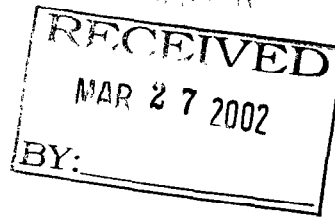




March 20, 2002



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):
Folic acid, also known as folate and folacin, is essential in cell division, DNA synthesis, and the manufacturing of brain chemicals, or neurotransmitters in the body. Without adequate levels of folic acid, cells do not divide properly. Folic acid is vital to the development of the nervous system of a fetus.. A deficiency of folic acid during pregnancy has been linked to several birth defects, such as the neural tube defect spina bifida. Therefore, it is critical for women of child-bearing age to consume 400 mcg of folic acid per day. In addition, folic acid may also play a significant role in heart health. It does so by helping to keep homocysteine levels down in the blood. Homocysteine is a substance that formed when Vitamin B12 and folic acid levels are low, and research has indicated it may be a possible factor for heart health.
- (3) Name of the dietary ingredient if not provided in the text of the statement:
Folic Acid
- (4) Name of the dietary supplement:
Folic 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.

975 0162 LET 9730

Also see docket 975-0163

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®
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 Krøpp
Director, Regulatory and Consumer Affairs