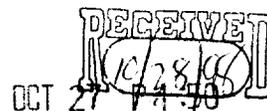


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October 15, 1998

VIA UPS NEXT DAY AIR

Dr. Elizabeth Yetley
Office of Special Nutritionals (HFS-450)
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

Re: Fulfillment of Reporting Obligation Under 21 U.S.C. § 343(r) and 21 CFR § 101.93

Dear Dr. Yetley:

Pure Encapsulations, Inc.,¹ by counsel and in accordance with 21 U.S.C. § 343(r) and 21 CFR § 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 retains scientific documentation supporting the statements.

1. Supplement Brand Name

BCAA

Supplement Ingredients

Amino Acids
Leucine
Isoleucine
Valine

Text of Statements of Nutritional Support

Branched chain amino acids provide safe nutritional support for athletes and individuals seeking optimal lean muscle mass.

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

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The three branched chain amino acids leucine, isoleucine, and valine boost energy while helping to counteract muscle protein breakdown during exercise.

The ingredients in this product promote the biosynthesis of other amino acids, nucleotides, and biological amines.

BCAA promotes healthy muscle mass by boosting energy metabolism in working muscle and by inhibiting protein breakdown during exercise.

2. Supplement Brand Name

Black Cohosh 2.5

Supplement Ingredients

Black Cohosh, *Cimicifuga racemosa*
2.5% triterpene glycosides

Text of Statements of Nutritional Support

Black cohosh is well known for promoting health during menopause.

Black cohosh functions by maintaining healthy levels of luteinizing hormone (LH), allowing for optimal comfort and physical well being.

The herb also exhibits mild estrogenic activity by binding to estrogen receptors.

Black cohosh extract modulates LH secretion and supports healthy estrogen levels during menopause.

3. Supplement Brand Name

Chitosan 90

Supplement Ingredients

Chitosan

Text of Statements of Nutritional Support

In the body, chitosan dissolves into a gelled form that may entrap fat in the intestine and help inhibit its absorption.

Chitosan also appears to enhance lipolytic enzymes and has been shown to help decrease HMG-CoA reductase activity, the primary enzyme of cholesterol synthesis.

Chitosan has demonstrated the ability to promote levels of beneficial HDL cholesterol.

Chitosan provides a natural way to influence fat digestion and maintain healthy cholesterol levels.

4. **Supplement Brand Name**

dl-phenylalanine

Supplement Ingredients

Amino Acids

d-phenylalanine

l-phenylalanine

Text of Statements of Nutritional Support

Together, these compounds promote mental functioning, support a positive outlook, and relax the musculoskeletal system.

L-phenylalanine is a precursor to tyrosine, which converts to the neurotransmitters norepinephrine, epinephrine, dopamine, and tyramine. Tyrosine and its metabolites have been shown to support emotional well being, memory, and learning.

D-Phenylalanine may regulate the levels of certain endorphins, thereby calming stressed muscles and joints.

By maintaining healthy tyrosine and endorphin levels, dl-Phenylalanine nutritionally supports mental acuity and emotional well being, while relaxing stressed muscles and joints.

5. **Supplement Brand Name**

Elderberry extract

Supplement Ingredients

Elderberry Extract

Text of Statements of Nutritional Support

This elderberry extract is standardized to contain 34% anthocyanins, a specialized group of flavonoids responsible for elderberry's immune system support.

Studies have shown that the anthocyanins found in elderberries not only support immune health but help to maintain a healthy environment for cells as well.

These natural compounds also maintain the strength and integrity of the vascular walls.

Elderberry extract provides natural support for the optimal functioning of the immune system.

6. **Supplement Brand Name**

EPA/DHA essentials

Supplement Ingredients

Eicosapentaenoic acid
Docosahexaenoic acid

Text of Statements of Nutritional Support

EPA/DHA essentials is an ultra-pure fish oil concentrate offering nutritional support to the cardiovascular system.

EPA and DHA from fish oil promote cardiovascular health by supporting healthy triglyceride and VLDL cholesterol levels, maintaining blood flow, and reducing platelet aggregation.

Fish oil is also important for optimal joint function.

It regulates the production of prostaglandins and leukotrienes which are not conducive to connective tissue health.

EPA/DHA essentials is a pure fish oil concentrate, helpful for safely maintaining cardiovascular and joint health.

7. **Supplement Brand Name**

VeinPro

Supplement Ingredients

Horse chestnut seed extract

Text of Statements of Nutritional Support

Compounds isolated from the seeds of the *Aesculus hippocastanum*, or horse chestnut, have a long folk history of venous support.

VeinPro is a horse chestnut seed extract providing a natural way to promote healthy circulation in the legs.

It helps to support normal venous pressure and maintain vascular permeability.

Studies have also demonstrated that horse chestnut helps decrease connective tissue formation in veins.

It may also help protect against lipid peroxidation.

VeinPro provides sage and effective nutritional support for leg vein health.

8. Supplement Brand Name

MSM

Supplement Ingredients

Methylsulfonylmethane or dimethylsulfone

Text of Statements of Nutritional Support

MSM, the major metabolite of DMSO (dimethyl sulfoxide) is 34% elemental sulfur, a compound which is crucial in maintaining healthy tissues.

