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September 7, 2004

**VIA UPS NEXT DAY AIR**

Dr. Robert Moore  
Office of Nutritional Products,  
Labeling and Dietary Supplements (HFS-810)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Pkwy.  
College Park, MD 20740



***Re: Fulfillment of Reporting Obligation  
Under 21 U.S.C. § 343(r) and 21 C.F.R. § 101.93***

Dear Dr. Moore:

Pure Encapsulations, Inc.,<sup>1</sup> by counsel and in accordance with 21 U.S.C. § 343(r) and 21 C.F.R. § 101.93, hereby submits an original and two copies of its notification within thirty days of first marketing its products with the statements presented below. Pure Encapsulations, Inc. retains scientific documentation supporting the statements.

**1. Supplement Brand Name**

Cinnulin PF™

**Ingredients**

Cinnamon (*Cinnamomi cassia*) extract (20:1) (bark), vitamin C (as ascorbyl palmitate), hypoallergenic plant fiber added to complete capsule volume requirement

**Text of Statements of Nutritional Support**

*Supports healthy glucose metabolism and cardiovascular function.*

*Traditionally, this popular aromatic spice has been used to support healthy microbial balance and gastrointestinal function.*

<sup>1</sup> The address for Pure Encapsulations, Inc. is 490 Boston Post Road, Sudbury, MA 01776.

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*Recently, there has been a growing amount of literature, including a study performed at the Beltsville USDA Human Nutrition Research Center, suggesting that cinnamon's water-soluble polyphenol polymers support healthy glucose metabolism and provide antioxidant protection.*

*A clinical trial reported that supplementation with cinnamon promoted healthy glucose balance and was well tolerated.*

*The investigators also reported that cinnamon provided statistically-significant support for healthy lipid and triglyceride metabolism.*

*Additional studies indicated that cinnamon extract promoted an upregulation of glucose metabolism in skeletal muscle cells.*

*Furthermore, an animal study is currently underway . . . that is further exploring, at a cellular level, the potential for cinnamon to support glucose function.*

*Studies also indicate that the numerous water-soluble polyphenol polymers found naturally in cinnamon may support healthy blood flow.*

*Cinnulin PF™, a unique concentrated 20:1 cinnamon extract, provides unmatched potential to support healthy glucose and cardiovascular function, as well as provide antioxidant protection.*

## **2. Supplement Brand Name**

NSK-SD™ (Nattokinase)

### **Ingredients**

Nattokinase, hypoallergenic plant fiber added to complete capsule volume requirement

### **Text of Statements of Nutritional Support**

*Promotes fibrinolytic activity for healthy blood flow and cardiovascular function.*

*Nattokinase, a fibrinolytic enzyme isolated from natto, helps to maintain healthy activity of the body's natural clotting and fibrinolytic processes. This enzyme has demonstrated enhanced oral fibrinolytic potential when compared with other fibrinolytic enzymes from over 200 foods.*

*One study suggested that nattokinase inactivates plasminogen activator inhibitor, maintaining healthy fibrinolytic activity.*

*Nattokinase may also directly degrade fibrin in much the same way as plasmin.*

*In another study, nattokinase provided positive support for healthy circulation in animals.*

*In an additional animal study conducted by Biotechnology Research Laboratories and JCR Pharmaceuticals of Kobe, Japan, nattokinase promoted healthy blood flow.*

*Researchers from JCR Pharmaceuticals, Oklahoma State University, and Miyazaki Medical College examined the effect of nattokinase from natto food consumption in 12 healthy Japanese participants. The results suggested that natto supported healthy clotting function compared to placebo.*

*In 1995, scientists at the Miyazaki Medical College and Kurashiki University in Japan demonstrated the potential for nattokinase to support blood vessel health in human subjects.*

*NSK-SD™ is a highly purified fibrinolytic enzyme that has demonstrated encouraging potential for supporting endogenous fibrinolytic activity and promoting healthy blood flow, circulation, and blood vessel function.*

