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JUN 21 2004

June 17, 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**

Cortimin

**Ingredients**

Milk protein hydrolysate (standardized to contain 2.5 mg  $\alpha_{s1}$  casein peptide), sodium caseinate, hypoallergenic plant fiber added to complete capsule volume requirement

**Text of Statements of Nutritional Support**

*Minimizes cortisol production and the stress response.*

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

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*Milk has long been associated with having a calming or comforting effect, a finding primarily associated with its major protein casein.*

*This decapeptide has demonstrated the potential to bind to GABA receptors, enhancing the inhibitory effect of GABA and moderating the effects of occasional stress.*

*In a study, this milk protein hydrolysate helped to reduce stress-related behavior in animals.*

*A trial with healthy volunteers indicated that it promoted positive outcomes on stress evaluation scores.*

*The results of a clinical trial suggested that it may also moderate perceived stress in a dose-dependent manner.*

*In a trial, its effects on physiological responses to stress were evaluated. The data suggests that this milk protein hydrolysate may help to maintain healthy vascular function and stress hormone levels, including cortisol, under stressful conditions.*

*A study involving biathletes revealed that milk protein hydrolysate may help moderate cortisol production associated with rigorous training, mediating physical and psychological stress in athletes.*

*Studies demonstrate gentle and well-tolerated support without any reported contraindications.*

*Cortimin contains a patented, readily absorbed milk casein hydrolysate providing a novel decapeptide for rapid acting moderation of occasional stress.*

## **2. Supplement Brand Name**

TMG (trimethylglycine)

### **Ingredients**

Trimethylglycine (anhydrous betaine), vitamin C (as ascorbyl palmitate)

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

*Supports liver health and healthy homocysteine levels.*

*TMG (trimethylglycine), also known as anhydrous betaine, acts as a methyl donor important for a wide range of physiological reactions in the body.*

*One of the major roles of TMG is in promoting healthy homocysteine metabolism.*

*In a recent study, a betaine-rich diet or betaine supplementation supported healthy homocysteine metabolism in men and women.*

*It is believed that betaine may be especially supportive when vitamin B<sub>12</sub>, folic acid, and vitamin B<sub>6</sub> are not sufficient to maintain healthy homocysteine.*

*Additionally, this nutrient possesses the ability to generate s-adenosylmethionine, one of the most important cofactors in healthy liver function.*

*TMG is also a highly recognized lipotropic factor because it maintains healthy fat metabolism in the liver.*

*TMG supports healthy homocysteine metabolism and maintains healthy fat metabolism and cellular protection in the liver.*

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

Alpha Lipoic Acid 600 mg

#### **Ingredients**

Alpha lipoic acid (thioctic acid), vitamin C (as ascorbyl palmitate), hypoallergenic plant fiber added to complete capsule volume requirement

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

*Water and lipid soluble antioxidant; supports glucose metabolism and nerve health.*

*Alpha lipoic acid is a potent antioxidant which neutralizes harmful free radicals and enhances the activity of vitamins C and E.*

*A key component of the metabolic process, alpha lipoic acid produces energy in muscles and directs calories into energy production.*

*In addition, this potent nutrient can be used as part of the diet to support healthy blood sugar levels, supports the nervous system, and provides nutritional support for normal liver functioning.*

*In one study, alpha lipoic acid decreased serum lactate and pyruvate and promoted healthy glucose metabolism in lean and overweight individuals.*

*Alpha lipoic acid supported nerve health in subjects who participated in a four-month randomized, double-blind, placebo-controlled, multicenter trial.*

*The ability of alpha lipoic acid to modulate nitric oxide metabolite activity and to promote healthy microcirculation accounted for its ability to promote nerve cell health in two separate studies.*

*Alpha Lipoic Acid is a multifunctional, versatile nutrient which plays a key role in the antioxidant network and the metabolic process.*

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

L-Proline

#### **Ingredients**

L-proline (free-form), vitamin C (as ascorbyl palmitate)

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

*Support for healthy skin, cardiovascular function, and the musculoskeletal system.*

*L-Proline is an amino acid that serves as a precursor for hydroxyproline, one of the most abundant and important constituents of stable collagen fibers.*

