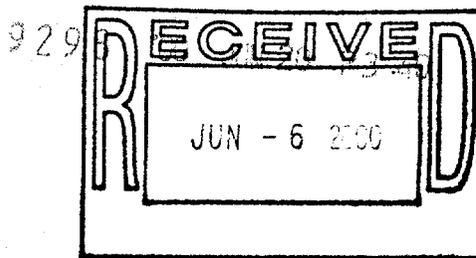




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May 31, 2000

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) Copper is a component of many important enzymes and is involved in one way or another in multiple physiological functions in mammals. Copper, in concert with other substances, is needed to form bone, elastin, and myelin tissues, as well as red and white blood cells, and hemoglobin. Copper is necessary for metabolizing cholesterol, producing energy, and keeping nerves and joints healthy.
- (2) Copper Liver Chelate supports skeletal health.
- (3) Copper is needed to perform multiple functions in different areas of the skeletal system. It helps to add minerals to the skeleton, synthesizes connective tissues, and works with vitamin C and zinc to form elastin. Copper is required for the formation of collagen – an important protein found in bones, skin, and connective tissue.
- (4) Copper Liver Chelate keeps your heart healthy.
- (5) Copper is needed to metabolize cholesterol.
- (6) Copper Liver Chelate promotes a healthy immune response.
- (7) Copper supports immune function. Copper protects antioxidant function, thereby helping to support the immune system when it is challenged by free radicals. Honey provides a source of energy by virtue of its many important nutrients.

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- (8) Copper is required to maintain many different enzymes in the body and is an actual component of some of them. Copper enzymes form many of the brain nerve transmitters. Copper is also involved with glucose metabolism.
- (9) Plants and substances extracted from bovine glands and organs provide nutrients and support for the corresponding organs in humans.

These statements are made for a dietary supplement containing a proprietary blend of bovine liver, dried beet (root) juice, carrot (root), and oat flour. Other ingredients include copper liver chelate, honey, cellulose, and calcium stearate. The name of the product is Copper Liver Chelate.

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.

