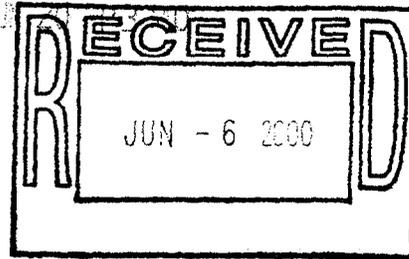




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May 31, 2000

The Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C. Street S.W.
Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- (1) Our knowledge regarding the body's need for iron is far more sophisticated than that of the early Egyptians who used the mineral to support a healthy head of hair. And historical documents from ancient Greece reveal the use of iron mixed with wine to help restore age-related reduction of sexual function.
- (2) We now understand that without iron our bodies could not synthesize hemoglobin, the protein-iron compound found in the blood responsible for carrying oxygen from the lungs to each cell, and then returning carbon dioxide from the cells back to the lungs for cleansing. Iron also plays a key role in the essential enzyme activity of every cell in the human body.
- (3) Ferrofood keeps your blood healthy.
- (4) Iron is needed to deliver oxygen to the red blood cells. The iron content of the foods we eat together with an increased need for iron at certain times in our lives can compromise the amount of useful iron we actually absorb, which can leave us at risk for developing anemia. The variety of ingredients in Ferrofood are combined to promote a consistent amount of iron along with complimentary nutrients, such as vitamin C, that aid in iron absorption. The alfalfa and mushrooms (shiitake and reishi) contribute both their minerals and other nutritional compounds to further enhance iron absorption. The vitamin B12 from alfalfa and bovine liver works along with iron to encourage healthy red cell formation.
- (5) Ferrofood maintains cellular health.

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**Standard
Process®**

- (6) Flaxseed oil contains unsaturated essential fatty acids to produce and rebuild new cells. Iron is also a necessary part of some enzymes required for cell respiration. Vitamin B12 helps to form cells and supports cellular longevity.
- (7) Contains a wide variety of ingredients from diverse sources to promote a consistent amount of iron along with complimentary nutrients, such as vitamin C, that aid in iron absorption.
- (8) Bovine PMG™ extract contains uniquely derived nucleoprotein-mineral extracts to support cellular health.

These statements are made for a dietary supplement containing a proprietary blend of bovine liver, bovine bone, carbamide, defatted wheat (germ), porcine duodenum, bovine spleen PMG™ extract, bovine adrenal, carrot (root), oat flour, veal bone, choline bitartrate, bovine spleen, ovine spleen, citric acid, porcine stomach parenchyma, dried alfalfa juice, mushroom, *Tillandsia usneoides*, peanut (bran), di-calcium phosphate, licorice (root), potassium para-aminobenzoate, magnesium citrate, flaxseed oil extract, bovine liver fat extract, and mixed tocopherols. Other ingredients include gelatin, ferrous lactate, ascorbic acid, water, calcium stearate, natural colors, and cyanocobalamin. The name of the product is Ferrofood®.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden
Standard Process Inc.

