

2415 '03 MAY -5 P1:55

April 2, 2003

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 LLC, PO Box 9606, Mission Hills, CA 91346
- (2) Text of the statement(s):
 Eye Essentials and/or Eye Defense

EYE ESSENTIALS formula is uniquely formulated with Lutein, Zeaxanthin and other essential antioxidants to support the eyes in age-related vision conditions. Lutein and Zeaxanthin are carotenoids that occur naturally in the eye to help protect it from UV light damage. These materials accumulate in the eye as a result of dietary intake. A diet deficient in fruits and vegetables allows the content of Lutein and Zeaxanthin to diminish over time. EYE ESSENTIALS provides the eye with the nutrition it may be lacking. The perfect, natural 5:1 ratio of Lutein to Zeaxanthin can increase the levels of these carotenoids and help maintain a healthy macula, where they are stored. This comprehensive formula also includes Beta Carotene, Vitamins C and E, with Zinc and Copper to provide the most beneficial and complete protection for strong and healthy eyes.

Lutein and Zeaxanthin are stored in the macular region of the eye and help prevent damage from UV rays. Healthy levels of these carotenoids are necessary to support age-related vision health that may result from a diet lacking fruits and

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vegetables, the body's natural source. EYE ESSENTIALS perfect blend of Lutein, Zeaxanthin and other key nutrients provides the combination nature intended to fight against the effects of aging on eye health. Nature Made's strict standards for quality, purity and potency ensure you are providing the best supplementation for your eyes.

- Name of the dietary ingredient(s) if not provided in the text of the statement:
 Vitamin A (as Beta Carotene)
 Vitamin C (Ascorbic Acid)
 Vitamin E (dl Alpha Tocopheryl Acetate)
 Zinc (from Zinc Oxide)
 Copper (from Copper Oxide)
 Lutein
 Zeaxanthin
- (4) Name of the dietary supplement:

 Eye Essentials and/or Eye Defense and other products containing the above ingredients

The above statement(s) may be used in one or more of the following brands of products: B.J.'s Wholesale, Kirkland Signature, Jogmate, Nature Made, Nature's Resource, Nutri - Plus, Optimize, Spring Valley, Target, 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

Director, Regulatory and Consumer Affairs