



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

4350 '01 MAY 15 P2:30

MAY - 1 2001

Mr. David Kropp
Acting Director, Regulatory and Consumer Affairs
and Assistant General Counsel
Pharmavite Corporation
P.O. Box 9606
Mission Hills, California 91346

Dear Mr. Kropp:

This is in response to your letter of March 22, 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, among others, for the product **Daily Diabetic Pack**:

“May help enhance glucose metabolism.”

“...maintaining normal blood pressure”

“...helping to protect LDL cholesterol from oxidation which may accumulate in the arteries and cause cellular damage.”

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 this product suggest that it is intended to treat, prevent, cure, or mitigate disease, namely, coronary heart disease, and diabetes. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). 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. 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-3 10, 7520 Standish Place, Rockville, Maryland 20855.

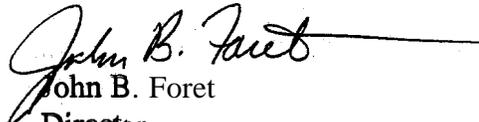
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Please contact us if we may be of further assistance.

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

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cc:

HFA-224 (w/incoming)

HFA-3 05 (docket 97S-0 163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-8 10 (Foret)

HFS-8 11 (file)

HFD-40 (Behrman)

HFD-3 10

HFD-3 14 (Aronson)

HFS-607 (Bayne-Lisby)

HFV-228 (Benz)

GCF- 1 (Nickerson)

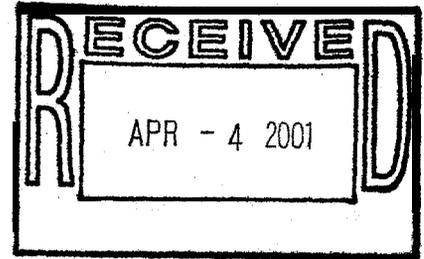
f/t:HFS-8 11:rjm:4/25/01:docname:75296.adv:disc56



PHARMAVITE

March 22, 2001

Office of Special Nutritionals @IFS-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):

Daily Diabetic Pack is especially formulated for nutritional support for people with Diabetes.

Alpha Lipoic Acid is an antioxidant that protects against free radicals and helps bridge the nutritional gaps often found among people with diabetes. May help enhance glucose metabolism.

Chromium helps with normal metabolism of carbohydrates, protein and fat.

Folic Acid is a B vitamin and is one of the factors involved with B-12 in the production of new red blood cells and the synthesis of RNA and DNA, the carriers of genetic information. Folic Acid may help maintain healthy homocysteine levels. Studies show that Folic Acid may be related to maintaining normal blood pressure.

Multivitamins - a high potency supplement providing essential vitamins and minerals for nutritional support of the heart and digestive system of the body.

Vitamin C increases antioxidant defense in the body and enhances the immune system.



Vitamin E contributes to a healthy cardiovascular system by helping to protect LDL cholesterol from oxidation which may accumulate in arteries and cause cellular damage. Vitamin E may be important in helping diabetics and other adults maintain a healthy heart.

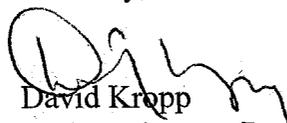
Selenium is a natural antioxidant and essential mineral. Selenium works closely with Vitamins C and E to help maintain healthy metabolic functions. Selenium acts as a powerful antioxidant. Selenium may supply important nutritional support to diabetics and other adults.

- (3) Name of the dietary ingredient if not provided in the text of the statement:
Alpha Lipoic Acid, Chromium, Folic Acid, Multivitamins, Vitamin C, Vitamin E, Selenium
- (4) Name of the dietary supplement:
Daily Diabetic Pack with Alpha Lipoic Acid

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

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