*The collagen matrix consists of a series of proline and lysine triple helices, which become hydroxylated to form hydroxylysine and hydroxyproline polypeptide chains. Hydroxyproline provides the structural integrity for collagen, a major component of connective and epidermal tissue found throughout the body.*

*As a result, proline provides potential support for bone, ligament, tendon, cartilage, and skin health.*

*One study indicated that proline also serves as a primary binding site and promoter for keratinocyte growth factor (KGF), a key stimulator of healthy epithelial cell formation.*

*Studies have reported that proline may play a role in supporting healthy lipoprotein and lipid metabolism, as well as promoting arterial integrity and function.*

*L-Proline helps moderate the natural age-related decrease in collagen production, helping to support cardiovascular function and promote bone, ligament, tendon, cartilage, and skin health.*

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

Essential Aminos powder

## **Ingredients**

L-histidine (free-form), l-isoleucine (free-form), l-leucine (free-form), l-lysine (HCl), l-methionine (free-form), l-phenylalanine (free-form), l-threonine (free-form), l-valine (free-form)

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

*Supports healthy muscle and tissue.*

*Amino acids are the building blocks for all proteins, making them essential for a number of body functions, including fluid balance, enzyme production, cellular development, and energy metabolism.*

*Proper intake of these amino acids is important for the synthesis, repair, and metabolism of muscle, cells, and tissues.*

*A number of studies have been conducted at the University of Texas, including a clinical study that suggested essential amino acid supplements may support muscle anabolism in the elderly.*

*Another clinical study performed at the university's metabolism unit in the Department of Surgery indicated that supplementing with essential amino acids promotes healthy muscle protein synthesis after resistance exercise.*

*This formula provides a balanced ratio of essential amino acids for optimal support of protein synthesis and metabolism.*

## **6. Supplement Brand Name**

Artichoke leaf extract

## **Ingredients**

Artichoke (*Cynara scolymus L.*) extract (leaf) (standardized to contain a minimum of 5% cynarin and 3% caffeoylquinic acids), vitamin C (as ascorbyl palmitate), hypoallergenic plant fiber added to complete capsule volume requirement

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

*Supports healthy digestion and gastric comfort, maintains healthy lipid and triglyceride metabolism, and promotes healthy liver function.*

*Cynara scolymus L., or artichoke extract, has been used extensively in Europe for decades to enhance the digestive process by promoting healthy bile flow and fat digestion, gastric comfort, and intestinal motility.*

*In one study involving 20 volunteers, artichoke leaf extract supported healthy bile secretion.*

*A study with 60 subjects suggested that artichoke leaf extract also promoted healthy digestive function by enhancing bile production.*

*In this study, subjects noted support for gastrointestinal comfort and reduced feelings of bloating and fullness.*

*A study of over 500 individuals supplementing with artichoke for six weeks indicated digestive support, including feelings of gastric comfort, reduced flatulence, and enhanced fat tolerance.*

*In this same study, it was reported that artichoke extract also supported healthy lipid and triglyceride metabolism.*

*Artichoke is well recognized for its liver support properties, attributed to the extract's ability to maintain healthy bile metabolism, antioxidant activity, blood flow in the liver, detoxification processes, as well as its general ability to promote hepatic cell function.*

*Artichoke leaf extract supports healthy digestive function by promoting bile flow, fat digestion, and gastric discomfort, including reduced feelings of bloating and fullness, especially as related to fatty meals.*

*This extract is also helpful for supporting healthy lipid and triglyceride metabolism as well as liver function.*

## **7. Supplement Brand Name**

Grapefruit Seed extract

### **Ingredients**

Grapefruit seed extract (standardized to contain 49% polyphenols), vitamin C (as ascorbyl palmitate)

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

*Intestinal support formula.*

*Promotes the balance of intestinal microorganisms and maintains a healthy gastrointestinal tract.*

*Grapefruit seed extract is a highly concentrated fungal and microbial balancing extract.*

*Grapefruit seed extract exerts these effects within the gastrointestinal (GI) tract, promoting healthy microflora and gut ecology.*

*A clinical trial reported that grapefruit seed extract supplements helped support healthy GI function and comfort.*

*A study using human skin fibroblast cells indicated that grapefruit seed extract promoted healthy gram-positive and gram-negative balance.*

