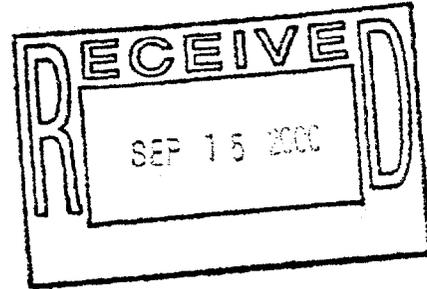


72469

August 30, 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) Vasculin is formulated to provide nutrients that will help keep the heart muscle strong and the vascular system healthy.
- (2) Keeps the heart and blood vessels healthy.
- (3) The bovine heart and veal bone PMG™ extracts provide cytotrophic cellular material, the "blueprint" portion found in the nucleus. Nutritional yeast, unlike live baker's yeast, contains no live yeast cells that deplete both B vitamins and other vital nutrients from the yeast, leaving beneficial nutrients intact. Bovine liver and spleen, and ovine spleen each provide multiple nutrients to support corresponding human organs. Inositol helps metabolize fats. Bovine adrenal Cytosol™ extract contributes acids, enzymes, hormone precursors, steroid precursors, etc., to maintain the health of corresponding human tissue. Beets are rich in silicon to help keep vessels flexible and the heart muscle strong and healthy. Responsible for cellular renewal, ribonucleic acid (RNA) maintains healthy cells against normal wear and tear. Essential fatty acids, vitamin B complex, vitamin E, calcium, magnesium, phosphorus, and several trace minerals all found in wheat germ help keep the heart muscle strong and healthy. Choline helps metabolize fat. Buckwheat contains rutin, a bioflavonoid that helps to strengthen capillary walls and maintain circulation.
- (4) Contains bovine heart Protomorphogen™ extract in combination with complete vitamin B and E complexes to support the healthy functioning of the heart muscle.
- (5) Bovine heart and veal bone PMG™ extracts contain uniquely derived nucleoprotein-mineral extracts to support heart health.

7506
OCT 10
P259

975-0162



L 5858



Whole Food Supplements

These statements are made for a dietary supplement containing a proprietary blend of bovine heart PMG™ extract, nutritional yeast, veal bone PMG™ extract, rice (bran) extract, bovine liver, oat flour, porcine duodenum, inositol, dried pea (vine) juice, bovine adrenal Cytosol™ extract, dried beet (root) juice, ribonucleic acid, defatted wheat (germ), choline bitartrate, dried alfalfa juice, dried buckwheat (leaf) juice, buckwheat (seed), mushroom, alfalfa flour, bovine spleen, ovine spleen, soy bean lecithin. Other ingredients include calcium lactate, calcium citrate, honey, niacinamide, potassium para-aminobenzoate, ascorbic acid, calcium stearate, gelatin, mixed tocopherols, pyridoxal 5-phosphate, cocarboxylase, cellulose, and cyanocobalamin. The name of the product is Vasculin®.

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.

