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October 25, 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) The vitamins and minerals in kelp are all responsible in some way for the day-to-day cellular processes that maintain the health and functioning of all of the body's major organs and glands.
- (2) Rutin enhances absorption of the vitamin C complex, maintains healthy capillary function and stimulates bile production.
- (3) Allorganic Trace Minerals – B12 helps maintain a healthy skeletal system.
- (4) Manganese is a trace mineral essential for the proper formation and maintenance of bone, cartilage, and connective tissue.
- (5) Allorganic Trace Minerals – B12 enhances metabolic efficiency.
- (6) Phosphorus plays an important role in almost every cellular metabolic activity. Zinc supports DNA synthesis and cell replication cycling. Copper works to metabolize cholesterol in the body to help maintain healthy cholesterol. Iodine is required to produce the two hormones in the thyroid gland responsible for regulating the body's rate of metabolism, growth and development.
- (7) Allorganic Trace Minerals – B12 stimulates healthy cell division and growth.
- (8) Vitamin B12 is essential for the formation of red blood cells and myelin synthesis.
Iron is needed to combine with protein and make hemoglobin for the red blood cells.

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**Standard
Process®**

- (9) Allorganic Trace Minerals – B12 maintains healthy thyroid function.
- (10) Iodine stimulates the thyroid gland and is involved in a myriad of enzyme systems related to other physiological functions such as energy production, the conversion of body fat to energy, and the regulating of basal metabolic rate.
- (11) This unique combination of iodine and vital trace minerals helps support the thyroid gland, general metabolism, fat metabolism, and energy production.

These statements are made for a dietary supplement containing a proprietary blend of kelp, alfalfa, magnesium citrate, dried pea (vine) juice, bovine orchic extract, bovine bone, dried buckwheat (leaf) juice, buckwheat (seed), defatted wheat (germ), oat flour, dicalcium phosphate, carrot (root), and peanut (bran). Other ingredients include manganese lactate, potassium para-aminobenzoate, honey, iron liver chelate, zinc liver chelate, copper liver chelate, calcium stearate, prolamine iodine (zein), and cyanocobalamin.. The name of the product is Allorganic Trace Minerals – 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.

