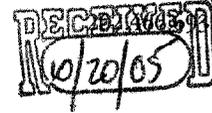


 & Associates, P.C.

1047 5 OCT 28 P2:21

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October 18, 2005

**VIA UPS NEXT DAY**

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:

We hereby submit on behalf of Pure Encapsulations,<sup>1</sup> in accordance with 21 U.S.C. § 343(r) and 21 CFR § 101.93, an original and two copies of its notification. Pure Encapsulations retains scientific documentation supporting the statements. Please find enclosed a certification from Pure Encapsulations that the information contained in this notice is complete and accurate and that Pure Encapsulations has substantiation that the statements are truthful and not misleading.

**1. Supplement Brand Name**

Protect & Nourish A.M.

**Supplement Ingredients**

Vitamin C (as ascorbyl palmitate), ascorbic acid, alpha lipoic acid (thioctic acid), green tea extract (*Camellia sinensis*) (leaf), pine bark extract (standardized to contain 65-75% proanthocyanins), pomegranate (*Punica granatum L.*) extract (whole fruit) (standardized to contain 5% ellagic acid), freeze-dried coconut water solids, Hawaiian spirulina (*Arthrospira platensis*).

**Text of Statements of Nutritional Support**

- Protect & Nourish\*

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16907

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

- Skin Health\*
- High-powered daytime formula to protect and nourish the skin.\*
- This formula contains powerful antioxidant and photoprotective ingredients combined with exceptional nutritive factors.\*
- Alpha lipoic acid is a dual-protection fat and water soluble antioxidant and also regenerates skin-shielding compounds including vitamin C, vitamin E, glutathione and CoQ10.\*
- It maintains a healthy cellular response in keratinocytes and protects collagen by maintaining healthy advanced glycation end product (AGE) activity.\*
- Vitamin C is an integral collagen synthesis cofactor, promoting skin elasticity and resiliency.\*
- As an antioxidant and immune defense stimulator, it helps counter the effects of oxidative stress.\*
- The photoprotective action of epigallocatechin gallate (EGCG) and other green tea polyphenols includes preserving DNA integrity of dermal fibroblasts and epidermal keratinocytes.\*
- These polyphenols also moderate matrix metalloproteinase (MMP) activity, supporting the extracellular matrix (ECM) of the skin.\*
- Alongside the well-known antioxidant activity of ellagic acid, anthocyanins and tannins found in pomegranate retain a healthy immune cascade in skin cells.\*
- This extract may also boost antioxidant enzymes.\*
- In addition to super-charged proanthocyanidin antioxidant support, Pycnogenol® pine bark extract selectively binds to collagen and elastin, protecting these proteins from free radicals and enzymatic degradation.\*
- Studies also suggest its potential to minimize temporary redness and to lessen the appearance of age spots.\*
- By promoting healthy circulation and vascular integrity, this extract also optimizes nutrient and oxygen delivery for renewed looking skin.\*
- Coconut water is a reservoir of vitamins, minerals and amino acids, as well as RNA-phosphorous, shikimic acid and quinic acid, which support tissue health.\*

- It also contains plant messenger molecules involved in healthy cell growth and differentiation for additional skin restoration.\*
- Its natural enzymes support toxin elimination to promote skin clarity.\*
- Phycocyanin and chlorophyll both contribute to healthy detoxification and cleansing.\*
- This strain of spirulina is also particularly rich in mixed carotenoids and provides antioxidant enzymes, including superoxide dismutase (SOD), for enhanced protection and epidermal immune function.\*
- Essential fatty acids contained in spirulina, including gamma linolenic acid (GLA), support skin smoothness.\*
- Combined, these factors optimize the performance of skin functions and help promote invigorated and radiant skin.\*
- This dynamic combination helps defend skin from free radical damage and photoaging in addition to providing vital nourishment factors, maximizing skin function while minimizing the appearance of fine lines and wrinkles.\*

## **2. Supplement Brand Name**

Renew & Hydrate P.M.

## **Supplement Ingredients**

Vitamin C (as ascorbyl palmitate), coenzyme Q10 (ubiquinone), grape (*Vitis vinifera*) seed extract (standardized to contain 92% oligomeric proanthocyanidins), n-acetyl-l-cysteine (free-form), methylsulfonylmethane, aloe vera (*Aloe barbadensis*) extract (inner fillet) (200:1) (standardized to contain 10% polysaccharides), hydrolyzed type II collagen (chicken sternal cartilage), hypo-allergenic plant fiber added to complete capsule volume requirement.

