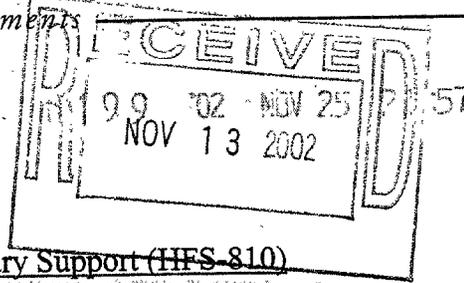




Whole Food Supplements



October 25, 2002

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

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) Encourages healthy kidney function; Juniper berries contain essential oils that help the body excrete uric acid and other waste materials while helping to maintain proper fluid balance.
- (2) Encourages healthy gastrointestinal elimination; the intestinal environment influences the levels of nutrients and other substances in the body.
- (3) Apple pectin modifies intestinal bacterial enzyme activity in favor of the reduction of toxic breakdown products in the gut.
- (4) Barley grass contributes many nutrients and contains a significant percentage of digestive enzymes that help breakdown toxic substances found in some foods.
- (5) Nutrients from kale, barley grass, broccoli, celandine, Oregon grape root, milk thistle, and fringe tree support a healthy liver.
- (6) SP Cleanse is a completely vegetarian product formulated specifically to provide support to the body's detoxifying organs and their functions.
- (7) It combines over 20 different whole food and botanical ingredients to provide robust systemic support from natural sources.
- (8) The cayenne pepper in SP Cleanse offers multiple nutrients and works to enhance the efficiency of the other herbal and nutritional ingredients found in the product.
- (9) The different herbs and whole foods used in SP Cleanse provide a natural and consistent way for you to help your body rid itself of natural toxins.

These statements are made for a dietary supplement containing a proprietary blend of juniper berry powder, red clover flower powder, collinsonia root powder, psyllium husk powder, apple pectin, burdock root powder, barley grass powder, celandine powder, Spanish black radish root, Oregon grape root powder, cayenne pepper powder, fenugreek seed powder, choline bitartrate, inositol, fringe tree root, fennel seed, oat flour, beet leaf juice powder, beet root powder, milk thistle, wildcrafted tillandsia powder, carrot powder, broccoli powder, and

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kale powder. Other ingredients include cellulose and water. The name of the product is SP Cleanse™.

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.

