Food and Drug Administration
Washington DC 20204

David Kropp
Manager Quality Assurance
and Regulatory Affairs
Pharmavite Corporation
P.O. Box 9606
15451 San Fernando Mission Boulevard
Mission Hills, California 91346-9606

Re: Nutritional Support Statement Notification

Dear Mr. Kropp:

This acknowledges receipt on August 4, 1995, of your letter, dated August 3, 1995, notifying the Food and Drug Administration (FDA) that the dietary supplement product, Evening Primrose Oil, is being marketed with a statement of nutritional support on its label or in its labeling.

Pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act), a manufacturer must notify FDA no later than 30 days after the first marketing of a dietary supplement product that bears a nutritional support statement on its label or in its labeling. Pursuant to the act, a manufacturer of such a product must have substantiation that the nutritional support statement is truthful and not misleading. In addition, the nutritional support statement must include, prominently displayed and in bold face type, the following: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

No action on the part of FDA is required before a manufacturer can market a dietary supplement product bearing a nutritional support statement on its label or in its labeling. While the act requires that certain information appear on the label of a dietary supplement in conjunction with such statements, FDA does not approve them. This letter serves only to acknowledge the receipt by FDA of your notification.

Sincerely yours,

Margaret C. Binzer

Margaret C. Binzer
Consumer Safety Officer
Regulatory Branch
Division of Programs
and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

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