



11 49 '99 NOV 15 P3:19

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 B complex family of vitamins directly affect the health and general well-being of most of our major organ systems, influencing things like nerve conduction, immune response, skin health, visual acuity, gastrointestinal efficiency, liver function, energy production, just to name a few.
- (2) The niacin (or vitamin B3 as it is also called) found in Circuplex can help encourage proper circulation and keep the skin healthy. Vitamin B3 also plays a part in nervous system function and assists in metabolizing carbohydrates, fats, and proteins.
- (3) Vitamin B6 helps to regulate the delicate fluid balance in the body, promotes red blood cell formation, enhances brain function, and is necessary in synthesizing the RNA and DNA that carries our unique genetic coding to regulate all of our cellular growth and reproduction.
- (4) Circuplex promotes healthy nervous system function.
- (5) Vitamin B6 is intimately involved in numerous metabolic processes within the central nervous system (CNS) and is necessary for normal brain function.
- (6) Circuplex keeps your heart healthy.
- (7) Niacin helps promote healthy cholesterol levels in the blood. Vitamin B6 discourages the formation of homocysteine, helping the body to keep compound at healthy levels.
- (8) Circuplex maintains cellular health.

LET 4572

67914

975-0162





- (9) Niacin functions as two important co-enzymes that are key to cell respiration, carbohydrate and protein metabolism, and lipid synthesis. Vitamin B6 plays a direct role in regulating proper cell growth and division. It also promotes red blood cell formation. Vitamin B6 helps maintain the sodium/potassium balance, so important in helping maintain proper water levels in the body.
- (10) Circuplex supports digestive function.
- (11) Both niacin and vitamin B6 are needed to produce hydrochloric acid that is used to digest food properly. Niacin is involved with normal bile secretion and stomach fluids.
- (12) Circuplex helps to stimulate and support the corresponding organs in human.

These statements are made for a dietary supplement containing a proprietary blend of ribonucleic acid, arrowroot flour, dried buckwheat (leaf) juice, buckwheat (seed), bovine liver, phosphoric acid, porcine stomach, bovine spleen, ovine spleen, soy (bean), calcium lactate, defatted wheat (germ), bovine adrenal Cytosol™ extract, inositol, bovine brain, ascorbic acid, and magnesium citrate. Other ingredients include gelatin, niacinamide, water, pyridoxine hydrochloride, potassium para-aminobenzoate, calcium stearate, and natural colors. The name of the product is Circuplex®.

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.

