



PHARMAVITE

September 11, 1998

2470 '98 SEP 25 P2:16

9/21/98

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):  
HELPS PROMOTE SLEEP

Melatonin is a natural hormone in the body which helps promote sleep.

(3) Name of the dietary ingredient if not provided in the text of the statement:  
see above

(4) Name of the dietary supplement:  
products containing Melatonin as a single ingredient or in combination with other ingredients

The above statement(s) may be used in one or more of the following brands of products: Nature Made, Sunny Maid, Nature's Resource, AAFES, AARP, Osco, Sav-On, Valu Wise, Bartell Drug, CVS, Duane Reade, Walgreens, Longs, Spring Valley, Brite Life, Family Pharmacy, GNP, Valu-Rite.

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  
Manager, Regulatory and Legal Affairs  
975 - 0162

melatonin.wpd

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