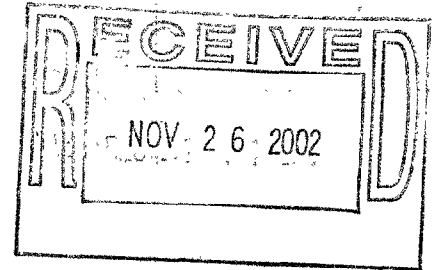


EMORD & ASSOCIATES, P.C.

BURKE PROFESSIONAL CENTER
5282 LYNKATE COURT
BURKE, VIRGINIA 22015

1050 SEVENTEENTH STREET, N.W.
SUITE 600
WASHINGTON, D.C. 20036

PHONE: (202) 466-6937 • FAX: (202) 466-6938
WEB SITE: www.emord.com
E-MAIL: mgayeski@emord.com



November 25, 2002

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.,¹ 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 (ingredient)**

Calcium (aspartate)
Calcium (aspartate), vitamin C (as ascorbyl palmitate)

Text of Statements of Nutritional Support

The aspartate form of calcium is easily absorbed, ensuring proper utilization of this important mineral.

2. **Supplement Brand Name (ingredient)**

Calcium Magnesium (aspartate)
(Calcium (aspartate), Magnesium (aspartate), vitamin C (as ascorbyl palmitate))

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

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Text of Statements of Nutritional Support

Provides a 1:1 balance of calcium and magnesium in highly bioavailable aspartate form.

3. Supplement Brand Name (ingredient)

Indole-3-Carbinol 400 mg
(Indole-3-carbinol)

Text of Statements of Nutritional Support

Phytochemical support for healthy cells.

Cytochrome P450 is a phase I detoxifying enzyme complex in the liver that supports healthy estrogen metabolism and has been shown to increase the production of 2-OHE. Indole-3-carbinol (I3C) induces cytochrome P450 and phase I detoxification enzymes and also supports phase II detoxification enzymes.

A double-blind, placebo controlled study of women supplementing with Indole-3-carbinol resulted in a favorable shift in estrogen metabolism.

Clinical trials involving human volunteers demonstrate that I3C has the ability to promote healthy 2-OHE and 16alpha-OHE metabolism, providing a potential mechanism for breast health support.

In an in vitro study, I3C moderated cellular enzyme function. This maintained healthy cellular metabolism in a culture of human breast cells.

A placebo-controlled trial indicated that I3C supports cervical cell health as a result of healthy estrogen balance.

By enhancing cytochrome P450 enzymes and others, including glutathione-s-transferase, I3C has also been shown to support various tissues and to scavenge free radicals.

I3C has shown a promising ability to support prostate cell metabolism.

In the stomach, I3C is converted to various active metabolites, most notably diindolylmethane (DIM), believed to be responsible for the health benefits associated with I3C.

Indole-3-carbinol, the powerful phytochemical found in cruciferous vegetables, provides breast, cervical, and prostate cell support by activating detoxification enzymes, promoting healthy estrogen balance and cellular metabolism, and scavenging free radicals.

4. **Supplement Brand Name (ingredient)**

Indole-3-Carbinol 200 mg
(Indole-3-carbinol)

Text of Statements of Nutritional Support

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5. **Supplement Brand Name (ingredient)**

l-Arginine
(l-arginine HCl)

6. Supplement Brand Name (ingredient)

l-Carnosine
(l-carnosine (beta-alanyl-L-histidine))

Text of Statements of Nutritional Support

Antioxidant dipeptide for cell protection.

It is a water-soluble antioxidant with well-documented free-radical scavenging activity and is believed to promote cell health and cell longevity.

The primary function of l-carnosine appears to involve mediating the interaction between proteins and sugars.

In vitro, it helps to protect proteins from the formation of advanced glycosylation end-products.

The end-products are formed when aldehydes (such as aldose and ketose sugars) and lipid peroxidation by-products bind to vital proteins and compromise their function.

l-Carnosine plays a role in protecting DNA from acetaldehyde and formaldehyde.

Glycoaldehyde inactivation of superoxide dismutase also appears to be moderated by carnosine.

L-Carnosine may help to maintain healthy peptide metabolism in the brain, and its membrane-stabilizing properties support healthy lactate dehydrogenase activity of cardiovascular cells.

The concentration of l-carnosine in muscle may prove to be an important factor in high-intensity exercise performance based on a recent human study.

l-Carnosine provides unique protective mechanisms in the body to maintain healthy protein and cellular function in various tissues.

Supplementation may support optimal levels of l-carnosine, which can naturally decline with age.

7. Supplement Brand Name (ingredient)

l-Tyrosine
(l-tyrosine (free-form))

Text of Statements of Nutritional Support

Neurotransmitter precursor for mood and memory.

Text of Statements of Nutritional Support

In the body, the metabolism of l-arginine leads to the formation of nitric oxide.

Versatile nitric oxide precursor.

Arginine-derived nitric oxide is an important catalyst for healthy dilation of blood vessels, circulation, and blood flow.

In a prospective, double-blind trial, l-arginine supplementation supported healthy endothelial function in blood vessels of male volunteers.

In other studies, l-arginine promoted healthy platelet function and enhanced exercise tolerance.

Additional trials indicate that l-arginine may support healthy lipid metabolism and lipid peroxidation, enhancing its cardiovascular support properties.

Arginine has demonstrated immuno-stimulatory activity and may promote the utilization of nitric acid by scavenger cells for defense mechanisms.

Enhancement of immune messenger compounds has also been observed in several studies with l-arginine.

In a study involving elderly individuals, l-arginine facilitated healthy tissue recovery, accelerated tissue repair, and supported immune health.

In men with low urinary nitric oxide values, l-arginine may support healthy sexual function.

Some but not all research involving l-arginine supplementation for sperm motility have produced positive results.

Arginine plays a role in the syntheses of hormones such as insulin and growth hormone and has demonstrated the potential to support glucose metabolism and growth hormone production respectively.

Nitric oxide is also a mediator of neurotransmission in the brain, supporting memory under the circumstances of reduced intracellular arginine.

Preliminary studies suggest that l-arginine may support bladder comfort and function in some individuals.

l-Arginine is a safe, versatile amino acid precursor of nitric oxide associated with promoting cardiovascular health, immune support, sexual function, and memory.

The amino acid tyrosine is a precursor of catecholamine neurotransmitters, including l-dopa, dopamine, epinephrine, and norepinephrine. These neurotransmitters are responsible for supporting emotional well-being and mental function.

l-Tyrosine plays a role in promoting healthy neurotransmitter function in response to environmental and emotional stress.

It has demonstrated the potential to promote cognitive function and memory under stressful conditions.

In one study, l-tyrosine enhanced mood and sleep in subjects with low dopamine levels.

Tyrosine is also a key component in the synthesis of thyroid hormones.

l-Tyrosine supports production of catecholamine neurotransmitters, enhancing mood and cognitive function, especially under situations involving stress or when dopamine, epinephrine, or norepinephrine levels require additional support.

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

Certification

I, Ray Hamel, 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:

11/15/02

Raymond F. Hamel

Ray Hamel