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October 13, 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) Allantoin, a primary ingredient in Okra Pepsin E3, has been known to promote skin health.*
- (2) The properties of the combined nutrients in Okra Pepsin E3 also give this product bowel-cleansing capabilities.*

These statements are made for a dietary supplement containing a proprietary blend of okra, *Tillandsia usneoides* extract, bovine orchic extract, pepsin (1:10,000), carbamide, alginic acid, and allantoin. Other ingredients include gelatin, lactose, water, calcium stearate, and natural colors. And the name of the product is Okra Pepsin E3.

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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