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July 8, 1999

7/15/99

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) The antigenic properties promote healthy cellular division, function, and growth.*
- (2) The bovine eye PMG™ extract in Oculotrophin PMG appears to neutralize the circulating antibody, thereby contributing to the maintenance of cellular health.*
- (3) Calcium is important for the healthy functioning of the nervous system and transmission of nerve impulses.*
- (4) Maintains cellular health. *
- (5) Supports nervous system **function**.*
- (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) Oculotrophin PMG sustains metabolic efficiency.*
- (10) Oculotrophin PMG provides nutritional ingredients and support for the eyes. *

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

