 2006. We informed you on May 25, 2006, that the date by which FDA would either file or deny your petition is August 18, 2006. We have completed our initial review of this petition and are filing it as specified in section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (the act). The filing date is August 18, 2006. The Food and Drug Administration Docket number assigned for your petition is 2006 P-0316. We will either publish a proposal in response to the petition or deny the petition within 90 days of the filing date, i.e., not later than November 16, 2006.

Sincerely yours,

Barbara O. Schneeman, Ph.D.

Director

Office of Nutritional Products, Labeling and Dietary Supplements

Center for Food Safety and Applied Nutrition

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