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July 8, 1999

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 53 156-0904, is making the following statements:

- (1) Cardi trophin PMG is a product formulated to help maintain the healthy functioning of the heart and cardiovascular system.*
- (2) The antigenic properties promote healthy cellular division, function, and growth.*
- (3) The bovine heart PMG™ extract in Cardi trophin PMG appears to neutralize the circulating antibody, thereby contributing to the maintenance of cellular health.*
- (4) Maintains cellular health.*
- (5) Supports a healthy heart.*
- (6) Magnesium and calcium play an important role in human metabolism.*
- (7) Magnesium functions in such reactions as nerve conduction and nerve excitability; transfer of energy, muscular activity; and many other specific processes.*
- (8) Magnesium functions as a co-factor, assisting enzymes in catalyzing many chemical reactions.*
- (9) Coenzyme Q10 complex is a vitamin-like substance, well established in the scientific literature as an important nutrient in maintaining healthy cardiovascular function. One of its many functions is its anti-oxidant effect to help scavenge free radicals.*

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- (10) Calcium is also an important nutrient in supporting sound cardiovascular function.*
- (11) Cardiotrophin PMG sustains metabolic efficiency.*
- (12) Cardiotrophin PMG provides nutritional ingredients and support for the heart.*

These statements are made for a dietary supplement containing a proprietary blend of bovine heart PMG™ extract and magnesium citrate. Other ingredients include calcium lactate, cellulose, and calcium stearate. And the name of the product is Cardiotrophin PMG®.

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.

