

EMORD & ASSOCIATES, P.C.

1050 SEVENTEENTH STREET, N.W.

SUITE 600

WASHINGTON, D.C. 20036

TELEPHONE: (202) 466-6937

TELECOPIER: (202) 466-6938

February 24, 1997

VIA UPS OVERNIGHT

Dr. Elizabeth Yetley  
Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street, S.W.  
Washington, D.C. 20204

0031 '97 SEP 19 P1:29

Re: Statements of Nutritional Support Notice  
Required Pursuant to 21 U.S.C. § 343(r)(6)

Dear Dr. Yetley:

Simone Protective Pharmaceuticals, Inc., 123 Franklin Corner Road, Lawrenceville, NJ 08648, by counsel, hereby submits an original and two copies of its notice of intent to use the following statements of nutritional support in accordance with 21 U.S.C. § 343(r)(6) and 61 FR 50771 (September 27, 1996). Each statement when appearing in product labeling is followed by an asterisk; a corresponding asterisk appears in that same labeling with the statutorily required disclaimer: **This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.**

1. Dietary Supplement Name:

Simone *Super*ENERGY™

Dietary Ingredients:

complex carbohydrates, fructose, potassium bicarbonate, natural flavor, sodium phosphate, potassium chloride, potassium phosphate, ascorbic acid, sodium bicarbonate, vitamin E, L-carnitine, calcium carbonate, magnesium carbonate, choline bitartrate, dl-aspartic acid, glutamic acid, creatine, leucine, isoleucine, valine, betaine hydrochloride, methionine, pyridoxine hydrochloride, d-calcium

975-0162

51380  
LET 543

pantothenate, beta-carotene, thiamine hydrochloride, octasanol, cyanocobalamin, vitamin D, folic acid, and biotin.

Statements of Nutritional Support:

Physical exhaustion and dehydration results from the depletion of sugars, electrolytes, amino acids, vitamins, minerals, and water. *SuperENERGY™* replaces these.

*SuperENERGY™* has antioxidants that can neutralize free radicals.

This healthy, new formula has the major antioxidants that can neutralize free radicals.

[*SuperENERGY™*] provide[s] essential nutritional support for the maintenance of overall health and [helps] prevent dehydration, loss of vital nutrients, and electrolytes.

*SuperENERGY™* also repletes losses that occur during strenuous exertion or any dehydrating condition.

This patented formula restores energy, electrolytes, protein, minerals, virtually all US RDA vitamins and other vital nutrients.

This new formula repletes body losses that occur during strenuous exertion or any dehydrating condition.

2. Dietary Supplement Name:

*ONCCOR®*

Dietary Ingredients:

beta carotene, lutein, lycopene, vitamin A (palmitate), vitamin D (ergocalciferol), vitamin E (succinate), vitamin C (ascorbic acid), folic acid, vitamin B 1 (thiamine mononitrate), vitamin B2 (riboflavin), vitamin B-12 (cyanocobalamin), biotin, pantothenic acid, iodine, copper, zinc, potassium chlorate, selenium, chromium, manganese, molybdenum, inositol, paraaminobenzoic acid, arginine HCl, bioflavonoids, choline, L-Cysteine

Statements of Nutritional Support:

Antioxidants neutralize harmful free radicals that damage cells.

Antioxidants neutralize harmful chemicals called free radicals that occur in the body constantly and arise from fatty foods, smoking, alcohol, environmental pollutants, toxins, carcinogens, iron, smog, and radiation. Free Radicals attack vital cell structures.

3. Dietary Supplement Name:

*CALCOR®*

Dietary Ingredients:

calcium carbonate, magnesium, potassium bicarbonate, boron, L-Lysine, L-threonine, silicon

Statement of Nutritional Support:

Magnesium provides important nutritional support for normal functioning of the circulatory system.

**CERTIFICATION OF RESPONSIBLE INDIVIDUAL**

I, Dr. Charles B. Simone, President of Protective Pharmaceuticals, Inc., hereby certify that I have read the foregoing notice and confirm that it is true, correct, and complete to the best of my knowledge, information, and belief.

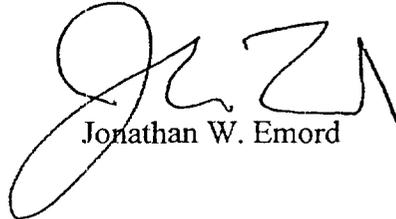
Dated: 5/26/97



Dr. Charles B. Simone

---

Respectfully submitted,

  
Jonathan W. Emord