



MAY 25 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 – phytosterols and reduced risk of coronary heart disease

Dear Ms Schnell:

This letter acknowledges receipt on May 10, 2006 by the Food and Drug Administration (FDA) of your petition submitted pursuant to Sections 403(r)(4) and 403(r)(5)(D) of the Federal Food, Drug and Cosmetic Act (FFD&C Act) (21 U.S.C. §§ 343(r)(4) and 343(r)(5)(D)). You requested that the FDA amend its current health claim regulations for phytosterols (21 CFR 101.83) to permit a claim that consumption of at least 2.0 g phytosterols daily in one serving eaten with meals will reduce total and LDL-cholesterol and therefore reduce the risk of CHD and that this claim be permitted on foods that contain at least 2.0 g phytosterols per RACC or per serving.

Your petition is undergoing initial FDA review. In accordance with Section 403(r)(4)(A)(i) of the FFD&C Act (21 U.S.C. § 343(r)(4)(A)(i)) and 21 CFR 101.70(j)(2), within 100 days of receipt of a petition, the petition will either be filed for comprehensive review or denied. A denial may be by either FDA action within the 100-day period, which ends on August 18, 2006, or by a lack of FDA action within the initial 100-day period in which case the petition shall be deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner.

2006 P-0316

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Please feel free to contact me at 301-436-1450 if you have questions concerning this petition.

Sincerely yours,

/s/

Constance Henry  
Nutrition Programs and Labeling Staff  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition