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October 1, 1999

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

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) Lact-Enz is a gastrointestinal support product that combines digestive enzymes with normal intestinal flora.*
- (2) The combination of these ingredients assists in the breakdown of macronutrients and maintains a healthy intestinal environment.*

These statements are made for a dietary supplement containing a proprietary blend of maltodextrin, amylase, protease, cellulase, lipase, *Lactobacillus acidophilus*, and *Bifidobacterium longum*. Other ingredients include gelatin, water, natural colors, and calcium stearate. And the name of the product is Lact-Enz®.

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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