



July 8, 1999

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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) Dermatrophin PMG is a product formulated to help maintain the healthy functioning of the epithelial cells.\*
- (2) The antigenic properties promote healthy cellular division, function, and growth.\*
- (3) The bovine epithelial PMG™ extract in Dermatrophin PMG appears to neutralize the circulating antibody, thereby contributing to the maintenance of cellular health.\*
- (4) Calcium is important for the healthy functioning of the nervous system and transmission of nerve impulses.\*
- (5) Magnesium and calcium play an important role in human metabolism. \*
- (6) Maintains cellular health.\*
- (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) Dermatrophin PMG sustains metabolic efficiency.\*

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- (10) Dermatrophin PMG provides nutritional ingredients and support for the epithelial cells. \*

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

