



**Standard
Process®**

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December 15, 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 is necessary for bone growth, development, and replacement. Manganese is involved with the health and maintenance of ligaments and tendons as demonstrated in numerous animal studies. It helps to form cartilage and synovial fluid, and is required to synthesize bone. Manganese is also necessary (in small quantities) for protein and fat metabolism. It supports healthy nerves and strengthens immunity. Manganese also plays a role in blood sugar regulation and energy production.
- (2) Maintains cellular health.
- (3) The antigenic properties promote healthy cellular division, function, and growth.
- (4) The veal bone PMG™ extract in Biost appears to neutralize the circulating antibody, thereby contributing to the maintenance of cellular health.
- (5) Supports skeletal health.
- (6) Manganese acts as a catalyst and a cofactor in many enzymatic processes important in skeletal and connective tissue development. Manganese plays a prominent role among the enzymes necessary for mucopolysaccharide synthesis. Mucopolysaccharide is an important constituent of the bone and cartilage structural matrix, as well as in the health and maintenance of ligaments and tendons.
- (7) Improves calcium absorption.

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- (8) The veal bone PMG™ extract contains bone tissue and bone marrow providing natural support for the healthy formation of red blood cells.
- (9) Biost provides nutritional ingredients and support for healthy cellular division, growth, repair, and function.

These statements are made for a dietary supplement containing a proprietary blend of veal bone PMG™ extract, calcium lactate and magnesium citrate. Other ingredients include manganese lactate, honey, and cellulose. The name of the product is Biost®.

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.

