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March 21, 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

APR - 4 2005

***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**

Cranberry / d-Mannose

**Supplement Ingredients**

Cranberry juice extract  
d-Mannose  
Vitamin C

**Text of Statements of Nutritional Support**

- Cranberry extract combined with d-mannose for dual support of urinary tract comfort.

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

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- The role of cranberry extract includes enhancing the acidity of urine and maintaining a healthy urinary tract ecology.
- In one study, healthy urinary function was observed in subjects shortly after drinking cranberry juice cocktail.
- Another study suggested the potential for cranberry juice to interact with lectin receptors and maintain a healthy bladder wall.
- At Brigham and Women's Hospital in Boston, MA, a randomized double blind, placebo-controlled trial involving over 150 female volunteers reported positive support for a healthy urinary tract after administration of a cranberry beverage.
- d-Mannose, a simple sugar found in cranberries and other fruit, is included in this formula to provide concentrated support.
- The majority of it is excreted via the urine where it promotes a healthy urinary tract environment.
- One study examining the effect of d-mannose on epithelial cells suggested that it may play a role in supporting healthy genitourinary function by maintaining a healthy mucosal surface.
- d-Mannose in this formula is derived from natural plant sources and is combined with cranberry extract for high capacity urine tract support.
- Cranberry / d-Mannose combines cranberry extract made from 100% cranberry fruit solids and d-mannose for both time-tested and concentrated support of urinary tract comfort.

## **2. Supplement Brand Name**

Melatonin 20 mg.

## **Supplement Ingredients**

Melatonin

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

- Promotes healthy angiogenesis balance, immune function and antioxidant activity.

- Melatonin is primarily associated with supporting the body's natural sleep cycle, however recent scientific advances suggest that it may play a role in cellular health.
- More than a dozen preliminary clinical trials have examined the role of melatonin in supporting health cells and tissues, in part by maintaining healthy angiogenesis balance, promoting immune cell activity, and scavenging free radicals.
- Randomized studies have revealed the potential for melatonin to positively support colon, breast, prostate and lung tissues.
- Melatonin 20 mg provides high capacity cellular support for tissues including the colon, breast, prostate and lung tissues.

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

Vinpocetine 20 mg

### **Supplement Ingredients**

Vinpocetine

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

- Supports cognitive function and cerebrovascular health.
- Vinpocetine enhances healthy cerebrovascular blood flow, possibly by supporting cyclic GMP phosphodiesterase activity, allowing for healthy oxygen distribution to cells.
- Furthermore, studies have reported that vinpocetine may provide neuroprotection via its antioxidant properties.
- In a double blind placebo-controlled clinical trial, 84 elderly subjects were given vinpocetine or a placebo over a period of 90 days. Results indicated that those supplementing with vinpocetine experienced positive cognitive function.
- An additional placebo-controlled, randomized, double-blind, multicenter trial of 203 individuals suggested that vinpocetine significantly enhanced cognition and other subjective measures.
- Vinpocetine has the potential to support healthy memory, as indicated by a randomized, double blind, crossover study.

- Vinpocetine promotes healthy cognition and memory by supporting healthy blood flow and oxygen utilization.

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

DHA Enhance

#### **Supplement Ingredients**

Fish Oil Concentrate

DHA (docosahexaenoic acid)

EPA (elcosapentaenoic acid)

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

- Docosahexaenoic acid (DHA), an omega-3 long-chain polyunsaturated fatty acid, is a component of neuronal and retinal cellular membranes and supports health mental and visual function.
- Initial research indicates that supplementation with both EPA and DHA may support respiratory health, including healthy bronchial smooth muscle function.
- Omega-3 essential fatty acids may also support immune health in children.
- In general, omega-3 fatty acids are well recognized for supporting cardiovascular function, emotional well-being, and healthy skin and joints.
- It may be helpful for promoting healthy vision and mental function as well as supporting respiratory and immune health.

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

EPA / DHA with lemon

#### **Supplement Ingredients**

Fish Oil Concentrate

EPA (elcosapentaenoic acid)

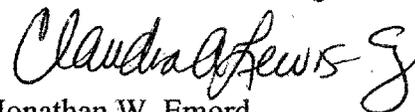
DHA (docosahexaenoic acid)

### Text of Statements of Nutritional Support

- Ultra-pure, microfiltered lemon-flavored fish oil concentrate for heart and joint health.
- This ultra-pure fish oil concentrate offers nutritional support to the cardiovascular system and the joints.
- EPA and DHA from fish oil promote cardiovascular health by supporting healthy triglyceride and lipid metabolism, maintaining healthy blood flow, and supporting healthy platelet function.
- Fish oil is also important for optimal joint function.
- It maintains healthy prostaglandin and leukotriene production, which is important for maintaining connective tissue health and comfort.
- EPA/DHA with lemon is an ultra-pure fish oil concentrate, helpful for safely maintaining cardiovascular and joint health.

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,



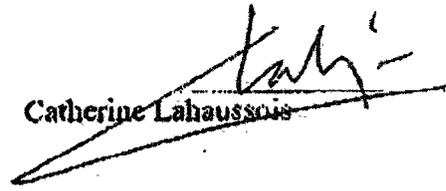
Jonathan W. Emord  
Claudia A. Lewis-Eng  
Karl M. Nobert

Encl.

**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: 3/22/05

  
~~Catherine Lahaussais~~