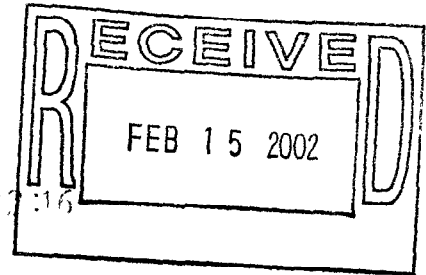




February 7, 2002

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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):  
Evening Primrose Oil is a wildflower native to eastern North America. The small, reddish seeds of evening primrose contains oil that is rich in an essential fatty acid called, Gamma-linoleic acid (GLA). GLA is necessary for normal body function, and is especially important for the production of a hormone-like substance in the body called, prostaglandin E-1 (PG E-1). Many experts believe that a variety of disorders are caused by a deficiency of essential fatty acids in the body, such as GLA. Evening Primrose Oil is considered safe for most people at the recommended dosage of 3 – 6 grams per day. It is not recommended for individuals taking phenothiazines (medication), due to the possibility of an increased risk for epileptic episodes. EPO may also increase the effects of Non-steroidal Anti-Inflammatory Drugs (NSAIDS), and caution should be used (consult your physician) with patients who are taking anti-coagulant medication. The long-term safety of EPO has not been established.
- (3) Name of the dietary ingredient if not provided in the text of the statement:  
Evening Primrose (seed, oil)
- (4) Name of the dietary supplement:  
Evening Primrose Oil 500 mg with Vitamin E

978 0162

LET 9410

79279



PHARMAVITE

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