

October 25, 2002 NOV 1 3 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) Supports healthy digestive system function; flaxseed meal contains both soluble and insoluble fibers that promote healthy gastrointestinal function, maintain healthy cholesterol in individuals with health cholesterol levels and to help support healthy blood glucose levels when accompanied by a healthy diet. Flaxseed meal also provides a healthy dose of plant lignans, fiber-like phytochemicals that support immune function and promote healthy cell growth. Enzymes from barley grass aid in the digestion of food.
- (2) Macronutrients make up the highest percentage of our diet. They supply energy and the essential amino acids, carbohydrates, fats, nucleotides, minerals, and vitamins for proper growth, maintenance, and activity. Micronutrients include other vitamins and trace minerals as well as some unknown nutrients. These nutrients, needed in only minute amounts, serve important functions in the proper metabolism of protein, fat, and carbohydrate macronutrients.
- (3) SP Complete supports healthy liver function.

These statements are made for a dietary supplement containing a proprietary blend of whey protein powder, flax meal powder, brown rice protein powder, calcium citrate, magnesium citrate, buckwheat juice powder, Brussels sprouts powder, kale powder, choline bitartrate, inositol, barley grass juice powder, alfalfa sprout powder, Ginkgo biloba extract, soy bean lecithin powder, milk thistle extract, gotu kola leaf powder, Ginkgo biloba leaf powder, grape seed extract, carrot powder, green tea leaf powder, red wine extract, green tea extract, and standardized bilberry extract. The name of the product is SP CompleteTM.

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Whole Food Supplements

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.