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

- Collagen reinforcing and skin hydrating nighttime revitalization formula for healthy skin\*
- Renew & Hydrate\*
- This formula contains essential components for collagen reinforcement and skin hydration combined with restorative antioxidant and immune defense compounds.\*

- These structural components support the elasticity and firmness of skin and their age-related decline contributes to the appearance of fine lines and wrinkles.\*
- Furthermore, hyaluronic acid (HA) attracts water, promoting hydration and moisture retention within the dermal matrix.\*
- In a peak absorption study, serum levels of HA increased gradually and with statistical significance after BioCell Collagen II supplementation.\*
- Case reports have revealed that BioCell Collagen II helped moderate the appearance of wrinkles and blemishes.\*
- ACTIValoe™ is a patented extract that contributes to the synthesis of collagen and connective tissue.\*
- Aloe also enhances phase II antioxidant enzyme activity, reducing oxidative stress from environmental factors.\*
- Furthermore, ACTIValoe is enriched with modified polysaccharides of medium molecular weight, stimulating macrophage activity and promoting immune defense.\*
- CoQ10 enhances mitochondrial function, supporting the high-energy demands of skin cell renewal and collagen biosynthesis.\*
- It is also one of the only known naturally occurring lipophilic antioxidants present in the skin surface lipids of the epidermis, providing first-line protection from oxidative and environmental assaults.\*
- CoQ10 also helps maintain DNA integrity and recycles other powerful antioxidants.\*
- Proanthocyanidin-rich grape seed extract helps stabilize collagen and elastin by moderating activities of the proteolytic enzymes collagenase and elastase.\*
- It may also help minimize the appearance of pigmentation in sun-exposed skin.\*
- N-acetyl-l-cysteine (NAC) is a hydrophilic amino acid antioxidant that helps boost cellular glutathione levels depleted by reactive oxygen species (ROS).\*
- Immune cell activity in the skin may also be enhanced by NAC's antioxidant capabilities, restoring vital skin defense.\*

- Methylsulfonylmethane (MSM) is a source of elemental sulfur, an important building block of proteins and other compounds that helps strengthen hair, skin and nails.\*
- This multifaceted, balanced-approach nighttime formula is designed to bolster the skin's collagen network, enhance cellular energy, boost antioxidant protection and hydrate the skin, supporting healthy function and renewal and minimizing the appearance of wrinkles and fine lines.\*

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

Defy the Elements *extra*

### **Supplement Ingredients**

Vitamin C (as ascorbyl palmitate), tetrahydrocurcumin (standardized to contain 95% tetrahydrocurcuminoids), astaxanthin (naturally derived from *haematococcus microalgae*), white tea (*Camellia sinensis*) extract (leaf), varuna (*Crataeva nurvala*) extract (bark) (standardized to contain 1.5% lupeol), milk thistle (*Silybum marianum*) extract (fruit) (standardized to contain 80% silymarin), CelluPhase (broccoli (*Brassica oleracea italica*) sprout concentrate (20:1) (standardized to contain a minimum of 332 mcg. sulforaphane), broccoli (*Brassica oleracea italica/alba*) extract (whole plant) (standardized to contain 4% glucosinolates)).

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

- Advanced extra skin protection and restoration formula\*
- Skin Health\*
- This formula is designed to provide extra protection for the chemical and physical factors that compromise and age the skin, including sun exposure and pollution.\*
- A series of comparative studies indicated that various curcuminoids neutralize free radicals but that tetrahydrocurcuminoids (THC) had the strongest antioxidant capacity.\*
- As a powerful fat and water soluble antioxidant and immune system modulator, BioAstin® astaxanthin is patented for its photoprotective ability.\*
- Initial trials suggest that it may boost the skin's natural antioxidant defenses against sun-induced free radicals.\*
- In a human clinical evaluation, supplementation with BioAstin® astaxanthin for two weeks provided significant cutaneous antioxidant protection.\*

- It may also maintain healthy arachidonic acid metabolism in response to environmental stresses and promote immune defense.\*
- Furthermore, astaxanthin may influence the activity of a large group of enzymes known as transglutaminases, a family of proteins that promote protective cellular responses and tissue homeostasis.\*
- The least processed of all teas, white tea extract containing EGCG and other polyphenols provides remarkable antioxidant and cellular support, in part by enhancing liver detoxification enzymes and glutathione production.\*
- It also plays a role in the modulation of transcription factor and MMP activities to maintain healthy skin function and integrity.\*
- Lupeol supports the replenishment of antioxidant enzymes, including catalase, glutathione peroxidase, glutathione reductase and glutathione S-transferase, which are depleted by environmental toxins.\*
- It has also demonstrated the potential to maintain healthy immune activity at the cellular level.\*
- Milk thistle extract, providing bioflavonoids, and the concentrated broccoli extracts in CelluPhase, standardized for glucosinolates and sulforaphane, offer unique phytochemical support. They are included in this formula to enhance phase II liver antioxidant enzyme activity and detoxification for protection from chemically induced oxidative stress.\*
- This extra protection formula helps revive lack luster skin compromised by physical and chemical environmental elements and provides added antioxidant, photoprotective and detoxification support to preserve skin function and to help diminish the general signs of aging.\*

