



Unilever

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November 3, 2008

VIA OVERNIGHT MAIL and  
EMAIL TO: [kathy.ellwood@fda.hhs.gov](mailto:kathy.ellwood@fda.hhs.gov)

Kathleen Ellwood, Ph.D.  
Director, Nutrition Programs and Labeling  
Staff Office of Nutritional Products, Labeling and Dietary Supplements (HFS-830)  
Center for Food Safety and Applied Nutrition Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: **Health Claim Petition to Amend 21 CFR 101.83**  
**Phytosterols and Risk of Heart Disease**  
**Docket No. 2006P-0316**

Dear Dr. Ellwood:

This relates to the above-referenced petition to amend the phytosterol health claim, 21 CFR 101.83, which was filed by FDA on August 18, 2006.

The petitioner hereby agrees to a further extension of FDA's review period to and including September 16, 2009.

Sincerely,

Nancy L. Schnell  
Deputy General Counsel  
Marketing & Regulatory  
Unilever United States, Inc.

cc: Constance B. Henry (HFS-832)

FDA-2006-P-0033

LET



Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

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Mr. Lyle Jaffe  
Dockets Management Branch  
Food and Drug Administration  
5630 Fishers Lane, Room 1061 (HFA-305)  
Rockville, MD 20852

Proposed Rule: Phytosterols and Reduced Risk of Coronary Heart Disease (Docket No. FDA-2006-P-0033 [formerly Docket Nos. 2006P-0316])

Dear Mr. Jaffe:

Will you please add the enclosed extension letter to the docket entitled, "Phytosterols and Reduced Risk of Coronary Heart Disease?" Thanks in advance for your time.

Sincerely,

Annie-Marie Brown, MS.  
Nutrition Programs and Labeling Staff  
Office on Nutritional Products, Labeling and Dietary Supplements  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration

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Enclosures (1)

Letter, dated November 3, 2008 from Nancy L. Schnell, Global Foods Counsel and U.S. Deputy, Unilever, to Kathy Ellwood, Ph.D., FDA, HFS-830.