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BY:.....

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):
Melatonin is a hormone manufactured from serotonin. The human body secretes various hormones at different times to regulate body functions. Melatonin plays a role in these timely secretions. Release of melatonin is stimulated by darkness and promotes sleep when the hormone levels are sufficient. Supplementation may also enhance mood and help your body adjust better to travel.
- (3) Name of the dietary ingredient if not provided in the text of the statement:
Melatonin
- (4) Name of the dietary supplement:
Melatonin
3 mg

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.

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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