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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 letters of February 8 and 13, 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 you are making claims that the product **Calcium plus Soy** is useful to treat or prevent calcium deficiency. 21 U.S.C. 343(r)(6)(A) provides, among other things, that the labeling of a dietary supplement may bear a statement that "claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States."

The statements that you are making for **Calcium plus Soy** misbrand this product under 21 U.S.C. 343(r)(6)(A) because they describe a benefit related to a classical nutrient deficiency disease but do not disclose the prevalence of the subject deficiency disease in the United States.

21 U.S.C. 321(g)(1) (last sentence) provides that a food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) is not a drug under clause (C) (i.e., 21 U.S.C. 321(g)(1)(C)) solely because the label or the labeling contains such a statement. The statements being made for the product **Calcium plus Soy** are not made in accordance with 21 U.S.C. 343(r)(6), however, and these statements suggest that the products are intended to treat, prevent, mitigate, or cure diseases or are articles (other than food) intended to affect the structure or any function of the body of man. Therefore, these claims suggest that the product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B) and (C), and that it is subject to regulation under the drug provisions of the Act.

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Alternatively, the claim being made for the product **Calcium plus Soy** may not be a claim subject to 21 U.S.C. 343(r)(6), but rather a claim subject to 21 U.S.C. 343(r)(1)(B). FDA has authorized a health claim on the relationship between calcium and osteoporosis (see 21 CFR 101.72). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between calcium and osteoporosis. 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 101.72 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 101.72 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, osteoporosis.

Your submission states that Pharmavite Corporation is making the following claim, among others, for the product **Zinc 50 mg**:

“Zinc is required for improving the sense of taste...people with anorexia nervosa”

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 statement that you are making for this product suggests that it is intended to treat or mitigate a disease, namely anorexia nervosa, a disease which is primarily of psychiatric origin rather a nutritional deficiency disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests 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

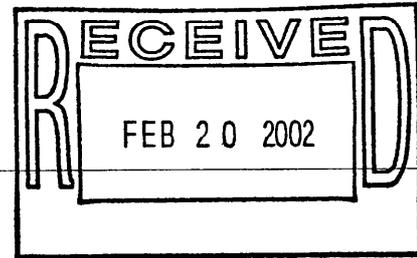
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Copies:

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



February 13, 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 Corporation, PO Box 9606, Mission Hills, CA 91346
- (2) Text of the statement(s):
Calcium is the most abundant mineral in the body and more than 99% of the body's calcium is found in our bones. Its major function is in building and maintaining bones and teeth, but it is also important in many enzymatic reactions in the body. Calcium is also necessary for the contraction of muscles, the release of neurotransmitters, regulation of heart beat, and the clotting of blood. Calcium deficiency in children may lead to rickets, which results in bone deformities and growth retardation. In adults, calcium deficiency may result in the softening of bone, or a condition called osteomalacia or osteopenia, where bone breakdown exceeds bone formation. Over time, a calcium deficiency may ultimately lead to osteoporosis, which thins and weakens bones making them frail to the point where they break easily. The symptoms of osteoporosis may not be noticed until most of the bone loss has already occurred. Calcium supplementation is a key factor in helping to prevent osteoporosis. Soy isoflavones are compounds called "phytoestrogens" that come from soybeans. Isoflavones possess estrogen-like activity in the body, and may offer beneficial effects for menopausal women. A higher intake of soy isoflavones may help maintain a healthy heart and may contribute to bone health. Vitamin D is essential for the absorption of calcium and is necessary for bone development. Magnesium helps regulate the metabolism of calcium and is an important component in bone health. Zinc is required for the growth and development of bones. Copper is necessary for collagen and elastin

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formation, and bone and joint integrity. Manganese is essential for normal bone and skeletal growth. Vitamin K is necessary for activating a major bone protein, osteocalcin, and bone mineralization. Boron is necessary for the action of Vitamin D, which stimulates the absorption of calcium.

- (3) Name of the dietary ingredient(s) if not provided in the text of the statement:
- Calcium (from calcium carbonate)
 - Copper (from copper sulfate)
 - Magnesium (from magnesium oxide)
 - Manganese (from manganese sulfate)
 - Soy isoflavones (from powdered soy extract)
 - Vitamin D
 - Vitamin K (phylloquinone)
 - Zinc (from zinc oxide)
- (4) Name of the dietary supplement:
- Calcium plus Soy

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