



Division of Advertising Practices

UNITED STATES OF AMERICA  
FEDERAL TRADE COMMISSION  
WASHINGTON, D.C. 20580

April 16, 2009

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1140 Nineteenth Street, N.W.  
Washington, D.C. 20036-6606

Re: Pharmavite LLC – Advertising for NatureMade CholestOff  
Matter No. 0723233

Dear Mr. Young and Ms. Maher:

As you know, the staff of the Federal Trade Commission conducted an investigation of Pharmavite LLC for possible violations of Sections 5 and 12 of the Federal Trade Commission Act (“FTC Act”), 15 U.S.C. §§ 45 and 52. The investigation concerned Pharmavite’s advertising campaign for NatureMade CholestOff and CholestOff Complete, dietary supplements containing free form plant sterol/stanols.

The staff’s inquiry focused on advertising and labeling claims that CholestOff is clinically proven to lower cholesterol and, more specifically, that CholestOff lowers LDL cholesterol up to 24% or 42 points. Staff was concerned that the general cholesterol-lowering claims and the specific percentage and point reduction claims may not be adequately substantiated for the form of plant sterol/stanols in the CholestOff product.

Staff recognizes that there is a substantial body of scientific evidence suggesting that the consumption of foods enriched with plant sterol/stanol esters may reduce the risk of heart disease by lowering blood cholesterol levels. Based on that evidence, the Food and Drug Administration issued an interim final rule in 2000, authorizing a health claim for foods enriched with plant sterol/stanol esters and reduced risk of heart disease.<sup>1</sup> Staff is also aware that, in 2003, after reviewing additional scientific evidence, the FDA issued a letter indicating that it would exercise its enforcement discretion to allow expanded use of the authorized health claim for other forms and sources of phytosterols. The letter expanded use of the health claim to include both the esterified and free forms of plant sterol/stanols and to include dietary

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<sup>1</sup> See 21 C.F.R. § 101.83 “Health Claims: Plant Sterol/Stanol Esters and Risk of Coronary Heart Disease (CHD); Interim Final Rule,” 65 F.R. 54686 (Sept. 8, 2000).

supplements, in addition to conventional foods.<sup>2</sup>

A number of additional studies have been reported since FDA's interim final rule and the issuance of the 2003 letter of enforcement discretion. FDA has indicated that it is in the process of responding to comments to the interim final rule and a petition submitted since the issuance of the letter of enforcement discretion. The FTC staff has reviewed the clinical studies on plant sterol/stanols and has consulted with FDA staff on the current state of scientific evidence. While the available scientific evidence continues to support a cholesterol-lowering effect of plant sterol/stanols, the consistency of that effect and the degree of benefit appear to vary depending on the form (free form or esterified), how it is delivered (whether in food or in dietary supplement), and other factors including amount, frequency, and timing of intake.

Staff is concerned that there appears to be little clinical evidence directly relating to the cholesterol-lowering effect of a dietary supplement containing the specific formulation of free form plant sterol/stanols contained in CholestOff. Most of the publicly available evidence involves studies on plant sterols/stanols delivered in conventional foods. There are relatively few clinical trials on plant sterol/stanols in dietary supplements and even fewer on free form plant sterol/stanols, the form used in CholestOff. The clinical evidence supporting a cholesterol-lowering benefit for dietary supplements has generally involved supplements containing the esterified form of plant sterols/stanols, not the free form. The more limited evidence available on dietary supplements containing free form plant sterols/stanols has shown inconsistent results.

Given the variability in outcomes and the inconsistent results for free form plant sterol/stanol supplements, staff believes that any claims for CholestOff suggesting a specific percentage or point reduction in blood cholesterol would need to be substantiated by clinical trials on the CholestOff product or a substantially similar dietary supplement containing the same amount, form, and formulation of plant sterols/stanols. Staff notes that the clinical studies cited in Pharmavite's marketing materials in support of its specific cholesterol-lowering claims all involved free form plant sterol/stanols delivered in foods, not supplements.<sup>3</sup> Staff also notes that the 24% and 42 point reduction claims prominently featured in CholestOff advertising and labeling singled out the most dramatic reductions from among these various food studies and were not adjusted to net out the reductions in cholesterol attributable to diet alone.

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<sup>2</sup> "FDA Letter Regarding Enforcement Discretion with Respect to Expanded Use of an Interim Health Claim Rule about Plant Sterol/Stanol Esters and Reduced Risk of Coronary Heart Disease," (Feb. 14, 2003), *available at* <http://www.cfsan.fda.gov/~dms/ds-ltr30.html>.

<sup>3</sup> CholestOff's web site, for example, at <http://www.cholestoff.com/infoHealthcare.asp>, provides a link to the manufacturer's site for Reducol, the free form plant sterol/stanol ingredient used in CholestOff. The Reducol web site, at <http://www.reducoc.com/s/HealthCarePro.asp>, provides descriptions of studies of Reducol in margarine, chocolate, and milk, including the Jones et al., 1999 study on margarine that is the basis for the specific CholestOff claim.

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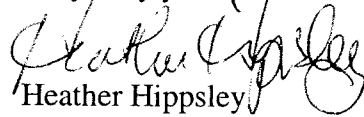
We appreciate Pharmavite's willingness to address our concerns about the specific numerical claims with changes to advertising and labeling materials for CholestOff. Based on Pharmavite's assurances that it has eliminated numerical and percentage claims from television advertising and its Internet sites and is in the process of removing the claims from labeling, we have determined that no further action is warranted at this time.

With respect to more general claims about the cholesterol-lowering and heart health benefits of CholestOff, we would prefer to have additional substantiation that more directly demonstrates efficacy for this specific form and formulation of plant sterol/stanol supplement. We have decided, however, to defer to FDA's 2003 letter of enforcement discretion allowing such claims for free form plant sterol/stanol supplements.

Staff is therefore closing its investigation. We will continue to monitor developments in the scientific literature and may reevaluate claims for CholestOff and other plant sterol/stanol products should FDA make revisions to its current policy on the heart health claim.

This action is not to be construed as a determination that a violation has not occurred, just as the pendency of an investigation should not be construed as a determination that a violation has occurred. The Commission reserves the right to take further action as the public interest may require.

Very truly yours,



Heather Hipsley  
Acting Associate Director  
Division of Advertising Practices