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July 8, 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 53 156-0904, is making the following statements:

- (1) Veal bone **PMG™** extract serves a myriad of functions beyond providing shape and support for the body, Together these ingredients contribute to the overall functioning and well being of the skeletal system by a number of physiological processes.*
- (2) The antigenic properties promote healthy cellular division, function, and growth.*
- (3) The veal bone **PMG™** extract in Ostarplex appears to neutralize the circulating antibody, thereby contributing to the maintenance of cellular health.*
- (4) Ostarplex promotes joint health.*
- (5) Ostarplex supports joint health.*
- (6) Maintains cellular health.*
- (7) Numerous studies point to the importance of these vital nutrients in maintaining strong skeletal tissue.*
- (8) Vitamins and amino acids capable of stimulating serotonin production, such as vitamin B6, can improve joint comfort. *
- (9) Ostarplex provides nutritional ingredients and support for the corresponding organs in humans.*

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These statements are made for a dietary supplement containing a proprietary blend of alfalfa flour, nutritional yeast, veal bone **PMG™** extract, betaine hydrochloride, arrowroot flour, ammonium chloride, soy (bean), choline bitartrate, bovine liver, phosphoric acid, porcine stomach, calcium lactate, manganese glycerophosphate, bovine adrenal, magnesium citrate, bovine spleen, ovine spleen, licorice (root), defatted wheat (germ), inositol, allantoin, bovine brain, and ascorbic acid. Other ingredients include gelatin, potassium citrate, water, calcium stearate, natural colors, potassium **para-aminobenzoate**, niacinamide, pyridoxal 5-phosphate, and riboflavine 5-phosphate. The name of the product is **Ostarplex®**.

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.

