

Whole Food Supplements

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December 16, 2002

The Office of Nutritional Products, Labeling and Dietary Supplements (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:

- Taken regularly, garlic and garlic supplements can help promote a healthy heart in (1) several important ways.
- In conjunction with a healthy diet and exercise, garlic helps maintain normal cholesterol (2) and triglyceride levels in persons with normal levels.
- Garlic is a powerful antioxidant against "free radicals" highly unstable oxygen molecules that effect body tissues and are believed responsible for many of the effects of aging.
- Garlic has tremendous value as an antioxidant and protects the body against free radicals. (4)
- It also helps maintain a healthy heart and circulatory system. (5)

These statements are made for a dietary supplement containing vacuum dried garlic (organically grown) and vacuum dried parsley (organically grown). Other ingredients include gelatin, water, colors, and calcium stearate. The name of the product is Garlic (Organically Grown).

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

Sincerely yours,

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Ann Holden

Standard Process Inc.