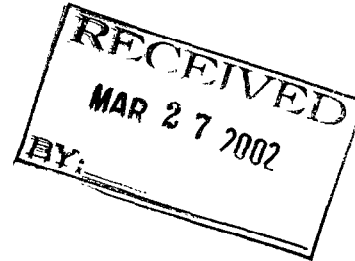




PHARMAVITE

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):
Vitamin B12, or cobalamin, is involved in many body processes and works very closely with another B vitamin, folic acid. They both work to synthesize DNA in our body and manufacture red blood cells. Vitamin B12 is also necessary for the proper functioning of our nervous system. Therefore, if a B12 deficiency occurs, nerve function can become impaired and characterized by tingling sensations and numbness. A B12 deficiency can also cause impaired mental function. A deficiency in Vitamin B12 is thought to be quite common among the elderly, and it is a major cause of depression among this age group. In addition, as we age, we have a lower amount of stomach acid secreted that is necessary for vitamin B12 absorption. Vitamin B12 deficiency is again likely among the elderly population, since we lose the ability to absorb nutrients as we age. Therefore, it is strongly recommended that people over the age of 50 consume a B12 supplement. A deficiency in Vitamin B12 may also be mistaken for dementia-like symptoms or depression, and patients may end up being mistreated. Folic acid may also mask the symptoms of a B12 deficiency, so it is recommended that Vitamin B12 and folic acid are taken together. In addition, Vitamin B12 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.

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- (3) Name of the dietary ingredient if not provided in the text of the statement:
Vitamin B-12 (cyanocobalamin)

- (4) Name of the dietary supplement:
Vitamin B-12

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
Director, Regulatory and Consumer Affairs