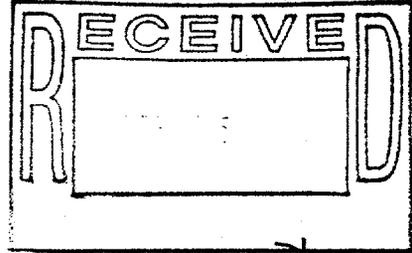


72469

August 30, 2000

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



7501 00 OCT 17 P 2:59

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 combines carbamide with arrowroot flour to support healthy fluid transfer among tissues.
- (2) A-C Carbamide promotes healthy osmotic transfer of tissue fluids.
- (3) Carbamide is a necessary blood and lymph salt made by the cell to function as an osmotic regulator. Either carbamide or sodium chloride must be available to encourage water output in the kidneys or sweat glands.
- (4) A-C Carbamide supports kidney function.
- (5) Carbamide acts as a physiological diuretic to promote the formation and excretion of urine.
- (6) A-C Carbamide works as a blood buffer salt.
- (7) Due to its chemical makeup it must be considered a blood buffer salt, for while it is neutral itself, it is able to release ammonia to neutralize acids in the presence of urease, the enzyme catalyst.
- (8) Carbamide denatures protein for mineral salts and reduces the electrical conductivity of water.
- (9) Vitamin A and C complex are essential for the maintenance of proper kidney function and when combined with carbamide, will encourage osmotic transfer of tissue fluids promoting healthy systemic fluid balance.

975-0162



L 5853

72469



Whole Food Supplements

(10) Mixed with arrowroot flour to promote digestibility and provide mineral support.

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. 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.

