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September 29, 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) A-C Carbamide promotes the osmotic transfer of tissue fluids.*
- (2) Substances such as carbamide cause increased concentration of molecules or ions that facilitate osmosis.*
- (3) The osmotic pressure of these substances reduces water retention, flushing large amounts of fluid into the urine.*

These statements are made for a dietary supplement containing a proprietary blend of carbamide, and arrowroot flour. Other ingredients include gelatin, water, calcium stearate, ascorbic acid, natural colors, and vitamin A palmitate. And the name of the product is A-C Carbamide®.

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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