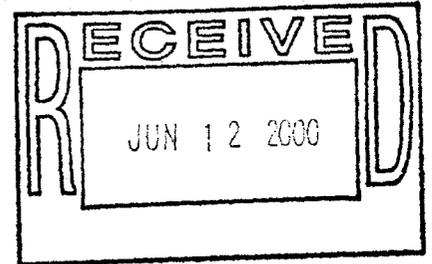




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May 31, 2000



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) Amino acids provide the body with the fundamental building blocks, from which the construction of all human protein is made possible. Amino acids are also used directly by the body to maintain several functions of the immune, nervous, muscular, and skeletal systems. Protefood supports these and other functions by providing enzymes that spark amino acid utilization. It provides ribonucleic acid (RNA) to help strengthen the immune system and support protein metabolism. Working together, the amino acids, minerals, enzymes, and vitamin C contained in Protefood interact throughout the human body to support healthy cardiovascular function, immune response, bone development, and protein metabolism.
- (2) Protefood maintains healthy protein metabolism and cellular function.
- (3) Lysine assists in the production of enzymes and hormones. Potassium is also directly involved in the construction of proteins, and is involved in the correction of metabolic processes, the proper function of the nervous system, and the formation of energy-rich glycogen. Calcium also supports cellular function by maintaining normal growth and repair of cells, and promoting healthy nerve function. RNA supports protein metabolism by decoding genetic instructions, activating amino acids for protein construction, and by assisting in building ribosomes to serve as the sites for protein synthesis.
- (4) Protefood supports cardiovascular health.
- (5) Methionine helps prevent buildup in arteries by assisting breakdown of fat. Likewise, vitamin C plays a major role in the metabolism of cholesterol. Potassium and calcium are important minerals to cardiovascular health: potassium is necessary to initiate heart muscle contractions, while proper regulation of heart muscle contraction and heartbeat is maintained by calcium-rich muscle fluids in the heart.

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**Standard
Process®**

- (6) Protefood supports healthy immune response.
- (7) Methionine helps inactivate free radicals making it a powerful antioxidant and detoxifying agent. It also helps protect the liver. Lysine is involved in the production of antibodies and ribonucleic acid (RNA) helps strengthen the immune system. High concentrations of Vitamin C are found in cells involved in the immune response, and vitamin C stimulates some cells of the immune system. Vitamin C also has antioxidant properties.
- (8) Protefood promotes healthy bone, muscle, and teeth.
- (9) Lysine is required for proper growth and bone development in children, and facilitates calcium absorption. Calcium keeps bones and teeth at the proper density to sustain daily wear and tear. Vitamin C promotes healthy teeth, bone, and muscle tissue through its primary role of collagen formation, a function found in all cells of the body. Lysine also helps in the formation of collagen. Potassium is required for contraction of all skeletal muscle, and is necessary for the building of muscle and normal body growth.
- (10) Contains food protein concentrates high in the amino acids to facilitate complete protein metabolism.
- (11) Contains 60 mg of Ribonucleic acid to strengthen immune function.
- (12) Glandular animal tissues support the corresponding organs in humans.

These statements are made for a dietary supplement containing a proprietary blend of defatted wheat (germ), bovine adrenal, choline bitartrate, carrot (root), ribonucleic acid, *dl*-methionine, *l*-lysine mono-hydrochloride, glutamic acid, and peanut (bran). Other ingredients include bovine bone, gelatin, veal bone, water, calcium stearate, natural colors, and ascorbic acid. The name of the product is Protefood®.

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.

