



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

NOV 24 2000

0202 '00 DEC -7 P3:08

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 of November 3, 2000 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 claim, among others, for the product Optimize Hi-Fiber:

"Helps maintain normal cholesterol levels."

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, prevent, cure, or mitigate disease, namely, hypercholesterolemia. 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.

975-0163

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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-PA140

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 (Dorsey, Nickerson)
f/t:HFS-811:rjm:11/22/00:docname:73373.adv:disc52



PHARMAVITE
November 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):
Helps maintain normal cholesterol levels
Supports digestive health
Promotes regularity
- (3) Name of the dietary ingredient if not provided in the text of the statement:
inulin & maltodextrin
- (4) Name of the dietary supplement:
Optimize Hi-Fiber

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, Kirkland Signature, Jogmate, Longs, 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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