*Other studies support these findings, citing that grapefruit seed extract promotes a healthy environment when exposed to a wide range of bacterial biotypes.*

*Pure Encapsulations Grapefruit Seed extract provides 49% polyphenolic compounds, supporting healthy microbial and fungal balance in the gastrointestinal tract.*

## **8. Supplement Brand Name**

MicroDefense

### **Ingredients**

Black walnut hull (*Jugians nigra L.*) extract (10:1), olive leaf (*Olea europaea L.*) extract (standardized to contain 17-23% oleuropein), Artemisia (*Artemisia annua L.*) extract (whole plant) (standardized to contain 5% artemisinin), clove (*Syzygium aromaticum*) (whole plant), grapefruit seed extract (standardized to contain 49% polyphenols), vitamin C (as ascorbyl palmitate), hypoallergenic plant fiber added to complete capsule volume requirement.

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

*Intestinal support formula.*

*Supports healthy gastrointestinal, reproductive, and urinary tract health by maintaining a healthy microbial balance.*

*MicroDefense is a highly concentrated blend of herbs and botanicals that are supportive of intestinal, urinary, female reproductive, and upper respiratory tract health.*

*Artemisia has been used traditionally in China for thousands of years to promote healthy microbial balance within the body.*

*It contains many health-promoting constituents, one of which is artemisinin. A sesquiterpene lactone, artemisinin reportedly supports a healthy fungal and microbial environment as well as promotes cellular health.*

*A number of studies have indicated that artemisinin, along with a number of its derivatives, such as dihydroartemisinin, may provide such support through an iron and oxygen-based free-radical mechanism within the cell membranes of certain microbes.*

*Black walnut hull extract maintains healthy fungi levels and genitourinary function, and studies indicate that this extract provides broad-spectrum support for healthy microorganism balance.*

*Olive leaf extract contains the active constituent oleuropein, a phenolic glucoside that helps maintain healthy GI and respiratory tract microorganism balance and may help boost immune function.*

*Clove has been used traditionally to promote healthy fungal and microbial levels, and grapefruit seed extract has been reported to help support healthy GI function and comfort, as well as promote healthy gram-positive and gram-negative balance.*

*Pure Encapsulations MicroDefense provides an enhanced formulation of phytonutrients to support immune, respiratory, genitourinary, and gastrointestinal tract health.*

## **9. Supplement Brand Name**

G.I. Fortify

### **Ingredients**

Vitamin C (as ascorbyl palmitate), psyllium husk powder (*Plantago indica*), flax seed powder, L-glutamine (free-form), deglycyrrhizinated licorice extract (root), marshmallow root (*Althaea officinalis*) extract (8:1), unripe plantain banana (*Musa paradisiaca*) (fruit), slippery elm (*Ulmus fulva*) extract (root), triphala (a proprietary blend of *Terminalia chebula*, *Terminalia bellerica*, and *Emblica officinalis* fruit extracts)

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

*Intestinal support formula.*

*Supports the function, integrity, tone, comfort, cellular health, and detoxification of the gastrointestinal tract.*

*This product is a blend of high-impact fiber, herbs, and nutrients, supporting overall gastrointestinal function and occasional constipation.*

*Psyllium is combined with Nutra-Flax™ high-lignan flax seed, glutamine, DGL Plus™, and triphala to provide broad, far-reaching support for the GI tract.*

*Soluble fiber is fermented in the large intestines by intestinal microflora, producing short chain fatty acids (SCFAs). SCFAs are extremely important energy sources for the colon and have protective effects for healthy colon cell function.*

*Furthermore, SCFAs keep the intestinal environment acidic, providing optimal conditions for lactobacillus and other beneficial bacteria to thrive.*

*Soluble fiber also increases the stool volume when taken with appropriate amounts of water, supporting larger and softer stools for healthy bowel movements.*

*As the bulk moves through the intestine, it helps to collect and eliminate other waste and toxins from the intestinal walls. This helps to minimize the amount of exposure of the gastrointestinal tract to toxins.*

*Nutra-Flax™ provides a source of lignans, fatty acids, and both soluble and insoluble fibers, enhancing the gut health potential of this complex.*

