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BY FEDERAL EXPRESS

Division of Dockets Management  
U.S. Food and Drug Administration  
Department of Health & Human Services  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**PETITION FOR STAY OF ACTION**

Pursuant to 21 C.F.R. § 10.35, we hereby submit this Petition for Stay of Action on behalf of our client Pharmachem Laboratories, Inc. ("Pharmachem"), 265 Harrison Avenue, Kearny, NJ 07032, the manufacturer of free phytosterols used in dietary supplements,

A. Decision Involved

On December 8, 2010, FDA published a proposed rule to amend 21 C.F.R. § 101.83, the regulation authorizing the health claim that diets including certain foods containing plant sterol esters may reduce the risk of coronary heart disease ("CHD health claim").<sup>1</sup> Under a 2003 letter of enforcement discretion ("2003 Letter"), this claim can currently be made in the labeling of the dietary supplements identified below that contain non-esterified (free) phytosterols.<sup>2</sup>

However, the proposed rule would prohibit the CHD health claim for these products. FDA has also announced that, beginning February 21, 2011, the 2003 Letter will no longer apply, and enforcement discretion will only be exercised for the claims and products permitted by the proposal, despite the fact that no final regulation has been promulgated.<sup>3</sup>

<sup>1</sup> 75 Fed. Reg. 76526-76571 (Dec. 8, 2010).

<sup>2</sup> Center for Food Safety and Applied Nutrition, Food and Drug Administration. Letter of Enforcement Discretion from FDA to Cargill Health & Food Technologies. Docket No. FDA 2000-P-0102 and Docket No. FDA-2000-P-0133, February 14, 2003.

<sup>3</sup> 75 Fed. Reg. at 76546.

*FDA 2006.P.0033*

*PSA*  
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B. Action Requested

Pharmachem requests FDA to: (i) stay revocation of the 2003 Letter as noted above; and (ii) **continue to permit** dietary supplements containing free phytosterols at 0.4 g free sterol equivalent per reference amount customarily consumed (RACC) to be marketed with the CHD health claim, under the Agency's enforcement discretion, **until a final rule is issued**.

C. Statement of Grounds

1. Good Faith

Pharmachem's instant petition is submitted in good faith. While FDA has stated that the results of studies evaluating the cholesterol-lowering effect of free phytosterols in dietary supplements are inconsistent, the agency has termed this observation "tentative."<sup>4</sup> The Agency has explicitly said that it will reevaluate this issue in light of any additional data received during the comment period.<sup>5</sup>

Pharmachem intends to submit comments and data to demonstrate that dietary supplements containing free phytosterols have been shown to be efficacious in lowering blood cholesterol levels. Based on these materials, Pharmachem will urge that such products are eligible for the CHD health claim.

2. Public Policy

Based on the above, public policy is served by a grant of the petition.

3. Delay not Outweighed

Waiting to evaluate comments and data offered in support of the CHD claim for dietary supplements with free phytosterols is not outweighed by public health or interest concerns. This claim for these products has been permitted by FDA for nearly 8 years, and a number of scientific studies to substantiate the claim have been generated.

4. Irreparable Injury

Pharmachem formulates a free phytosterol ingredient (Reducol<sup>®</sup>) into a granulated form

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<sup>4</sup> 75 Fed. Reg. at 76540-76541.

<sup>5</sup> 75 Fed. Reg. at 76541.

that can be compressed directly into tablets.<sup>6</sup> Pharmachem's major customer for this ingredient supplies a considerable percentage of the U.S. market for dietary supplements containing free phytosterols, through major retail chains. In addition, Pharmachem sells free phytosterol tablets and/or powder to a number of other companies selling finished supplement products.

The availability of these ingredients and products, with the informative CHD health claim, will be prematurely and severely disrupted unless FDA continues to exercise its enforcement discretion under the 2003 Letter **pending promulgation of a final rule**.

Consumers will be irreparably harmed from the loss of these products. Many consumers will have to change to supplements containing esterified plant sterol esters, which are in a softgel cap form carrying a higher retail price. This could very well put dietary supplements with phytosterols **out of their reach**.

Moreover, Pharmachem and its customers will be irreparably injured by the loss of the free phytosterol dietary supplement market, which will **evaporate swiftly** if the stay is not granted.

Respectfully submitted,



Charles J. Raubicheck

cc: Pharmachem Laboratories, Inc.

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<sup>6</sup> Reducol® is the subject of GRAS Notification GRN 000039, April 24, 2000. (It is called by its prior name Phytrol in the submission).

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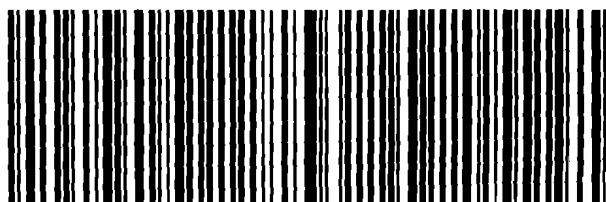
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