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March 19, 2003

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Pkwy.
College Park, MD 20740

MAR 21 2003

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 a special combination product formulated to support the body's immune system response to seasonal, environmental, and dietary stresses.
- (2) Allerplex contains vitamin A and C complexes which have been shown to be important supporters of the immune system.
- (3) It has also been formulated to maintain healthy liver function – the body's natural cleansing system.

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 meal, soy bean lecithin, peanut (bran), mixed tocopherols, and carrot oil. Other ingredients include gelatin, calcium lactate, magnesium citrate, potassium bicarbonate, water, calcium stearate, 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.

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Sincerely yours,

Ann M. Holden

Ann Holden
Standard Process Inc.