*The fiber content of flax seed provides additional support for healthy intestinal function, microflora balance, and overall colon health.*

*The ability of lignans to support colon health has been reported in numerous studies and may be due in part to antioxidant protection and the ability to promote healthy beta-glucuronidase activity and detoxification.*

*In times of stress or increased metabolic demand, glutamine is an especially important source of energy for the GI tract.*

*In the gut, glutamine maintains healthy integrity of the intestinal tract and enhances the protective mucosal lining.*

*This helps to ensure proper nutrient utilization and absorption while limiting the amount of toxins that pass through the intestinal barrier.*

*DGL Plus™ provides a synergistic combination of deglycyrrhizinated licorice (DGL), unripe plantain banana, slippery elm, and marshmallow root that enhances the protective mucous lining throughout the gastrointestinal tract, promoting gut integrity and providing a soothing effect.*

*Triphala is an Ayurvedic blend prized for supporting intestinal detoxification, occasional constipation, and overall colon health.*

*Triphala has a long traditional history of use for bowel tonification and consists of various nutritive compounds, including antioxidants, tannins, and polyphenols.*

*This product is designed to promote larger and softer stools and healthy bowel movement frequency; support short chain fatty acid (SCFA) production, providing an energy source for the colon and maintaining healthy colon cell function; provide prebiotic support, promoting beneficial microflora such as lactobacillus and bifidobacteria; maintain healthy gut integrity; minimize the time of exposure of the gastrointestinal tract by enhancing the gastric mucosa.*

#### 10. **Supplement Brand Name**

Bacopa monniera

#### **Ingredients**

*Bacopa monniera extract (leaf) (standardized to contain 20% bacosides A & B), vitamin C (as ascorbyl palmitate), hypoallergenic plant fiber added to complete capsule volume requirement*

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

*Supports memory, enhances mental performance, and moderates occasional stress.*

*Ayurvedic medicine has utilized Bacopa monniera traditionally for centuries to support the nervous system, enhance cognitive capacity, and sharpen memory.*

*A trial conducted by Australian scientists suggests that bacopa may support learning, moderate stress, and promote memory.*

*An animal study suggests the potential for bacopa to support mental function under stress.*

*In a double blind investigation, bacopa supported memory retention in adult subjects.*

*The effects of this extract may, in part, be explained by antioxidant protection of important processing centers in the brain, including the frontal cortex, striatum, and hippocampus.*

*Bacopa may also help to promote healthy synaptic activity and neurotransmission in the brain.*

*Bacopa monniera is a prized Ayurvedic herb supporting mental acuity, memory, and cognitive function under stress.*

11. Supplement Brand Name

Artemisia

Ingredients

Artemisia (*Artemisia annua L.*) extract (whole plant) (standardized to contain 5% artemisinin), vitamin C (as ascorbyl palmitate), hypoallergenic plant fiber added to complete capsule volume requirement

Text of Statements of Nutritional Support

*Intestinal support formula.*

*Supports healthy fungal and microbial balance.*

*Artemisia annua L., also known as sweet wormwood and as the Chinese herbal Qinghao, has been used traditionally in China for thousands of years to promote healthy microbial balance within the body.*

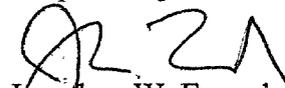
*This concentrated extract contains many health-promoting constituents such as nine terpenoids and flavonoids, one of which is artemisinin. A sesquiterpene lactone, artemisinin provides potential for a healthy fungal and microbial environment as well as cellular health.*

*A number of studies have indicated that artemisinin, along with a number of its derivatives such as dihydroartemisinin, may provide such support through an iron and oxygen-based free-radical mechanism within the cell membranes of certain microbes.*

*Pure Encapsulations Artemisia is standardized to contain 5% artemisinin, providing optimal support for healthy fungal and microbial balance.*

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

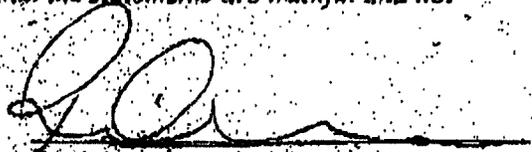
cc: René Augstburger

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:

June 14, 2004

  
René Augstburger