### **3. Supplement Brand Name**

Teavigo™

#### **Ingredients**

Green tea extract (standardized to contain 94% EGCG), vitamin C (as ascorbyl palmitate), hypoallergenic plant fiber added to complete capsule volume requirement

#### **Text of Statements of Nutritional Support**

*Over the years, numerous studies have reported that this polyphenolic compound provides optimal cellular function and antioxidant protection.*

*Multiple recent studies have suggested that EGCG supports prostate, colon, lung, and bladder health.*

*Additionally, a clinical study reported that EGCG promoted healthy cervical tissue.*

*An in-vitro study conducted at the Mayo clinic in Rochester, MN reported that EGCG helped promote cellular health through a number of pathways, including an iron-dependent oxidation mechanism, as well as a moderation of gene expression.*

*Furthermore, EGCG may promote healthy lipid metabolism.*

*Investigators in one study reported that the gallate moiety on the EGCG played a particularly important role in supporting healthy apolipoprotein metabolism.*

*Teavigo™ provides targeted and efficient antioxidant and cellular support.*

#### **4. Supplement Brand Name**

VenoBalance™

#### **Ingredients**

Dandelion (*Taraxacum officinale*) extract (4:1) (leaf), parsley (*Petroselinum crispum*) extract (4:1) (root), cornsilk (*Zea mays*) extract (4:1) (silk), butcher's broom (*Ruscus aculeatus*) extract (root) (standardized to contain 10% ruscogenins), rutin, vitamin C (as ascorbyl palmitate), hypoallergenic plant fiber added to complete capsule volume requirement

#### **Text of Statements of Nutritional Support**

*Promotes healthy fluid balance and supports healthy venous tone.*

*Dandelion leaf extract has been used traditionally to help maintain healthy fluid balance as noted in the German Commission E Monographs.*

*The flavonoid content of dandelion leaf may play a role in supporting healthy blood vessel integrity in the arms and legs. Rutin is a powerful flavonoid included in this formula to provide a similar mechanism of support.*

*Parsley root has also been used historically to maintain healthy fluid and water balance, as reported by the British Herbal Compendium. The action of constituents including its volatile oils and flavanoids account in part for the properties of this extract.*

*In a recent study, parsley demonstrated the potential to moderate Na<sup>+</sup>-K<sup>+</sup> pump activity, promoting healthy water balance and urinary flow rate.*

*Cornsilk, containing saponins, is reported to promote healthy fluid balance and to have a soothing effect on the genito-urinary system.*

*Butcher's broom extract, containing the saponin ruscogenin and flavonoids, has demonstrated the potential to support the strength and tone of veins and capillaries, as well as to promote healthy circulation.*

*In a multicenter, double-blind, placebo-controlled trial, butcher's broom extract supported lower leg vein health in women.*

*Over 15 studies examining the effect of butcher's broom preparations or combination products have revealed potential support for the integrity and comfort of arm and leg veins as well as fluid balance.*

*This herbal combination provides extracts with venotonic properties and the potential to support healthy water and fluid balance.*

#### 5. **Supplement Brand Name**

PediaNutrients™ capsules

#### **Ingredients**

Vitamin A (acetate), ascorbic acid, vitamin C (as ascorbyl palmitate), calcium (citrate), iron (glycinate), vitamin D<sub>3</sub>, d-alpha tocopherol succinate (vitamin E), thiamine HCl (B<sub>1</sub>), riboflavin (B<sub>2</sub>), niacinamide, pyridoxine HCl (B<sub>6</sub>), folic acid, methylcobalamin (B<sub>12</sub>), biotin, pantothenic acid (calcium pantothenate (B<sub>5</sub>), iodine (potassium iodide), magnesium (citrate), zinc (citrate), selenium (selenomethionine), copper (glycinate), manganese (aspartate), chromium (polynicotinate), molybdenum (aspartate), hypoallergenic plant fiber added to complete capsule volume requirement

