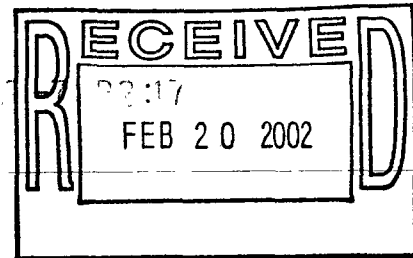




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February 13, 2002

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):  
Calcium is the most abundant mineral in the body and more than 99% of the body's calcium is found in our bones. Its major function is in building and maintaining bones and teeth, but it is also important in many enzymatic reactions in the body. Calcium is also necessary for the contraction of muscles, the release of neurotransmitters, regulation of heart beat, and the clotting of blood. Calcium deficiency in children may lead to rickets, which results in bone deformities and growth retardation. In adults, calcium deficiency may result in the softening of bone, or a condition called osteomalacia or osteopenia, where bone breakdown exceeds bone formation. Over time, a calcium deficiency may ultimately lead to osteoporosis, which thins and weakens bones making them frail to the point where they break easily. The symptoms of osteoporosis may not be noticed until most of the bone loss has already occurred. Calcium supplementation is a key factor in helping to prevent osteoporosis. Soy isoflavones are compounds called "phytoestrogens" that come from soybeans. Isoflavones possess estrogen-like activity in the body, and may offer beneficial effects for menopausal women. A higher intake of soy isoflavones may help maintain a healthy heart and may contribute to bone health. Vitamin D is essential for the absorption of calcium and is necessary for bone development. Magnesium helps regulate the metabolism of calcium and is an important component in bone health. Zinc is required for the growth and development of bones. Copper is necessary for collagen and elastin

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formation, and bone and joint integrity. Manganese is essential for normal bone and skeletal growth. Vitamin K is necessary for activating a major bone protein, osteocalcin, and bone mineralization. Boron is necessary for the action of Vitamin D, which stimulates the absorption of calcium.

- (3) Name of the dietary ingredient(s) if not provided in the text of the statement:  
Calcium (from calcium carbonate)  
Copper (from copper sulfate)  
Magnesium (from magnesium oxide)  
Manganese (from manganese sulfate)  
Soy isoflavones (from powdered soy extract)  
Vitamin D  
Vitamin K (phylloquinone)  
Zinc (from zinc oxide)
- (4) Name of the dietary supplement:  
Calcium plus Soy

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.

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