DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

OCT 30 2001

Mr. David Kropp
Acting Director, Regulatory and Consumer Affairs
Pharmavite Corporation
P.O. Box 9606
Mission Hills, California 91346-9606

Dear Mr. Kropp:

This is in response to your letter of October 8, 2001 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Pharmavite Corporation is making a number of claims for the product Cholest-Off™, containing the ingredient Reducol™, that represent the product as being intended to reduce blood cholesterol levels and support cardiovascular health.

The statements being made for this product are statements about the relationship between plant sterols and stanols and the risk of coronary artery disease and are not claims subject to 21 U.S.C. 343(r)(6), but instead are claims subject to 21 U.S.C. 343(r)(1)(B). FDA has authorized a health claim on the relationship between plant sterol esters and stanol esters and the risk of coronary artery disease (see 21 CFR 101.83). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between plant sterol esters and stanol esters and the risk of coronary artery disease in its labeling. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.83 would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, failure to make a claim in accordance with the requirements in 21 CFR 101.83 subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, coronary artery disease.

For several reasons, your product does not appear to meet the eligibility requirements to bear the health claim authorized in 21 CFR 101.83 in its labeling. Furthermore, the claims themselves do not appear to meet the message requirements set forth in the regulation. The product does not appear to contain plant sterol or stanol esters. Instead, it contains Reducol™, an ingredient that to our knowledge, contains only unesterified plant sterols and unesterified plant stanols. These ingredients do not qualify a product containing them to bear the authorized health claim in its labeling. Moreover, even if the product contained ingredients covered by 21 CFR 101.83, the amounts provided per

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serving of Reducol™ do not meet the eligibility requirement in 21 CFR 101.83(c)(2)(i)(G) and (H). Additionally, the claims made for the product do not meet the message requirements in the regulation. For example, the statements for Reducol™ do not state that the product "may" or "might" reduce the risk of heart disease (21 CFR 101.83(c)(2)(i)(B)); in fact, no where in the claim being made for your product are the terms "heart disease" or "coronary heart disease" used.

Therefore, since your statements are not claims under 21 U.S.C. 343(r)(6) and are also not authorized health claims under 21 U.S.C. 343(r)(1)(B), they are claims that suggest that this product is intended to treat, prevent, cure, or mitigate a disease, namely coronary artery disease. These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if you require further assistance.

Sincerely,

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, Los Angeles District Compliance, HFR-PA240

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RECEIVED
OCT 12 2001
BY:

October 8, 2001

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. SW
Washington, DC 20204

Dear Sir or Madam:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section 101.93 of FDA's regulations, we hereby notify you that we are using the following statement(s):

(1) Name and address of manufacturer:
Pharmavite Corporation, PO Box 9606, Mission Hills, CA 91346

(2) Text of the statement(s):

Clinically Proven to Reduce Cholesterol
Helps Support Cardiovascular Health
All Natural
Cholest-Off™ contains Reducol™, a unique, proprietary blend of natural plant sterols and stanols. Plant sterols and stanols, also known as phytosterols and stanols, are naturally occurring substances present in leaves, nuts, vegetables and other plants. Over 40 years of clinical research on plant sterols and stanols have demonstrated their long-term safety with no known adverse effects. Products containing at least 0.4 grams per serving of plant sterols and stanols, eaten twice a day with meals for a daily intake of at least 0.8 grams as part of a diet low in saturated fat and cholesterol, helps support cardiovascular health. One serving of Nature Made Cholest-Off supplies 0.9 grams of plant sterols and stanols. As part of a cholesterol management program, you should consult your physician and have your cholesterol levels checked regularly. Many factors such as diet, body weight, physical exercise and age can affect your cholesterol levels. That is why a diet low in saturated fat and regular exercise are recommended as part of a cholesterol management program. However, diet and exercise alone don't always reduce your cholesterol levels to the desired range. That's where Nature Made® Cholest-Off™ can help.

Pharmavite Corporation • P.O. Box 9606 • Mission Hills, CA 91346-9606 • 818/221-6200 • 800/423-2405
Deliveries Only: 8510 Balboa Blvd., Northridge, CA 91325

PHARMAVITE

Desirable Less than 200 mg/dL
Borderline 200 to 239 mg/dL
High 240 mg/dL or greater

Cholest-Off with Reducol™, is clinically proven to reduce LDL ("bad") cholesterol and total cholesterol by blocking cholesterol absorption. As a result, taken as directed, Cholest-Off will lower your cholesterol levels and help support your cardiovascular health. Cholest-Off starts to work within 30 days!

(3) Name of the dietary ingredient if not provided in the text of the statement:
plant sterols/stanols

(4) Name of the dietary supplement:
Cholest-Off
450 mg Plant Sterols/Stanols

The above statement(s) may be used in one or more of the following brands of products: B.J.'s Wholesale, CVS, Duane Reade, Kirkland Signature, Jogmate, Nature Made, Nature's Resource, Optimize, Spring Valley, Walgreens.

We certify the information in this notice is complete and accurate, and we have substantiation that the above statement(s) is truthful and not misleading.

Sincerely,

David Kropp
Acting Director, Regulatory and Consumer Affairs
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