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BY:

February 8, 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):
Kelp, Lecithin, and Vitamin B-6 supplement can help maintain good overall health. Kelp is a good source of folic acid, an essential B-vitamin, and iodine, which helps regulate thyroid function, or our body's metabolism. If an individual is deficient in iodine, kelp is a good source to provide iodine in a daily diet, within recommended amounts. Lecithin is a good source of the essential nutrient, choline. Choline is required for exporting fat from the liver. Phosphatidylcholine, an available form of choline found in lecithin, is linked to maintaining healthy cholesterol levels. Choline supplementation can result in increased levels of acetylcholine in the brain. Acetylcholine is a chemical in the brain that is utilized in many brain processes. Lecithin, a good source of choline, can promote liver health and healthy cholesterol levels and may benefit in enhanced memory. Vitamin B6, or pyridoxine, is a B-vitamin that is particularly important in the formation of our body proteins and structural compounds. It is also necessary for our nervous system and formation of red blood cells in our body. Vitamin B6 has a vital role in cell development and is critical for proper functioning of our immune system, as well as a healthy pregnancy. B6 also plays a significant role in our brain chemistry. It is involved in the formation of all our brain neurotransmitters, such as serotonin and dopamine, which effects our mood. Extreme deficiency of vitamin B6 is rare, however, a deficiency in B6 is characterized by depression, impaired nervous system function, anemia, and

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convulsions. Physical signs such as cracked lips or tongue, or eczema may also be due to a B6 deficiency. Clinical studies have demonstrated its importance in certain health conditions, such as morning sickness.

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

Iodine (from kelp)

Lecithin

Vitamin B-6 (pyridoxine hydrochloride)

(4) Name of the dietary supplement:

Kelp, Lecithin and Vitamin B-6

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

Acting Director, Regulatory and Consumer Affairs