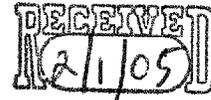


**& Associates, P.C.**

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January 31, 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 Encap 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**

CardioBran

**Supplement Ingredients**

Oat Bran Concentrate

**Text of Statements of Nutritional Support**

- Concentrated beta-glucan soluble fiber for heart and intestinal health.
- These beta-glucans exist in a blend of soluble beta-1, 3 and insoluble beta-1, 4 chains and provide a highly palatable source of cardioprotective fiber.

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

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- Over 40 published clinical trials describe the many cardiovascular health benefits of oat beta-glucans.
- Multiple studies have indicated that oat glucans promote healthy lipid metabolism.
- A clinical study performed at the USDA Beltsville Human Nutrition Research Center in Maryland reported that oat beta-glucan supplementation provided statistically significant lipid support.
- Another clinical study reported that beta-glucan from oat fiber promoted healthy bile secretion.
- A randomized study at Colorado State University indicated that oat cereal may support healthy lipoprotein production.
- Furthermore, a randomized, parallel-group pilot study suggested that oat consumption contributed to healthy lipid metabolism, glucose balance, and overall cardiovascular function.
- Inside the intestines, oat beta-glucan becomes a viscous polysaccharide, which contributes to its ability to delay gastric emptying, support healthy glucose and fat metabolism, and increase satiety.
- CardioBran also promotes intestinal health and motility, in part, by increasing stool weight and helping to alleviate constipation.
- Beta-glucans increase fermentation in the large bowel and promote probiotic growth. This enhances the production of short chain fatty acids, which are supportive of colon cell health.
- CardioBran is a concentrated source of oat beta-glucans, promoting healthy glucose and lipid metabolism as well as intestinal health and protection.

## **2. Supplement Brand Name**

CelluPhase

## **Supplement Ingredients**

Broccoli sprout concentrate

Broccoli extract

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

- Powerful detoxification and cellular support.
- Cruciferous vegetables of the brassica family have long been identified as having the ability to promote detoxifying enzymes in the body, maintaining healthy cells and tissues.
- Glucosinolates are converted to metabolites known as isothiocyanates after they are ingested and hydrolyzed. Isothiocyanates from a variety of plant sources have been widely investigated *in vitro* and *in vivo* for their cellular protection potential.
- The isothiocyanate sulforaphane has been identified as one of the most powerful activators of phase II enzyme function in the liver, supporting toxin elimination and maintaining cellular health.
- Sulforaphane is also believed to help maintain healthy cell metabolism and cell cycle function, possibly at the level of DNA transcription.
- Sulforaphane has demonstrated a role in maintaining healthy colon cell function, as demonstrated by cell studies at the Johns Hopkins University School of Medicine.
- It is also believed to have robust and long-lasting antioxidant capabilities, in part by enhancing the enzyme activity of glutathione S-transferase responsible for glutathione synthesis.
- These same studies illustrate that sulforaphane may also be an inducer of quinone reductase, another protective enzyme.
- In other studies, sulforaphane promoted healthy prostate cell function.
- Population-based, case control studies support these findings and suggest that cruciferous vegetable intake is positively correlated with a healthy prostate.
- Additional studies indicate a supportive action for liver cells as well as a protective role for stomach and breast cell health.
- CelluPhase is a powerful combination providing glucosinolates and sulforaphane from broccoli extract and broccoli sprout concentrate, compounds believed to be among the strongest inducers of phase II enzymes in the liver, helping to inactivate toxins and providing concentrated detoxification and cellular support.
- These compounds also maintain healthy cell cycle function and boost antioxidant activity, helping to maintain healthy cells in a variety of tissues.

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

Phyto-ADR

### **Supplement Ingredients**

Calcium pantothenate  
Panax ginseng extract  
Eleutherococcus senticosus extract  
Ashwagandha  
Rhodiola rosea extract  
Astragalus membranaceous extract  
Vitamin C

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

- Adrenal support.
- Vegetarian adrenal support formula.
- This vegetarian formula provides wide range herbal and nutritional support for the adrenal glands.
- *Panax ginseng* and *Eleutherococcus senticosus*, or eleuthero, are highly recognized adaptogens, promoting physiological balance and resistance to stress.
- In part, they help to moderate the production of adrenocorticotrophic hormone (ACTH) and ultimately corticosterone activity.
- Corticosterone promotes the conversion of amino acids into carbohydrates and glycogen by the liver and stimulates glycogen formation in the tissues, supporting optimal energy reserves.
- *Rhodiola rosea*, containing rosavins and salidroside, also acts to balance hypothalamic-pituitary-adrenal activity.
- Rhodiola can have a calming effect on the central nervous system and supports healthy thyroid, thymus, and adrenal gland function.
- In particular, rhodiola may moderate the effects of physical and emotional stress.
- Recently, a double blind cross-over study suggests that rhodiola may help to moderate fatigue under stressful conditions.

- Astragalus and ashwagandha promote immune support and complement the adaptogenic activity of this formula.
- Calcium pantothenate, a vitamin B<sub>5</sub> derivative, is essential for activating the adrenals.
- Collectively, these ingredients support the health and activity of the adrenal glands.
- Phyto-ADR provides comprehensive support for healthy adrenal function.

