

October 25, 2002

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The Office of Nutritional Products, Labeling and Dietary Support (HF)
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 and maintains intestinal lining; collinsonia has properties that help address gastrointestinal tract health.
- (2) Aids in the purification process; provides additional fiber to the diet and offers digestive system support when participating in a purification program.

These statements are made for a dietary supplement containing a proprietary blend of Psyllium (husk) powder, collinsonia (root) powder, apple pectin, fennel seed, and fenugreek seed powder. Other ingredients include cellulose and water. The name of the product is Gastro-Fiber<sup>TM</sup>.

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.

Ann M Holden

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