



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

NOV 18 1998 3 377 '98 NOV 25 P2:23

Mr. David Kropp
Manager, Regulatory and Legal 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 11, 1998 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 its products containing vitamin C:

“...may also protect the arteries against the effects of a high fat diet”

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 these products suggests that they are intended to prevent a disease, namely atherosclerosis, in that they are intended to prevent plaque formation and lipid deposition in blood vessels. 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 yours,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

975-0163

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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
San Francisco District Compliance, HFR-PA140

cc:

HFA-224 (w/incoming)
HFA-305 (Docket No. 97S-0163)
HFS-22 (CCO)
HFS-456 (file)
HFS-450 (r/f, file)
HFD-310 (Williams)
HFD-314 (Aronson)
HFS-600 (Reynolds)
HFS-605 (Bowers)
GCF-1 (Dorsey, Nickerson)
reviewed:GCF-1:LNickerson:11/17/98
f/t:HFS-456:RMoore:11/18/98:62280.adv:disc33

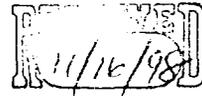


PHARMAVITE

November 11, 1998

62280

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 c
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):
Vitamin C can be exhausted by environmental stress, cigarette smoke and other pollutants. It's important to maintain a high level of Vitamin C in the bloodstream. Vitamin C is a powerful antioxidant that may also protect the arteries against the effects of a high fat diet.
- (3) Name of the dietary ingredient if not provided in the text of the statement:
Vitamin C
- (4) Name of the dietary supplement:
products containing Vitamin C 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.

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
Manager, Regulatory and Legal Affairs