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

Sytrinol™

#### **Supplement Ingredients**

Sytrinol™ (patented polymethoxylated flavonoid-tocotrienol complex), vitamin C (ascorbyl palmitate), hypo-allergenic plant fiber added to complete capsule volume requirement.

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

- Patented polymethoxylated flavonoid-tocotrienol complex for healthy lipid and triglyceride support.\*
- Sytrinol was developed after twelve years of research exploring the health benefits of PMFs and tocotrienols in heart health.\*
- This synergistic combination supports healthy lipid and triglyceride metabolism.\*
- PMFs are a subclass of citrus bioflavonoids that possess an extra methyl group, making them highly biologically active.\*
- The two predominant PMFs are tangeretin and nobilietin. These compounds have been associated with maintaining healthy liver microsomal triglyceride transfer protein (MTP) activity and diacylglycerol acetyl transferase (DGAT) liver enzyme activity, both involved in the pathway of triglyceride synthesis.\*
- Additionally, Sytrinol may support healthy PPAR activity (a receptor in the liver), enhancing  $\beta$ -oxidation and moderating the concentration of fatty acids available for the synthesis of triglycerides.\*
- PMFs also maintain healthy structural protein formation responsible for endogenous lipid production.\*
- Palm tocotrienols contain a powerful spectrum of alpha, gamma and delta isomers promoting healthy liver enzyme activity involved in lipid biosynthesis.\*
- In two 4- week clinical studies, Sytrinol demonstrated cardioprotective potential by supporting healthy lipid and triglyceride metabolism.\*
- The first two phases of a double blind 28-week three-phase crossover trial with 120 subjects also suggests that Sytrinol has important lipid and triglyceride support properties.\*
- Furthermore, Sytrinol provides general antioxidant protection, helps maintain a healthy immune response in the arterial vessel walls, and promotes healthy blood flow.\*
- Sytrinol™ is a synergistic complex of highly specialized flavonoids and tocotrienols for multifaceted lipid and triglyceride support as well as overall cardiovascular health.\*

## **5. Supplement Brand Name**

VitaTrienols

## **Supplement Ingredients**

Vitamin E (mixed tocopherols), full spectrum palm tocotrienol complex (*Elaeis guineensis*) (fruit) (standardized to contain 50% total tocotrienols/tocopherols), palm fruit oil, gelatin.

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

- Tocopherols and tocotrienols are widely recognized, highly complementary antioxidants of the vitamin E family.\*
- Both alpha and gamma tocopherol offer important antioxidant support for prostate health, though gamma tocopherol is believed to be more potent.\*
- In a recent study, mixed tocopherols supported healthy platelet function, nitric oxide metabolism, and superoxide dismutase activity more so than alpha tocopherol alone.\*
- Mixed tocopherols also appear to protect from lipid peroxidation to a greater degree than alpha tocopherol.\*
- Furthermore, the vitamin E family, including tocotrienols, has been reported to support healthy neurological function.\*
- The National Institute of Health has funded a study at the Ohio State University Medical Center investigating the role of alpha tocotrienol on nervous system health. Current findings suggest that alpha tocotrienol is several fold more powerful than alpha tocopherol in providing neuron cell antioxidant protection.\*
- Earlier studies also indicate that alpha tocotrienol might play a promising role in maintaining healthy glutamate activity in the brain.\*
- In addition, scientists from the United Kingdom, Canada, Malaysia and the US indicate that tocotrienols, especially the delta and gamma fractions, provide high capacity support for breast cell health, in part by maintaining healthy gene expression.\*
- Tocotrienols also help protect cell membranes from lipid peroxidation and are believed to be more supportive of lipid metabolism than tocopherols.\*

- A number of independent research centers in China, Australia and India reveal that dietary palm oil, the richest source of tocotrienols, supports healthy lipid metabolism.\*
- One proposed mechanism for this involves the ability of tocotrienols to maintain healthy lipid production and enzyme activity in the liver.\*
- Together, vitamin E and tocotrienols support healthy skin by boosting antioxidant defense, maintaining DNA integrity, and promoting smoothness.\*
- Natural full-spectrum VitaTrienols contains a comprehensive profile of mixed tocotrienols and mixed tocopherols providing all eight bioactive isomers for broad range support of lipid metabolism, cardiovascular health, prostate health, breast cell health, skin health and nervous system antioxidant protection.\*

