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JUL 22 2002

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 letter of June 18, 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 the claims identified below for various products marketed under the name **Joint Action**.

The products **Joint Action** use the claims "Joint Repair and Pain Relief," "...joint cartilage begins to break down...causing joint pain," and "...Joint Action...relieves joint pain." These claims are disease claims because they suggest that the products are 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 claims contained in your notification refer to pain associated with a non-disease state (i.e., aging). Although the statements identified above use other statements, among others, such as “cartilage rebuilding and regeneration are normal functions” and “cartilage begins to break down due to physical stress and aging” that are not themselves diseases, such actions would not be expected to result in joint pain unless a person already suffered from an underlying disease that 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 we may be of 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:

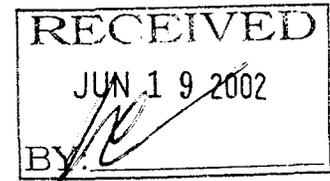
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

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

FDA, Los Angeles District Office, Office of Compliance, HFR-PA240



June 18, 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):  
Joint Repair and Pain Relief

Joint Action was designed combining two of today's most popular choices for joint health. SAM-e and Glucosamine have each been extensively studied and recommended in Europe and the U.S.

In Joint Action, these two ingredients have been clinically shown to:  
Relieve Joint Pain  
Repair Joint Damage

Cartilage rebuilding and regeneration are normal functions of the body. During your lifetime, joint cartilage begins to break down due to physical stress **and** aging, causing joint pain and making even everyday activities like walking difficult to perform. That's why it's essential to maintain healthy levels of nutrients that promote joint health and mobility. Through supplementation, Joint Action helps repair joint damage which relieves joint pain.

- (3) Name of the dietary ingredient(s) if not provided in the text of the statement:  
SAM-e and Glucosamine

80875



- (4) Name of the dietary supplement:  
Joint Action

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