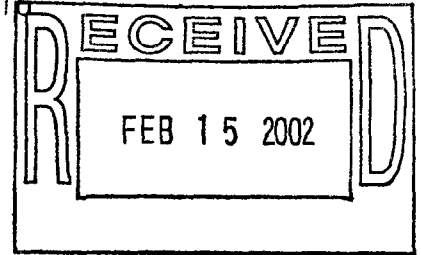




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February 8, 2002

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):
Iron has a central role in transporting oxygen in the body. It is an important part of hemoglobin in red blood cells and myoglobin within cells, to transport oxygen in the body. Iron helps prevent iron-deficiency anemia, which is the most common deficiency in the United States and the most common cause of anemia in the U.S., especially among children and women during their childbearing years (Mahan & Stump, 1996). Iron is necessary for iron-deficiency anemia, in which red blood cells are not able to carry enough oxygen to meet the body's needs. Symptoms of anemia include fatigue, poor concentration, and an increase in colds and infections. Iron also helps strengthen the immune system and helps in the manufacturing of collagen, a protein that builds connective tissues. In addition, a number of enzymes for body processes require adequate iron, such as the production of the neurotransmitters, serotonin and dopamine, which are brain chemicals that influence mood and behavior.
- (3) Name of the dietary ingredient if not provided in the text of the statement:
Iron (from ferrous sulfate)
- (4) Name of the dietary supplement:
Iron 65 mg

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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