## **6. Supplement Brand Name**

Polyphenol Nutrients

### **Supplement Ingredients**

Ascorbic acid, vitamin C (as ascorbyl palmitate), calcium (citrate), vitamin D<sub>3</sub>, d-alpha tocopherol succinate (vitamin E), thiamine HCl (B<sub>1</sub>), riboflavin (B<sub>2</sub>), riboflavin 5<sup>1</sup> phosphate (activated B<sub>2</sub>), niacin, niacinamide, pyridoxine HCl (B<sub>6</sub>), pyridoxal 5<sup>1</sup> phosphate (activated 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 (picolinate), selenium (selenomethionine), copper (glycinate), manganese (aspartate), chromium (polynicotinate), molybdenum (aspartate), potassium (aspartate), boron (glycinate), vanadium (aspartate), mixed carotenoids (beta carotene, alpha carotene, zeaxanthin, lutein, cryptoxanthin), lutein, zeaxanthin, n-acetyl-L-cysteine (free- form), choline (bitartrate), inositol, alpha lipoic acid (thioctic acid), quercetin, blueberry (*Vaccinium angustifolium*) extract (fruit) (standardized to contain 1.5% anthocyanins), olive (*Olea europaea L.*) extract (fruit), pomegranate (*Punica granatum L.*) extract (fruit) (standardized to contain 5% ellagic acid), grape (*Vitis vinifera*) extract (seed) (standardized to contain 92% oligomeric proanthocyanidins), green tea (*Camellia sinensis*) extract (leaf).

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

- Powerful polyphenol-rich multivitamin and multimineral formula with additional protection factors.\*
- Packed with flavonoids and phenolic compounds from a unique blend of olive fruit, grape seed, pomegranate, green tea, quercetin and blueberry, this formula offers powerful overall cellular protection.\*

- It also contains the protective nutrients alpha lipoic acid, NAC, inositol and choline to complement the neural, cognitive, cardiovascular, liver and skin health properties of this diverse profile.\*
- Furthermore, Polyphenol Nutrients provides the advanced mineral delivery systems and active vitamin cofactors found in Nutrient 950® and UltraNutrient® for optimal bioavailability and utilization.\*
- Polyphenol Nutrients is a nutrient dense multivitamin and mineral formula enhanced with an exceptional combination of polyphenols and specialized compounds for extensive physiological protection.\*
- Providing wide-range support for: cellular protection, heart health, skin health, cognitive function, nerve protection, liver health, and macular health\*
- Specialized protection factors\*

## **7. Supplement Brand Name**

Multi t/d

### **Supplement Ingredients**

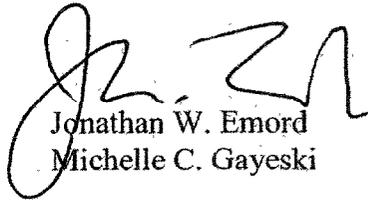
Ascorbic acid, vitamin C (ascorbyl palmitate), vitamin D<sub>3</sub>, d-alpha tocopherol succinate (vitamin E), thiamine HCl (B<sub>1</sub>), riboflavin (B<sub>2</sub>), riboflavin 5' phosphate (activated B<sub>2</sub>), niacin, niacinamide, pyridoxine HCl (B<sub>6</sub>), pyridoxal 5' phosphate (activated B<sub>6</sub>), folic acid, methylcobalamin (B<sub>12</sub>), biotin, pantothenic acid (calcium pantothenate) (B<sub>5</sub>), iodine (potassium iodide), zinc (picolinate), selenium (selenomethionine), chromium (polynicotinate), mixed carotenoids (beta carotene, alpha carotene, zeaxanthin, lutein, and cryptoxanthin), lutein, zeaxanthin.

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

- Enhanced with lutein and zeaxanthin, this formula couples fundamental support with convenience.\*
- Furthermore, Multi t/d provides the advanced mineral delivery systems and active vitamin cofactors found in Nutrient 950® and UltraNutrient® for optimal bioavailability and utilization.\*
- Multi t/d offers a highly bioavailable vitamin, trace mineral and antioxidant combination with a two capsule per day recommendation for simplicity and optimal compliance.\*

In accordance with 21 USC § 343(r)(6) and 21 CFR § 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,

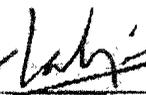


Jonathan W. Emord  
Michelle C. Gayeski

Certification

I, Catherine Lahaussais, 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: 10/18/05

  
\_\_\_\_\_  
Catherine Lahaussais