#### **Text of Statements of Nutritional Support**

*Children's multivitamin/ mineral formula for optimal health.*

*This formula provides the key vitamins and minerals that help support healthy growth and development in the doses that are consistent with the accepted scientific recommendations for children between the ages of 4 and 11.*

*PediaNutrients™ provides broad spectrum, scientifically-based vitamin and mineral support for young metabolic systems.*

#### 6. **Supplement Brand Name**

PediaNutrients™ powder

#### **Ingredients**

Vitamin A (acetate), ascorbic acid, calcium (citrate), vitamin D<sub>3</sub>, d-alpha tocopherol succinate (vitamin E), thiamine HCl (B<sub>1</sub>), riboflavin (B<sub>2</sub>), niacinamide, pyridoxine HCl (B<sub>6</sub>), folic acid, methylcobalamin (B<sub>12</sub>), biotin, pantothenic acid (calcium pantothenate (B<sub>5</sub>), iodine (potassium iodide), magnesium (citrate), zinc (citrate), selenium (selenomethionine), copper (glycinate), manganese (aspartate), chromium

(polynicotinate), molybdenum (aspartate), natural flavors, xylitol, hypoallergenic plant fiber

### **Text of Statements of Nutritional Support**

*Children's multivitamin/ mineral formula for optimal health.*

*This formula provides the key vitamins and minerals that help support healthy growth and development in the doses that are consistent with the accepted scientific recommendations for children between the ages of 4 and 11.*

*PediaNutrients™ provides broad spectrum, scientifically-based vitamin and mineral support for young metabolic systems.*

### 7. **Supplement Brand Name**

PreNatal Nutrients

### **Ingredients**

Ascorbic acid, vitamin C (as ascorbyl palmitate), calcium (citrate), iron (glycinate), vitamin D<sub>3</sub>, d-alpha tocopherol succinate (vitamin E), thiamine HCl (B<sub>1</sub>), riboflavin (B<sub>2</sub>), niacinamide, pyridoxine HCl (B<sub>6</sub>), folic acid, methylcobalamin (B<sub>12</sub>), biotin, pantothenic acid (calcium pantothenate (B<sub>5</sub>), iodine (potassium iodide), magnesium (citrate), zinc (citrate), selenium (selenomethionine), copper (glycinate), manganese (aspartate), chromium (polynicotinate), molybdenum (aspartate), mixed carotenoids (providing beta carotene, alpha carotene, zeaxanthin, cryptoxanthin, and lutein), DHA (docosahexaenoic acid) (derived from vegetable source), denatured corn starch, hypoallergenic plant fiber added to complete capsule volume requirement

### **Text of Statements of Nutritional Support**

*Nutritional support for pregnancy and lactation.*

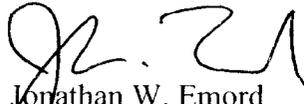
*Provides the core nutrients needed to help support maternal and fetal health and in the doses that are consistent with the accepted scientific recommendations for pregnant and lactating women.*

*PreNatal Nutrients provides broad spectrum vitamin and mineral support, including 1 mg of folic acid, for pregnant and lactating women.*

In accordance with 21 U.S.C. § 343(r)(6) and 21 C.F.R. § 101.93(c), each of the above statements will be followed by an asterisk that will be cross-referenced to another

asterisk on the very same panel or page next to which the following statement will appear in a box in bold face type: **“These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”**

Respectfully submitted,



Jonathan W. Emord  
Claudia A. Lewis-Eng  
Michelle C. Gayeski

cc: René Augstburger

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FROM:418 652 0151

TO:PURE ENCAPSULATIONS 09-02-04 08:36

Certification

*I, René Augstburger, General Manager of Pure Encapsulations, Inc., hereby certify that the information contained in the foregoing notice is complete and accurate and that Pure Encapsulations has substantiation that the statements are truthful and not misleading.*

Executed on: 9/2/04

  
René Augstburger