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

Flexosil

#### **Supplement Ingredients**

Devil's claw extract  
Vitamin C

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

- Joint support.
- Devil's claw extract for supporting musculoskeletal function.
- Despite its name, the herb is actually valued for its large tuberous roots, which contain the key components associated with its health benefits.
- A number of clinical studies have indicated that devil's claw helps to promote musculoskeletal flexibility and function.
- For instance, a randomized, double blind, multi-center trial in France reported that this herb promoted general joint comfort.
- A randomized, double blind, placebo-controlled clinical trial conducted in Germany at the University of Kiel suggested that a devil's claw extract encouraged back, shoulder, and neck muscle flexibility.
- Two additional German clinical studies indicated that an extract of devil's claw helped promote hip, knee, and non-radicular back mobility and function.
- Studies have proposed that devil's claw maintains healthy interleukin and leukocyte activity.

- Pure Encapsulations Flexosil is a standardized devil's claw extract containing 5% harpagosides, supporting healthy joint and muscle function by promoting comfort, motility and flexibility.

## **5. Supplement Brand Name**

Saw Palmetto 320

## **Supplement Ingredients**

Saw palmetto extract  
Vitamin C

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

- Concentrated support for prostate health.
- Saw palmetto has been utilized for decades to support healthy prostate and urinary function.
- In countries like New Zealand, France, Germany, and Austria, this herb has been the gold standard for prostate support for many years.
- Its primary mode of action involves maintaining healthy testosterone metabolism, in part by moderating 5-alpha-reductase enzyme activity and receptor binding.
- In a recently published *JAMA* meta-analysis involving 18 randomized controlled trials and almost 3,000 men, results suggest that saw palmetto provides important urologic support by promoting healthy urinary function.
- In a three-year German study, saw palmetto extract promoted healthy urination in volunteers.
- Comparative studies also suggest significant support.
- Saw Palmetto 320, concentrated to contain 85% total fatty acids and 0.15% phytosterols, provides fundamental, time-tested support for healthy prostate and urinary function

## **6. Supplement Brand Name**

BenfoMax

## **Supplement Ingredients**

Benfotiamine  
Vitamin C

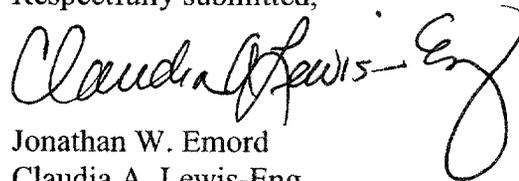
## **Text of Statements of Nutritional Support**

- Powerful support for nerve, retina and kidney health.
- Benfotiamine, S-benzoylthiamine-O-monophosphate, is a fat soluble vitamin B<sub>1</sub> (thiamine) derivative that exhibits enhanced bioavailability and bioactivity.
- Benfotiamine provides enhanced support for healthy thiamine levels in the body, which in turn promotes optimal production of the enzyme thiamine pyrophosphate, or TPP. This is key to the significance of benfotiamine, since TPP plays a role in directing metabolic pathways away from the production of advanced glycation end products, or AGEs. AGEs form when sugar molecules bind to and alter proteins in the body. In both human and animal studies, benfotiamine has been recognized for its ability to protect proteins from the effects of sugar molecules and the formation of these compounds. This is believed to be particularly supportive for maintaining healthy vascular, retinal, nerve and kidney function in some individuals.
- In one six-week study, benfotiamine demonstrated positive peripheral nerve support in male subjects.
- A double blind, randomized, controlled study involving twenty-four volunteers reported that benfotiamine contributed to healthy nerve conduction velocity in the feet over a twelve week period.
- An open clinical trial also indicated that benfotiamine provided significant support for nerve health.
- Benfotiamine modulated intracellular AGE production in participants in a twenty-eight day trial.
- In a cell study, benfotiamine maintained healthy renal glomerull function and moderated protein kinase C enzyme activity, protein glycation, and oxidative stress.
- One scientist from Albert Einstein Medical College in the U.S. recently collaborated with researchers from Germany, Italy, China and Japan to demonstrate that befotiamine moderates three metabolic pathways, providing protective support for vascular tissues.

- In their follow up experiment, they demonstrated the potential for benfotiamine to support the health of the retina.
- Pure Encapsulations offers pure, Japanese manufactures benfotiamine, providing powerful support for vascular protection, peripheral nerve health, retinal function, and kidney function in part by moderating the production of advanced glycation and products, or AGEs.

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,

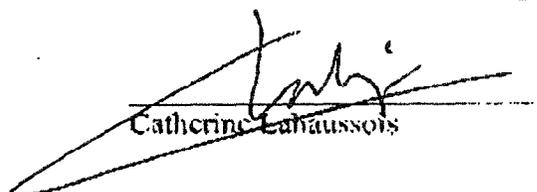
A handwritten signature in black ink that reads "Claudia A. Lewis-Eng". The signature is written in a cursive style with a large, looping flourish at the end.

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

**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: 1/27/2005

  
Catherine Lahaussais