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March 19, 2003

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810) Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Pkwy. College Park, MD 20740

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) Cal-Amo is a calcium product and an acidifying compound providing chlorides, which are useful in the support of proper acid/alkaline balance.
- (2) Cal-Amo helps maintain a healthy pH balance at the cellular level to help support and maintain respiratory and connective tissues and skeletal structures and support the immune system.

(3) In addition, calcium is a major nutrient building block for the body.

These statements are made for a dietary supplement containing ammonium chloride, betaine hydrochloride, calcium chloride, calcium lactate, magnesium citrate, and calcium stearate. The name of the product is Cal-Amo[®].

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Jun M. Halden

Ann Holden Standard Process Inc.

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