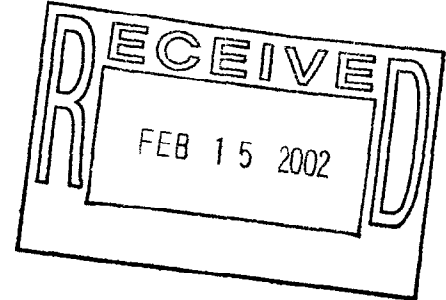




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February 7, 2002



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):
Cod Liver Oil is a good source of one of the essential fatty acids, Omega-3, the other being Omega-6. An essential fatty acid is "essential", because it cannot be produced by the body, and must come from dietary intake. Omega-3 fatty acids are utilized by many tissues of the body, such as the eyes and brain. They are necessary for good health and proper function of the body. Omega-3's help support and regulate virtually every system in the body, which includes the cardiovascular, immune and nervous systems. Essential fatty acids like Omega-3, assist in making cell membranes more fluid and flexible, along with transporting vital hormones in and out of cells. They also play a vital role in proper hormone function for mental and physical health by assisting and stabilizing hormonal levels. Recent research has suggested that supplementation with essential fatty acids, such as Omega-3, may help in fighting against damaging factors in the body and contribute to a healthy heart, as well as helping the immune system and nervous system function normally. Vitamin A plays a major role in our visual system, where it is necessary for the normal functioning of our eyes and vision. Vitamin A also affects growth and development of our lungs, teeth, gums and skin. It is essential for proper immune function. The main sources of Vitamin D are food and sunlight. Since we are able to produce vitamin D in our skin from sunlight, it has hormonal action in the body as well as vitamin activity. For those who do not get any sunlight (particularly the elderly in nursing homes), they

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may be at a higher risk of Vitamin D deficiency and supplementation is recommended. However, Vitamin D is a fat-soluble vitamin and should be taken in recommended amounts. Vitamin D's primary role in the body is stimulating the absorption of calcium and is necessary for bone development.

- (3) Name of the dietary ingredient if not provided in the text of the statement:
Vitamin A (from cod liver oil)
Vitamin D (from cod liver oil)
- (4) Name of the dietary supplement:
Cod Liver Oil

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