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September 29, 1999

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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) A member of the liver and digestive support family of product, Betacol enhances the cleansing function of these systems and supports their roles in metabolizing fats.*
- (2) Betacol also boosts the kidney's ability to metabolize protein.*

These statements are made for a dietary supplement containing a proprietary blend of *tillandsia usneoides*, soy (bean), bovine liver PMG™ extract, betaine hydrochloride, calcium lactate, defatted wheat (germ), potassium bicarbonate, choline bitartrate, inositol, disodium phosphate, bovine adrenal Cytosol™ extract, oat flour, and ascorbic acid. Other ingredients include gelatin, water, niacinamide, pyridoxal 5-phosphate, natural colors, and calcium stearate. And the name of the product is Betacol®.

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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