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April 26, 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) Allerplex is one of many products Dr. Lee developed to assist the body in defending itself naturally during seasonal challenges.*
- (2) Allerplex aids in maintaining proper pH balance.*
- (3) Allerplex helps maintain a healthy immune system. Among many other important functions, the role of calcium in the diet has also been shown to increase immune efficiency.*
- (4) Allerplex helps maintain healthy function of the sinuses and lungs.*
- (5) Allerplex helps maintain cellular health. The antigenic properties of these nucleoprotein-mineral molecules promote healthy cellular division, growth, repair, and function. The primary purpose of lung PMG™ extract is to support the healthy function of the lungs and upper respiratory system. Adrenal PMG™ extract is an ingredient that is formulated to help maintain the healthy functioning of the adrenal glands. *
- (6) Contains Yakriton, an uncommon bovine liver fat extract that has been shown to help maintain a healthy liver through it's ability to aid in filtering blood.*
- (7) Protomorphogen™ extracts provide nutritional ingredients and support for the corresponding organs in human.*

97S-0162

Also see docket 97S-0163

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**Standard
Process®**

These statements are made for a dietary supplement containing the proprietary blend of *tillandsia usneoides*, fenugreek (seed), betaine hydrochloride, soy (bean), bovine lung PMG™ extract, carbamide, carrot (root), oat flour, bovine adrenal PMG™ extract, bovine liver fat extract (Yakriton), alfalfa flour, dried alfalfa juice, bovine bone, dried buckwheat (leaf) juice, defatted wheat (germ), bovine kidney, veal bone, soy bean lecithin, peanut (bran), mixed tocopherols, and carrot oil. Other ingredients include gelatin, calcium lactate, magnesium citrate, potassium bicarbonate, water, calcium stearate, natural colors, ascorbic acid, and vitamin A palmitate. The name of the product is Allerplex™.

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.

