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January 3, 2005

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**

Cognizin™

Ingredients

Citicoline (cytidine 5' diphosphocholine) and hypoallergenic plant fiber

Text of Statements of Nutritional Support

Citicoline for supporting memory and delaying cognitive decline associated with aging.

Cognizin™ (citicoline, CDP-choline or cytidine 5' diphosphocholine) is a highly purified, endogenous, nucleic acid precursor to phosphatidylcholine, an important nutrient for brain cell membrane integrity and fluidity.

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

This highly bioavailable compound also converts to acetylcholine, a critical neurotransmitter essential for healthy cell-to-cell communication as well as for memory storage and recall.

Used throughout Europe and Japan to help promote neurological function and memory capacity, citicoline has been the focus of multiple studies.

A clinical trial held at the Consolidated Department of Psychiatry, Harvard Medical School, reported that oral citicoline supplementation promoted phospholipid biosynthesis.

Another study suggested that citicoline promotes the activity of phosphocoline cytidyltransferase (CTP), the rate-limiting enzyme in the phosphatidylcholine synthesis pathway in brain cells.

A study conducted at the Department of Neurological Surgery, Cardiovascular Research Center, University of Wisconsin, reported that citicoline attenuates phospholipase A2 (PLA2), which helps to maintain healthy arachidonic acid metabolism.

As a result, researchers suggested that citicoline may help to moderate the formation of reactive oxygen species, lipid peroxides, and leukotrienes within cerebral tissue.

A randomized, double blind, placebo controlled clinical trial conducted at the Clinical Research Center, Massachusetts Institute of Technology, indicated that citicoline promoted healthy verbal memory function.

Another clinical study reported that citicoline helped improve neurological health and was well tolerated.

Furthermore, a double blind, placebo-controlled study suggested that citicoline promoted healthy cerebral blood flow and brain bioelectrical activity.

Pure Encapsulations Cognizin™ is 98% pure citicoline, promoting neurological health and memory.

2. Supplement Brand Name

ALC arginate

Ingredients

Acetyl-l-carnitine arginate dihydrochloride

Text of Statements of Nutritional Support

May promote healthy erectile and sperm function; supports healthy neuron and cognitive function.

Precursors of carnitine and acetyl-l-carnitine, including the amino acid arginine, may help to enhance the metabolic activities of these compounds.

Acetyl-l-carnitine and arginine play roles in healthy male reproductive function, including antioxidant protection.

Acetyl-l-carnitine is present in human sperm and seminal fluid and plays an important part in energy metabolism, which may support healthy sperm motility and spermatogenesis, or sperm production.

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

As a nitric acid precursor, l-arginine may support healthy erectile function in some men.

In addition, an acetyl-l-carnitine arginine complex supported healthy neuron viability in a cellular in vitro experiment.

In the same study, the acetyl-l-carnitine arginine complex was able to help maintain calcium homeostasis in nervous system cells stimulated with glutamate, preserving healthy cerebellar cell function.

In a separate study, acetyl-l-carnitine arginine demonstrated potential support for maintaining healthy central nervous system function by promoting healthy neurite function.

Neurites are the hair like projections of neurons, or nervous system cells, responsible for proper signal transmission.

The acetyl group from acetyl-l-carnitine (ALC) is also responsible for production of acetylcholine, an important neurotransmitter for optimal mental functioning.

ALC arginate is an innovative acetyl-l-carnitine arginate complex providing potential support for male reproductive health and healthy cognitive function.

3. Supplement Name

PomEllagic™ Plus

Ingredients

Pomegranate (*Punica granatum* L.) extract (whole fruit), red raspberry (*Rubus ideaeus*) extract (whole fruit), vitamin C, and hypoallergenic plant fiber

Text of Statements of Nutritional Support

Ellagic acid antioxidant support for cardiovascular cellular health.

Polyphenols, tannins, and anthocyanins are just some of the components of pomegranate which contribute to its ability to scavenge free radicals and protect against oxidative stress.

One polyphenol, ellagic acid, has demonstrated powerful antioxidant support for cells.

Animal and cellular studies suggest that ellagic acid has the potential to support healthy tissues, including that of the liver, lung, esophagus, stomach and colon.

Research suggests that pomegranate may also help to maintain healthy angiogenesis.

Pomegranate also has the potential to support cardiovascular health, as illustrated by a study of individuals consuming pomegranate juice for at least one year.

An additional human trial of pomegranate juice indicated its potential to support vascular health and to maintain healthy angiotensin converting enzyme activity.

PomEllagic™ Plus provides a powerful combination of 70% ellagic acid from pomegranate and 40% ellagic acid from red raspberry for cardiovascular and cellular support.

4. Supplement Name

OculoNutrients

Ingredients

Ascorbic acid, vitamin C, beta carotene, alpha carotene, cryptoxanthin, lutein, zeaxanthin, vitamin D₃, d-alpha tocopherol succinate, thiamine HCl, riboflavin, riboflavin 5' phosphate, pyridoxine HCl, pyritioaxal 5' phosphate, niacinamide, inositol hexaniacinate, folic acid, biotin, pantothenic acid, methylcobalamin, calcium, magnesium, potassium, zinc, manganese, boron, copper, iodine, chromium, selenium, vanadium, and molybdenum

Text of Statements of Nutritional Support

Lutein and zeaxanthin are distinct from the rest of the carotenoid family, being the only two absorbed and utilized by the eyes.

