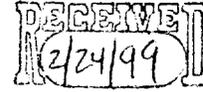




February 20, 1999

1242 '99 MAR 15 P1:58



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) Cardio-Plus contains bovine heart PMG™ extract, choline, vitamin B<sub>6</sub>, and coenzyme Q10, substances that help maintain the cardiovascular system.\*
- (2) The Vitamin B<sub>6</sub> in Cardio-Plus helps maintain a healthy heart. Studies suggest that Vitamin B<sub>6</sub> helps maintain a healthy and strong heart. Vitamin B<sub>6</sub> supplementation may also help maintain healthy blood pressure and circulation.\*
- (3) The choline in Cardio-Plus helps maintain proper levels of homocysteine in the blood. Choline maintains healthy homocysteine levels. Healthy homocysteine levels have been correlated with maintaining healthy blood vessel diameter.\*
- (4) The Coenzyme Q10 in Cardio-Plus helps maintain proper vascular functioning. Coenzyme Q10 protects lipoproteins in the blood from free radical oxygen and in so doing helps maintain the health of the cell walls of the cardiovascular system.\*

These statements are made for a dietary supplement containing Bovine heart PMG Extract, honey, bovine liver, choline bitartrate, calcium lactate, porcine stomach, bovine orchic extract, high selenium yeast, tillandsia powder, niacinamide, ascorbic acid, mixed tocopherols, defatted wheat germ, potassium para-aminobenzoate, nutritional yeast, allantoin, calcium stearate, inositol, bovine spleen, ovine spleen, bovine adrenal Cytosol Extract, bovine brain, oat flour, arabic gum, glycerine, riboflavine 5'-phosphate, and pyridoxal 5-phosphate. The name of the product is Cardio-Plus®.



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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.

