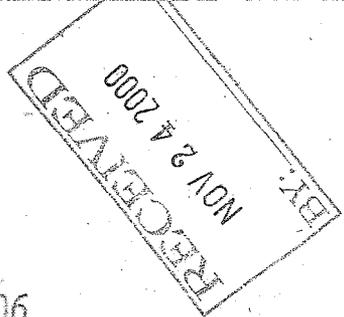




PHARMAVITE  
November 22, 2000

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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):

WHAT IS SAM-e?

SAM-e is not a vitamin, herb or hormone. Instead, SAM-e (S-adenosylmethionine) is a naturally occurring compound that is produced in all living cells. It is involved in over forty biological reactions throughout the body. SAM-e is critical to the functioning of several processes, including those affecting mood, emotional well-being, joint health and liver health.

WHY SHOULD I TAKE B VITAMINS WITH SAM-e?

SAM-e works better when your body has adequate levels of vitamins B6, B12 and folate. These nutrients not only play an important role in the metabolism of SAM-e, but are also important in helping your body maintain healthy levels of homocysteines. Healthy levels of homocysteines have been shown to be linked to good circulatory and heart health. Our advice, if you're taking SAM-e, make sure you're also getting the proper amounts of B6, B12 and Folic Acid.

HOW DOES SAM-e AFFECT SO MANY BODY PROCESSES?

SAM-e accomplishes its many natural body tasks by travelling through the body along three different biological pathways. As you'll notice in the diagram below, each pathway leads SAM-e to specific end purposes. The first path leads SAM-e to areas where it may help maintain liver and cartilage health. The second path

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leads SAM-e where it may help maintain joint flexibility and fluidity. And a third path guides SAM-e to areas where it may help enhance mood, emotional well-being and promote heart health.

#### LIVER AND CARTILAGE HEALTH

When taken with Vitamin B6, SAM-e:

Helps detoxify the liver and promote liver health.

Helps maintain cartilage health.

Helps produce a powerful cell protecting antioxidant called glutathione.

#### JOINT FLEXIBILITY

Helps maintain joint flexibility and fluidity.

Helps promote the synthesis of proteoglycans which interact with collagen to produce cartilage.

#### EMOTIONAL WELL-BEING AND HEART HEALTH

When taken with Vitamin B-12 and Folic Acid, SAM-e:

Helps regulate homocysteine levels.

Helps regulate DNA and cell membranes.

- (3) Name of the dietary ingredient if not provided in the text of the statement:  
see above
- (4) Name of the dietary supplement:  
SAM-e with Free Super B-Complex

The above statement(s) may be used in one or more of the following brands of products: AAFES, B.J.'s Wholesale, CVS, Duane Reade, Kirkland Signature, Jogmate, Longs, Nature Made, Nature's Resource, Optimize, Spring Valley, Walgreens.

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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 Kropp  
Acting Director, Regulatory and Consumer Affairs

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