founded 1881

January 31, 2011

Blakeley Denkinger
Center for Food Safety and Applied Nutrition
U. S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

Re: Food Labeling; Health Claims; Phytosterols and Risk of Coronary Heart Disease (Proposed Rule) 75 *Fed. Reg*. 76526-76571 (December 8, 2010). Docket Nos. FDA-2000-P-0102, FDA-2000-P-0133, and FDA-2006-P-0033 (formerly Docket Nos. 2000P-1275, 2000P-1276, and 2006P-0316, respectively)

Dear Ms. Denkinger:

The Consumer Healthcare Products Association (CHPA) was founded in 1881 and is the national trade association that represents manufacturers and distributors of over-the-counter (OTC) medicines and dietary supplement products. Members from the CHPA Dietary Supplements Committee (DSC) are submitting comments in response to the December 8, 2010, *Federal Register* (*FR*) notice announcing the proposed rule entitled "Food Labeling; Health Claim; Phytosterols and Risk of Coronary Heart Disease[1]." Although additional comments on the proposed rule may be submitted later, these remarks specifically address our concern regarding Section VI. of the *FR* notice regarding enforcement discretion.

VI. Enforcement Discretion

Page 76546 of the *Federal Register* notice[1] indicates that 75 days from publication of the proposed rule, FDA does not intend to exercise enforcement discretion based on its letter issued in 2003[2] on this matter.

[1] Food Labeling; Health Claim; Phytosterols and Risk of Coronary Heart Disease; Proposed Rule (December 8, 2010). Accessed January 12, 2011, from http://edocket.access.gpo.gov/2010/pdf/2010-30386.pdf.
[2] Letter on enforcement discretion. Accessed January 12, 2011, from http://www.fda.gov/Food/LabelingNutrition/LabelClaims/HealthClaimsMeetingSignificantScientificAgreementSSA/ucm074779.htm.

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Seventy five (75) days is not adequate to complete changes that might be required based on requirements of the proposed rule. Timing for enforcement discretion on this issue should permit manufacturers a reasonable amount of time (*i.e.*, 18 - 24 months) to reformulate and/or relabel dietary supplement products affected by the proposed rule.

The notice states that "pending issuance of the final rule, FDA intends to consider the exercise of its enforcement discretion on a case-by-case basis when a health claim regarding phytosterols is made in a manner that is consistent with the proposed rule[1]." CHPA members believe only products first marketed after the publication of the proposed rule should be subject to the conditions as outlined in the December 8, 2010, notice, not dietary supplement products marketed before this date. Also, dietary supplement (softgel) products marketed prior to the proposed rule and which currently use health claims based on the interim final rule[3] (IFR) on plant sterol/stanol esters and coronary heart disease published September 8, 2000, should not be subject to changes until the final rule has been published. To comply with dietary supplement cGMP and internal standard operating procedures, changes to product labeling require 6 - 12 months lead time, with additional time needed if a product must be reformulated to comply with the proposed rule. Product relabeling and reformulation are time and resource intense activities. The seventy five (75) day time frame stated in the *Federal Register* notice is simply not adequate to complete changes that might be required based on requirements of the proposed rule. For example, product reformulation requires validation and stability testing which take months to complete. Furthermore, companies would also be expected to comply with any revised requirements once the final rule is published and becomes effective, potentially leading to the need for further labeling and/or formulation changes.

CHPA DSC members strongly urge the agency to permit manufacturers of dietary supplement products with claims regarding free phytosterols and heart disease that were marketed before publication of the proposed rule (December 8, 2010) to continue marketing of such products until the final rule is published. At a minimum, dietary supplement products marketed prior to December 8, 2010, should not be subject to labeling changes until the next uniform compliance date for food, including dietary supplements, labeling (compliance date: January 1, 2014). This is consistent with past FDA acknowledgments that, lack of coordinated effective dates for labeling changes would have a substantial cumulative economic impact on the food industry (including dietary supplements) if companies had to respond separately to regulations requiring labeling changes[4]. In fact, the possibility of implementing multiple labeling changes will exist if companies are forced to make labeling changes based on this proposed rule and later based on any modifications to the final rule. As with previous regulatory implementation periods, timing for enforcement discretion on this issue should permit manufacturers a

[3] Food Labeling: Health Claims; Plant Sterol/Stanol Esters and Coronary Heart Disease; Interim Final Rule. Accessed January 12, 2011, from http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2000_register&docid=00-22892-filed.pdf.
[4] Uniform Compliance Date for Food Labeling Regulations, Final Rule. Accessed January 19, 2011, from http://edocket.access.gpo.gov/2010/pdf/2010-31382.pdf.

reasonable amount of time (*i.e.*, 18 - 24 months) to reformulate and/or relabel dietary supplement products affected by the proposed rule.

We look forward to your thoughtful consideration of our recommendations and are happy to answer any questions.

Sincerely,

Marcia D. Howard, Ph.D.
Director, Regulatory & Scientific Affairs

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