



8241 '99 MAR 15 P1:58



February 20, 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 involved in the health and maintenance of ligaments and tendons and is essential to the synthesis of cartilaginous tissues.*
- (2) Ligaplex I helps to maintain proper ligament strength.*
- (3) Ligaplex I supplies anti-oxidant protection. Vitamin E is an anti-oxidant vitamin that inhibits prostaglandin production protecting tissues from physical damage, injury, inflammation, and pain.*
- (4) Ligaplex I helps to maintain healthy cartilage. Vitamin A is essential for the growth, maturation, and degeneration of epiphyseal cartilage cells. Lack of vitamin A arrests this normal evolution of cartilage.*

These statements are made for a dietary supplement containing manganese lactate, gelatin, calcium lactate, bovine bone, dried peavine juice, oat flour, bovine liver, veal bone PMG™ extract, bovine kidney, beet root, water, inositol, nutritional yeast, calcium stearate, dried beet leaf juice, dried buckwheat juice, buckwheat seed, carrot, ribonucleic acid, bovine adrenal Cytosol™ extract, dried beet root juice, bovine spleen, ovine spleen, natural colors, mushroom, whole beet, mixed tocopherols, ascorbic acid, potassium

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para-aminobenzoate, soy bean lecithin, vitamin A palmitate, carrot oil, cellulose and cyanocobalamin. The name of the product is Ligaplex I®.

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.

