



**Standard  
Process®**

9138 '99 OCT -8 P3:38

October 1, 1999

RECEIVED  
10/5/99

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 statement:

- (1) Emphaplex supports the healthy function of the sinuses, bronchial passages, lungs, and adrenal glands.\*

This statement is made for a dietary supplement containing a proprietary blend of fenugreek (seed), defatted wheat (germ), oat flour, bovine bone, soy bean, bovine adrenal, carrot (root), bovine lung PMG™ extract, choline bitartrate, buckwheat (seed), arrowroot flour, nutritional yeast, okra, bovine liver, bovine adrenal PMG™ extract, porcine stomach, veal bone, dried alfalfa juice, ribonucleic acid, calcium lactate, phosphoric acid, mushroom, *dl*-methionine, bovine spleen, ovine spleen, *l*-lysine mono-hydrochloride, glutamic acid, mixed tocopherols, peanut (bran), allantoin, soy bean lecithin, bovine brain, inositol, and rice (bran) extract. Other ingredients include gelatin, water, natural colors, ascorbic acid, niacinamide, potassium para-aminobenzoate, vitamin A palmitate, riboflavin, pyridoxine hydrochloride, cocarboxylase, and cholecalciferol. And the name of the product is Emphaplex®.

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.

97S - 0162

67491  
LET 4392