DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

FEB 22 2001

3620 '01 MAR 16 A7:16

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 February 5, 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 following claims for products containing SAM-e and glucosamine in combination with or without other ingredients:

"Relieve Joint Discomfort"
"Promote Joint Mobility"
"Repair Joint Health"

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, cure, or mitigate disease, namely, joint disorders. 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.

97S 0163 LET 448

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

cc:
HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-800 (r/f, file)
HFS-811 (file)
HFD-40 (Behrman)
HFD-310
HFD-314 (Aronson)
HFS-605
HFV-228 (Benz)
GCF-1 (Nickerson)
f/t:HFS-811:rjm:2/16/01:docname:74448.adv:disc54

PHARMAVITE

74048

February 5, 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):
Relieve Joint Discomfort
Promote Joint Mobility
Repair Joint Health

(3) Name of the dietary ingredient if not provided in the text of the statement:
SAM-e (S-adenosylmethionine) and glucosamine

(4) Name of the dietary supplement:
products containing SAM-e and glucosamine in combination with or without other ingredients

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

DK:ak\FDA\SAM-e glucosamine notice. 1

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