

Recd 8-16-01 GMS



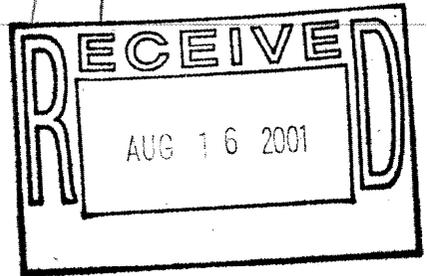
Whole Food Supplements

August 8, 2001

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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

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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. Dr. Lee chose the name *Catalyn* for this product because the vitamin and mineral complexes in *Catalyn* work, in effect, as organic catalysts, serving as the foundation product upon which all nutritional programs follow, stimulating and supporting both the physiological and the biochemical processes inside the human body.

These statements are made for a dietary supplement containing a proprietary blend of defatted wheat (germ), carrot (root), calcium lactate, nutritional yeast, bovine adrenal, bovine liver, bovine spleen, ovine spleen, bovine kidney, dried pea (vine) juice, dried alfalfa juice, mushroom, oat flour, soy bean lecithin, and rice bran extract. Other ingredients include honey, magnesium citrate, glycerine, arabic gum, ascorbic acid, pyridoxine hydrochloride, vitamin A palmitate, gelatin, cocarboxylase, riboflavin, and cholecalciferol. The name of the product is *Catalyn*®.

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.

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