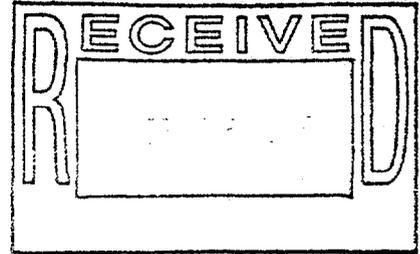


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August 30, 2000



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) B6-Niacinamide contains vitamin B6, niacinamide, and trace minerals to support protein metabolism, cellular function, and cardiovascular health.
- (2) B6-Niacinamide provides the water-soluble vitamin, niacinamide, which is widely known for its preventive effects against Pellagra, a neural-deficiency disease, which is no longer found in the United States.
- (3) B6-Niacinamide also contains vitamin B6, which augments niacinamide function by playing an important role in the conversion of tryptophan to niacinamide.
- (4) B6-Niacinamide also contains many of the same nutrients provided by mushrooms. Various mushrooms contain a diverse collection of nutrients and provide a variety of vitamins, minerals, proteins, and enzymes that support nutritional requirements for optimum health.
- (5) B6-Niacinamide maintains healthy protein metabolism.
- (6) Niacinamide functions as two important co-enzymes that are essential to cell respiration, carbohydrate and protein metabolism, and lipid synthesis.
- (7) Vitamin B6 is an essential nutrient for fat and protein absorption. It plays an important function in metabolizing unsaturated fatty acids to vitamin F.
- (8) Supports cardiovascular and circulatory health.

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Whole Food Supplements

- (9) Niacinamide works together with lecithin and vitamins E and C to promote and maintain a healthy blood and arterial system. To help keep blood healthy, vitamin B6 promotes red cell formation and supports normal hemoglobin levels. It inhibits the formation of homocysteine.
- (10) Promotes healthy cellular function.
- (11) Vitamin B6 is required to synthesize nucleic acids RNA and DNA – the complex molecules that carry genetic instructions for normal cellular growth and reproduction. Vitamin B6 also acts as a co-enzyme along side a variety of other enzymes concerned with cell growth and division. Vitamin B6 helps maintain the delicate water balance and sodium and potassium balance throughout the entire body. Vitamin B6 also helps in the production of hydrochloric acid. Mushrooms can provide a diverse collection of nutrients that may include proteins, lipids, carbohydrates, fiber, minerals (high in calcium), vitamins B2, C, and D and as many as 30 different enzymes and essential amino acids.
- (12) Combines vitamin B6 and Niacinamide to create a specific product containing the vitamin complexes and essential enzyme systems concerned with proper cellular respiration – vital for the appropriate functioning of the cardiovascular, digestive, endocrine, and central nervous systems.
- (13) Plants, along with 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 nutritional yeast, bovine liver, mushroom, and ascorbic acid. Other ingredients include honey, pyridoxine hydrochloride, niacinamide, calcium stearate, and arabic gum. The name of the product is B6-Niacinamide.

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.

