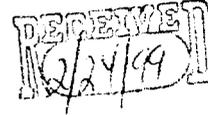




8244 '99 MAR 15 P1:58

February 20, 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) Calcium is also essential for various other body functions, including blood coagulation, muscle contraction, nerve conduction, maintenance and function of cell membranes and membrane permeability, and the proper functioning of many enzymes. The magnesium in this product aids in the uptake of calcium lactate by the body.\*
- (2) Bovine adrenal, kidney, and bone meal are utilized because they not only provide nutrients but they also provide nutritional stimulative support to the corresponding organs in humans. Bone marrow pre-processes lymphocytes while veal bone PMG™ extract supports the function of the bone marrow.\*
- (3) Alfalfa contains a variety of vitamin and mineral complexes vital to the function of the immune system.\*

These statements are made for a dietary supplement containing calcium lactate, magnesium citrate, bovine thymus Cytosol™ extract, carrot powder, ribonucleic acid, bone meal, defatted wheat germ, vacuum dried bovine adrenal, vacuum dried alfalfa juice, nutritional yeast, oat flour, vacuum dried buckwheat juice and seed, alfalfa meal, vacuum dried bovine kidney, veal bone meal, veal bone PMG™ extract, mushroom powder, ascorbic acid, peanut bran, vitamin A esters, soy bean lecithin, mixed tocopherols, and carrot oil. The name of the product is Congaplex®.

97S - 0162

63824

LET3218





**Standard  
Process®**

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

*Ann M. Holden*

Ann Holden  
Standard Process Inc.

