



11 54 '99 10V 15 P3:19

October 25, 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 53156-0904, is making the following statements:

- (1) Maintains cellular health.
- (2) The antigenic properties promote healthy cellular division, function, and growth.
- (3) The bovine kidney PMGTM extract in Renatrophin PMG appears to neutralize the circulating antibody, thereby contributing to the maintenance of cellular health.
- (4) Renatrophin PMG improves calcium absorption.
- (5) Renatrophin PMG enhances metabolic efficiency.
- (6) Magnesium functions as a co-factor, assisting enzymes in catalyzing many chemical reactions.
- (7) Magnesium functions in such reactions as nerve conduction and nerve excitability; transfer of energy, muscular activity; and many other specific processes.
- (8) Magnesium and calcium play an important role in human metabolism.
- (9) Renatrophin PMG helps to support the kidney's filtration of wastes and reabsorption of useful materials.
- (10) Renatrophin PMG provides nutritional ingredients and support for the kidneys.

97S - 0162

LET 4578

67914





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

