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September 29, 1999

10/5/99

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) Bone is the storehouse for minerals such as calcium, phosphorus, and manganese, as well as for proteins, amino acids, and enzymes.*
- (2) Bio-Dent supplies these important nutritional compounds to help maintain bone health.*

These statements are made for a dietary supplement containing a proprietary blend of defatted wheat (germ), carrot (root), bovine adrenal, bovine spleen, ovine spleen, licorice (root), and peanut (bran). Other ingredients include bovine bone, honey, cellulose, calcium lactate, veal bone, manganese glycerophosphate, and arabic gum. And the name of the product is Bio-Dent®.

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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