



79334

1784 02 780 -7 2

RECEIVED  
FEB 22 2002  
BY: \_\_\_\_\_

February 13, 2002

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 a more comfortable transition through menopause

A scientifically supported herb with naturally occurring isoflavones (powerful compounds known as phytoestrogens; plant-based substances that are chemically similar to the hormone estrogen - yet milder). These phytoestrogens can bind to estrogen receptors in the cells and produce various important health benefits to women at or near menopause.

Helps relieve Hot Flashes and Night Sweats  
Helps support Hormonal Balance  
A diet rich in soy protein has been shown to also promote bone and heart health.

(3) Name of the dietary ingredient(s) if not provided in the text of the statement:  
Soy Extract (bean)

(4) Name of the dietary supplement:  
Soy Balance  
65 mg Soy Isoflavones

97S 0162 LET 9431



PHARMAVITE

The above statement(s) may be used in one or more of the following brands of products: AAFES, B.J.'s Wholesale, CVS, Duane Reade, Health Summit, Kirkland Signature, Jogmate, Nature Made, Nature's Resource, 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  
Acting Director, Regulatory and Consumer Affairs