



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

MAY 22 2000 4 28 8 '00 MAY 25 P2:01

Mr. David Kropp
Acting Director, Regulatory and Consumer Affairs
Pharmavite Corporation
15451 San Fernando Mission Boulevard
P.O. Box 9606
Mission Hills, California 91346-9606

Dear Mr. Kropp:

This is in response to your letter to the Food and Drug Administration (FDA), dated May 3, 2000, 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 claim for products containing soy as a single ingredient or in combination with other ingredients:

“Studies show isoflavones, the active components of soy, may help maintain bone density and support the body through the natural changes due to menopause.”

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 products containing soy suggests that they are intended to treat, prevent, or mitigate a disease, namely osteoporosis. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests 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

975-0163

LET 371

Page 2 - Mr. David Kropp

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, Compliance Branch, HFR-PA240

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (file, r/f)

HFS-811 (r/f, file)

HFD-40 (Behrman)

HFD-310

HFD-314 (Aronson)

HFS-605

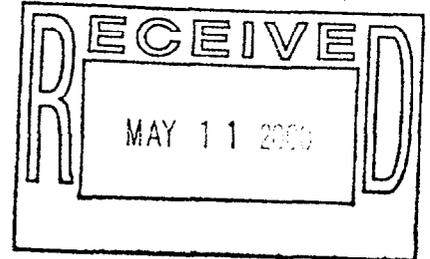
HFV-228 (Betz)

GCF-1 (Barnett, Nickerson, Dorsey)

f/t:rjm:HFS-811:5/18/00:70704.adv:disc47



May 3, 2000



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):

Studies show isoflavones, the active components of soy, may help maintain bone density and support the body through the natural changes due to menopause.
- (3) Name of the dietary ingredient if not provided in the text of the statement:
Soy Isoflavones
- (4) Name of the dietary supplement:
products containing Soy as a single ingredient or in combination with other ingredients

The above statement(s) may be used in one or more of the following brands of products: Nature Made, Sunny Maid, Nature's Resource, AAFES, AARP, Osco, Sav-On, Valu Wise, Bartell Drug, CVS, Duane Reade, Walgreens, Longs, Spring Valley, Brite Life, Family Pharmacy, GNP, Valu-Rite.

70704



PHARMAVITE

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

R:\FDASection6\Soy.doc