



PHARMAVITE

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October 7, 1998



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):

Homocysteine Reducer is a formula of B vitamins and antioxidants designed to enhance your present supplement regimen. Vitamin B6 has been shown to reduce homocysteine levels in the body. Normal homocysteine levels are important in maintaining heart health.

Folic Acid has been shown to reduce homocysteine levels in the body. Normal homocysteine levels are important in maintaining heart health.

Vitamin E and Selenium are antioxidants. When taken daily, Vitamin E may help contribute to a healthy heart.

(3) Name of the dietary ingredient if not provided in the text of the statement:  
see above

(4) Name of the dietary supplement:  
Homocysteine Reducer

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.

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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,

A handwritten signature in black ink, appearing to read 'David Kropp'. The signature is fluid and cursive, with a large initial 'D' and 'K'.

David Kropp  
Manager, Regulatory and Legal Affairs

DK:ecb/Homocysteine reducer.doc