



AUG 26 2002

*Rec'd 8/27/02
yb*

Mr. David Kropp
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 letters of July 30, 2002 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 products below.

The product Cholest-Off™ uses the claims "Cholesterol Fighter" and "Clinically proven to lower LDL cholesterol up to 24%," among other claims.

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 Redurol™, an ingredient that the claims make clear 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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servicing 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.

The product Diabetes Health Pack uses the claims “May help maintain blood glucose levels...” (for selenium) and “may help maintain glucose metabolism” (for alpha lipoic acid). These statements, rather than being statements about the product being intended to meet the dietary needs of persons with diabetes, are instead statements that represent the product to be intended to treat the characteristic sign or symptom of diabetes, namely, the inability of persons with diabetes to metabolize glucose effectively. These statements are not claims under 21 U.S.C. 343(r)(6) but rather they are claims that suggest that this product is intended to treat, prevent, cure, or mitigate a disease, namely diabetes. 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.

The product SAM-e uses the claim “Joint Pain Relief” and “Relieves joint pain by helping to repair and maintain joint cartilage which naturally deteriorates with physical activity and age.” These claims are disease claims because they suggest that the product is intended to treat, prevent, or mitigate diseases, namely joint disorders such as arthritis. In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1016-17), FDA stated that “joint pain” is characteristic of arthritis and that it is the most sensitive physical sign of rheumatoid arthritis. For that reason, the agency concluded that claims about relieving joint pain are implied disease claims because they represent that the product will have an affect on a characteristic sign or symptom of a disease (see 21 CFR 101.93(g)(2)(ii)). Moreover, elsewhere in the preamble to the final rule (see 65 FR 1000 at 1030) FDA discussed the circumstances under which claims about pain would imply disease treatment. We stated that since pain is not a normal state, nor are there “normal pain levels,” a claim about pain treatment or prevention is ordinarily a disease claim. We addressed the issue of joint pain claims in particular, noting that such claims are disease claims because joint pain is a characteristic symptom of arthritis. We added, however, that a acceptable structure/function claim could be made for pain associated with non-disease states, such as muscle pain following exercise.

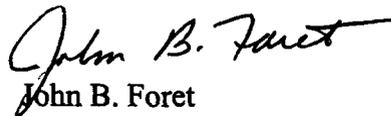
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The claim contained in your notification refers to pain associated with changes in cartilage associated with aging and physical activity. While cartilage changes associated with physical activity and age may not in themselves be diseases, such changes would not be expected to result in joint pain unless a person already suffered from an underlying disease or such changes were so extensive as to constitute a disease themselves, which in turn predisposed him or her to such pain.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are 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

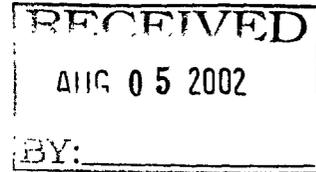
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Los Angeles District Compliance, HFR-PA240



PHARMAVITE

July 30, 2002



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 LLC, PO Box 9606, Mission Hills, CA 91346
- (2) Text of the statement(s):

CHOLEST-OFF™
Cholesterol Fighter

GET CHOLESTEROL MOVING IN THE RIGHT DIRECTION

Clinically proven to lower LDL cholesterol up to 24%

The Natural Cholesterol Fighter

Cholesterol and its importance

Whether you heard it from your doctor, on the news, or in discussions with family and friends, you know having high cholesterol is a bad thing. You may even know that according to the American Heart Association, more than 100 million Americans suffer from borderline high to high cholesterol levels. But do you really understand what cholesterol is and why having too much of it is bad for you?

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The ABC's of Cholesterol

Cholesterol is a substance found in all animals — our bodies make it, and it is found in some of the foods we eat. Cholesterol is vital to the formation of our cell membranes, hormones and other tissues. To carry it in and out of our bodies, cholesterol counts on two proteins — high density lipoproteins (HDL) and low density lipoproteins (LDL).

HDL is known as the “good cholesterol,” because it takes excess cholesterol from our bodies. LDL is known as the “bad cholesterol” as it carries cholesterol into our bloodstream.

Plant Sterols and Stanols — The Key to Fighting High Cholesterol Naturally and Effectively

Plant sterols, also known as phytosterols, are naturally occurring substances present in everything from nuts and legumes to leaves and vegetables. Plant stanols, or phytostanols, also occur naturally in many of the same substances, but at a lower levels.

The molecular structures of plant sterols and stanols are similar to that of dietary cholesterol, which is absorbed by the intestines and transported through the bloodstream. Because of this structural similarity to cholesterol, plant sterols and stanols may block cholesterol absorption in the intestines resulting in lower LDL cholesterol levels.

Most people consume 200-300 mg of plant sterols and stanols as part of their daily diet. However, studies prove that it takes at least 1.8 - 2 grams of plant sterols and stanols to have a cholesterol lowering effect. More than 40 years of research on plant sterols and stanols have proven their ability to help reduce cholesterol levels safely and effectively with no known adverse effects.

Nature Made® Cholest-Off™, the Natural Cholesterol Fighter

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.



Available in easy-to-swallow, convenient and calorie-free caplets, each Cholest-Off caplet contains a proprietary blend of plant sterols and stanols known as Reducol™. Taken daily with low fat, heart healthy meals, Nature Made Cholest-Off with Reducol blocks LDL cholesterol's ability to absorb in the intestines, and has been clinically proven to reduce LDL cholesterol levels up to 24 percent. As a result, a heart-healthy diet that includes Nature Made Cholest-Off every day is an important step in the right direction toward lowering your cholesterol levels and supporting your heart health.

