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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) Manganese acts as a cofactor and catalyst in many enzymatic processes.*
- (2) Manganese is involved in the health and maintenance of ligaments and tendons, and is essential to the synthesis of connective tissue.*
- (3) Manganese B12 plays an important role in pituitary function and blood coagulation.*

These statements are made for a dietary supplement containing a proprietary blend of carrot (root), and bovine bone. Other ingredients include manganese lactate, honey, zinc liver chelate, ascorbic acid, iron liver chelate, calcium stearate, copper liver chelate, cellulose and cyanocobalamin. And the name of the product is Manganese B12.

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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