



PHARMAVITE

September 18, 1998

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RECEIVED  
10/9/98

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):  
For Menstrual Or Menopausal Conditions  
  
Black Cohosh has been used worldwide for centuries. It has been taken for its benefits during menstrual periods and menopause. Black Cohosh may have a beneficial effect on hormone levels.
- (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 Black Cohosh 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

black cohosh.wpd

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