Taking 1.8-2 grams of plant sterols and stanols daily such as those found in Nature Made Cholest-off, has been clinically proven to lower bad (LDL) cholesterol levels up to 24 percent when taken with a low fat, heart healthy diet.

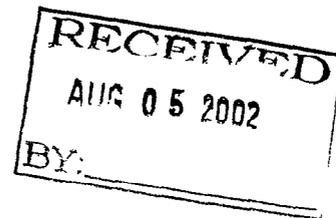
- (3) Name of the dietary ingredient(s) if not provided in the text of the statement:
Plant sterols/stanols
- (4) Name of the dietary supplement:
Cholest-Off

The above statement(s) may be used in one or more of the following brands of products: AAFES, B.J.'s Wholesale, CVS, Duane Reade, Kirkland Signature, Jogmate, Nature Made, Nature's Resource, Nutri - Plus, 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
Director, Regulatory and Consumer Affairs



July 30, 2002

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Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. SW
Washington, DC 20204

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- (1) Name and address of manufacturer:
Pharmavite LLC, PO Box 9606, Mission Hills, CA 91346
- (2) Text of the statement(s):
Diabetes Health Pack

Scientifically Formulated Nutritional Support For People with Diabetes

The Nature Made Diabetes Health Pack was scientifically formulated to meet the unique nutritional needs of people with diabetes. The Diabetes Health Pack provides essential nutrients that may be lacking due to the strain diabetes can often put on the body's health. Each packet contains a synergistic blend of vitamins, minerals and supplements that provides nutritional support for people with diabetes. If you are not always eating a balanced diet, Nature Made Diabetes Health Pack provides the nutrients that you may be missing.

ANTIOXIDANTS & DIABETES

High blood glucose levels appear to increase the production of free radicals, which are chemical compounds that can damage tissues. Though free radicals naturally occur in the body, they are toxic and may be harmful to people with diabetes.

Antioxidants help protect against free-radical damage and are particularly important for people with diabetes because of their tendency to experience an increased rate of oxidative stress. Antioxidants, such as Vitamins C and E, also supply key nutrients that may be lacking in people with diabetes.

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Diabetes & Cholesterol

It's especially important for people with diabetes to control weight and blood cholesterol with a low fat, heart-healthy diet and regular exercise.

If you have diabetes and want to lower your cholesterol naturally, try Nature Made Cholest-Off™. It's clinically proven to lower bad (LDL) cholesterol levels up to 24%.

Selenium – Antioxidant

May help maintain blood glucose levels and may promote a reduction in oxidative stress.

Multivitamin/mineral with Lutein

A high potency supplement providing essential vitamins and minerals for nutritional support of the heart and digestive system of the body. Lutein helps maintain eye health.

Vitamin C – Antioxidant

People with diabetes have been shown to have lower levels of Vitamin C. Vitamin C may lessen oxidative (free radical) damage frequently found in people with diabetes.

Alpha Lipoic Acid – Antioxidant

Stimulates other antioxidants. Protects against free radicals and helps bridge the nutritional gaps often found among people with diabetes. May help maintain glucose metabolism.

In combination with Vitamins C & E may create an “antioxidant network” which is believed to be more effective in combating free radicals than individual supplements alone.

Nature Made developed the Diabetes Health Pack and this guide to help the growing diabetes population support their health through nutritional supplementation.

- (3) Name of the dietary ingredient(s) if not provided in the text of the statement:
Selenium
Multivitamin/mineral with Lutein
Vitamin C
Alpha Lipoic Acid



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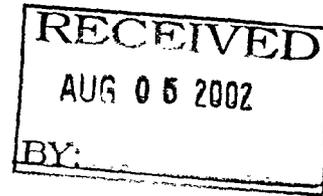
- (4) Name of the dietary supplement:
Diabetes Health Pack

The above statement(s) may be used in one or more of the following brands of products: AAFES, B.J.'s Wholesale, CVS, Duane Reade, Kirkland Signature, Jogmate, Nature Made, Nature's Resource, Nutri - Plus, 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
Director, Regulatory and Consumer Affairs



July 30, 2002

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Center for Food Safety and Applied Nutrition
Food and Drug Administration
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Pharmavite LLC, PO Box 9606, Mission Hills, CA 91346
- (2) Text of the statement(s):
mood plus™
Clinically Proven
Mood Support
Joint Pain Relief
Liver Health

SAM-e (s-adenosylmethionine) is a naturally occurring compound found in all living organisms. In humans SAM-e is distributed throughout the body and is involved in many biochemical processes. Since significant amounts of SAM-e are not available through diet alone, the body is primarily responsible for producing its own SAM-e. Scientists know that SAM-e declines as people age and that certain groups of people, including those with low mood and liver conditions, tend to have lower levels of SAM-e in their bodies. Over 100 clinical studies involving thousands of people have proven that SAM-e supplementation benefits a multitude of body functions including:

Mood Support: Enhances mood by promoting a healthy balance of neurotransmitters, dopamine and serotonin, which are part of overall healthy brain cell functions.

Joint Pain Relief: Relieves joint pain by helping to repair and maintain joint

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cartilage which naturally deteriorates with physical activity and age.

Liver Health: Helps support detoxification and overall healthy liver functions.

Short and long-term studies have proven that SAM-e is safe, non-toxic and efficacious product to support your health.

- (3) Name of the dietary ingredient(s) if not provided in the text of the statement:
S-adenosylmethionine

- (4) Name of the dietary supplement:
SAM-e

The above statement(s) may be used in one or more of the following brands of products: AAFES, B.J.'s Wholesale, CVS, Duane Reade, Health Summit, Kirkland Signature, Jogmate, Nature Made, Nature's Resource, Nutri - Plus, Optimize, Spring Valley, Target, 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
Director, Regulatory and Consumer Affairs