While sulfur supports many functions, it is well known for maintaining connective tissue health.

Sulfur also supports tissue containing significant amounts of collagen and keratin, including hair, skin, and nails.

MSM promotes healthy joint function and offers additional support through its sulfur content.

9. Supplement Brand Name

Panax Ginseng 27/30

Supplement Ingredients

Panax ginseng

Text of Statements of Nutritional Support

Panax ginseng has long been utilized to assist the body in adapting to physical and emotional stress.

During prolonged exercise, panax ginseng promotes endurance and stamina by sparing carbohydrates and allowing skeletal muscle to oxidize free fatty acids for energy production.

Panax ginseng also encourages adrenal gland health in times of stress by maintaining normal levels of certain adrenal hormones, most notably, corticosterone.

This versatile herb promotes male reproductive health by supporting testosterone and spermatozoa levels.

In addition, panax ginseng promotes memory and learning, and nutritionally supports immune function and cardiovascular health.

Panax ginseng helps the body adapt to its environment by enhancing endurance and adrenal gland health.

10. Supplement Brand Name

Resveratrol

Supplement Ingredients

Resveratrol

Text of Statements of Nutritional Support

It promotes cardiovascular health through its antioxidant action and its ability to modulate platelet aggregation and arachidonic acid metabolism.

Resveratrol is standardized to contain 8% total resveratrols, providing high-potency cardiovascular and antioxidant support.

11. Supplement Brand Name

Siberian Ginseng 0.8% E & B

Supplement Ingredients

Siberian ginseng
0.8% eleutheroside E & B

Text of Statements of Nutritional Support

Like Panax ginseng, Siberian ginseng is used as an adaptogen in times of stress.

By maintaining healthy adrenal hormone levels, specifically corticosteroids, the herb helps the body respond to mental and physical stress.

Vitamin E also plays a critical role in nucleic acid and protein metabolism, mitochondrial function, and hormonal support.

This combination of tocotrienols and vitamin E provides potent, synergistic support for the cardiovascular system and antioxidant protection for cells.

Supplement Brand Name

IsoProtein Plus

Supplement Ingredients

Soy Protein Isolate

Isoflavones

Genistein

Daidzein

Glycitein

L-glutamine

Fructooligosaccharides

Soy lecithin

Reduced glutathione

Green tea extract

1,3, Beta Glucan

Text of Statements of Nutritional Support

Protein-energy utilization and lean muscle mass during periods of peak stress

Promotes healthy weight management

Promotes healthy cardiovascular function and cholesterol levels

Immune system support

Supports healthy estrogenic activity in women

Blood vessel integrity and efficient blood flow

Healthy brain function

Cellular antioxidant supply, mitochondria energy support and protection against free radical damage.

Isoflavones and flax lignan have been shown in numerous studies to support physical health during menopause through its phytoestrogenic activity.

In addition soy protein with isoflavones supports long-term maintenance for bone, heart, and brain health.

L-glutamine: A nonessential amino acid which serves as the primary energy fuel for the maintenance of the gastrointestinal mucosal enterocyte, the regulation of normal muscle metabolism, the support of general support for the immune system and energy levels.

Fructooligosaccharides: Carbohydrates act as prebiotic (non-bacterial) growth factors for the maintenance of healthy populations of colon microflora. Helps support liver and immune function.

Soy Lecithin: Important for cardiovascular, brain, liver, and nervous system function.

Reduced Glutathione: One of the most important antioxidants for protection against cellular free radical damage and the proper functioning of mitochondria and ATP energy protection. Glutathione is a vital component, necessary for immune system, liver, and upper respiratory tract health.

Green Tea Extract (GTE): GTE polyphenols have been shown to be the most potent of all antioxidants in protecting vital cellular components, membrane structures, mitochondria and DNA genetic material from free radical damage. Collectively, GTE, vitamins C, E and beta carotene help recycle glutathione to prolong its reduced form and prevent its own oxidation, thereby preserving its antioxidant ability to scavenge oxygen radicals.

1, 3, Beta Glucan: Help support healthy cellular immune responses and thymus gland function through non-specific activation of macrophages.

14. Supplement Brand Name

DHEA

Supplement Ingredients

Dehydroepiandrosterone

Text of Statements of Nutritional Support

After it is made by the adrenal glands, it travels into cells throughout the body where it is converted into androgens and estrogens. These hormones regulate fat and mineral metabolism, endocrine, and reproductive function, and energy levels.

DHEA supplementation has been associated with increased emotional well being and immune function.

15. Supplement Brand Name

Pregnenolone

Supplement Ingredients

Pregnenolone

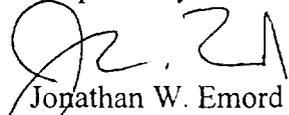
Text of Statements of Nutritional Support

Pregnenolone has been linked with positive support of the immune system, mood and memory.

Pregnenolone helps support the immune system, mood and memory.

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
Julie E. Gossman

Attachment

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: October 15, 1998 Raymond F. Hamel