



PHARMAVITE

September 11, 1998

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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 maintain urinary tract and prostate function

Saw Palmetto has been the subject of many scientific studies, showing it helps maintain proper urinary function in mature men. It can also be useful in maintaining prostate gland health.
- (3) Name of the dietary ingredient if not provided in the text of the statement:
see above
- (4) Name of the dietary supplement:
Men's Formula

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

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