Referred to as oxycarotenoids or xanthophylls, these fat-soluble compounds contain hydroxyl groups in their ring structures, making them more polar than their carotene counterparts, as well as more efficient at quenching free radicals.

Lutein and zeaxanthin are absorbed into the retina through specific xanthophylls binding proteins and provide the primary pigment that gives the macula its characteristic yellow color.

Studies have shown that zeaxanthin is more concentrated in the center of the macula, or the fovea, whereas lutein is more concentrated along the periphery of the macula and throughout the retina.

Furthermore, multiple clinical studies suggest a direct relationship between lutein and zeaxanthin supplementation and macular concentration of these xanthophylls.

Lutein and zeaxanthin have been reported in numerous studies, including a double blind, placebo controlled clinical trial held at the Department of Veterans' Affairs, Medical Center Eye Clinic in Chicago, to promote healthy macular pigment, lens optical density, and visual acuity.

Additionally, clinical trials have indicated that lutein and zeaxanthin support vision health through a combination of pigment associated antioxidant protection and blue-light screening mechanisms.

One study conducted at Schepens Eye Research Institute and Department of Ophthalmology at Harvard Medical School indicated that zeaxanthin promoted photoreceptor health as well as provided protection from light.

OculoNutrients is a broad-spectrum ophthalmoprotective formula, combining 10 mg lutein and 2 mg zeaxanthin in the optimal (5:1) ration, with the highly bioavailable vitamin and mineral core of Nutrient 950® without iron, which includes copper, beta carotene, vitamin E, and zinc for healthy eyes.

Pure Encapsulations OculoNutrients offers the conditionally essential carotenoids lutein and zeaxanthin in their most bioavailable, non-esterified forms for optimal macular, lens, and retina health.

5. Supplement Name

AnthoMax

Ingredients

Bilberry (vaccinium myrtillus) extract (fruit) (standardized to contain 18% anthocyanins), bilberry (vaccinium myrtillus) extract (fruit) (standardized to contain 50% anthocyanosides), vitamin C, and hypoallergenic plant fiber

Text of Statements of Nutritional Support

Unique bilberry extract combination for enhanced leg vein health, fluid balance, retinal protection, and cardiovascular function.

Furthermore, the resulting aglycon polymers (polymers with the sugar molecule removed) demonstrate enhanced stability, bioavailability and vascular permeability protection.

Only recently made available in the U.S., Carocyanic Complex has been utilized in France and Germany as a key source of phenolic compounds used primarily for supporting venous tone, the appearance of leg veins, healthy fluid balance and retinal health.

These effects are associated with the ability of Catocyanic Complex to maintain the integrity of collagen and blood vessel walls, moderate elastase enzyme activity, support healthy capillary permeability and resistance and promote circulation, including capillary, venular, and lymphatic flow.

In addition, Catocyanic Complex promotes the synthesis of rhodopsin, a compound that promotes light perception and healthy night vision.

Studies indicate the potential for this complex to maintain retina blood vessel integrity, microcirculation, and overall retina health.

Preliminary clinical studies also suggest that Catocyanic Complex supports healthy light refraction, helping to maintain overall ocular function.

Furthermore, a recent study performed on Catocyanic Complex indicated antioxidant protection of lipoproteins, suggesting a main mechanism for its cardioprotective properties.

AnthoMax also contains Antho 50®, a purified, enhanced potency bilberry extract concentrated to deliver 50% anthocyanosides.

These antioxidant molecules have also been indicated in a number of studies to be supportive of cardiovascular function and lipoprotein antioxidant protection; vascular integrity and leg vein health; visual acuity and retina protection; and cellular health.

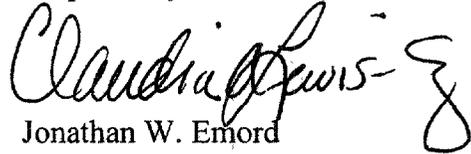
In addition, potential support for healthy joint function has been indicated.

In one study, efficient absorption of Antho 50® was observed, demonstrating enhanced bioavailability.

AnthoMax is a power packed combination of a unique fermented bilberry extract standardized to contain 18% aglycon anthocyanidins (anthocyanins) and a concentrated 50% anthocyanoside bilberry extract, providing enhanced antioxidant protection for eye, vascular, circulatory and cellular health.

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
Kathryn E. Balmford

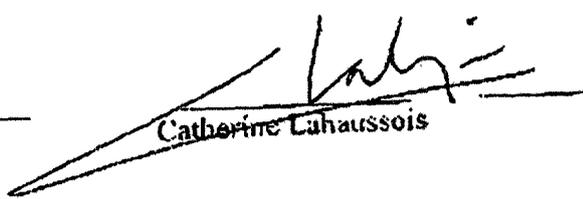
cc: Catherine Lahaussais

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:

1/3/05


Catherine Lahaussais