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May 17, 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

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***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,¹ 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

Siliphos®

Supplement Ingredients

Silybin Phospholipids
Ascorbyl Palmitate

Text of Statements of Nutritional Support

- Unique silybin-phospholipid complex for enhanced liver support.
- Siliphos® provides a concentrated silybin-phospholipid complex, that includes phosphatidylcholine, offering synergistic support for liver health.

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

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- Silybin scavenges free radicals and promotes antioxidant enzyme activity in the liver.
- It (Silybin) also stimulates protein synthesis, supporting the regeneration of hepatic cells, and promotes glutathione production.
- Phosphatidylcholine has the potential to support healthy liver enzyme and antioxidant function, as well as membrane fluidity.
- In a short-term, placebo-controlled pilot study with 20 individuals, a silybin-phospholipid complex supported liver health by maintaining healthy liver enzyme activity.
- A phase II randomized open trial conducted in Italy also indicated that this complex demonstrated the ability to support liver health and maintain healthy liver enzyme production.
- Furthermore, a separate study involving 232 individuals suggested that the same silybin-phospholipid complex maintains healthy liver enzyme function.
- Additionally, results from a small trial suggested that the complex may help enhance hepatic function and promote antioxidant protection.
- Siliphos®, a highly bioavailable silybin and phospholipid complex, provides advanced, dual support for healthy liver function by promoting glutathione concentration, superoxide dismutase antioxidant activity, and enhanced protein synthesis in hepatocytes.

2. Supplement Brand Name

Strontium

Supplement Ingredients

Strontium (citrate)

Vitamin C (as ascorbyl palmitate)

Text of Statements of Nutritional Support

- Trace mineral for bone health.
- Strontium is one of many trace minerals essential for bone health.

- Recent research has highlighted strontium’s potential to support bone strength and health.
- Strontium support’s healthy osteoblast differentiation and helps to keep osteoclast activity in balance.
- Additionally, strontium supplement supports healthy collagen formation by osteoblasts, enhancing bone tensile strength.
- In a multi-national, prospective two-year placebo-controlled trial with 353 women, strontium supplementation maintained healthy vertebrae integrity as well as healthy-bone mineralization.
- A three-year placebo-controlled, double blind study 1,649 postmenopausal women, indicated that a strontium salt supported healthy vertebrae composition was well tolerated.
- In a preliminary analysis of a three-year placebo-controlled, double blind study of 5,091 postmenopausal women, strontium supplementation promoted healthy hip bones.
- Strontium promotes healthy osteoblast activity while maintaining healthy osteoclast activity to support healthy bones.

3. Supplement Brand Name

CMO

Supplement Ingredients

Cetyl Myristaleate Complex (beef tallow)

Text of Statements of Nutritional Support

- Promotes joint function and comfort.
- In a 1994 study published in the Journal of Pharmaceutical Sciences, the original discovered of CMO revealed the joint support potential of this unique compound.
- This trial also suggested that the physiological activity of CMO was not matched by other related fatty acids.
- Later reports support these findings, indicating a positive effect on joint and collagen health.

- Furthermore, a multi-center, double blind, randomized trial indicated that CMO and a CMO-containing formula promoted joint comfort compared to placebo.
- Proposed mechanisms of action for CMO include maintaining a health immune response at the cellular level and promoting joint lubrication.
- Pure Encapsulations CMO is the same form of CMO identified by the original discovered and patented for promoting joint function and comfort.

4. Supplement Brand Name

OptiFerin

Supplement Ingredients

Iron (bis-glycinate)

Folic Acid

Methylcobalamin (B₁₂)

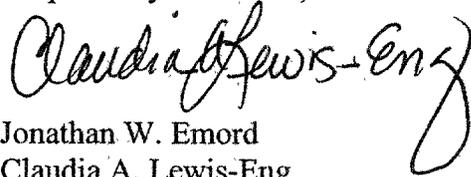
Text of Statements of Nutritional Support

- Promotes healthy ferritin, hemoglobin and red blood cell function.
- Iron is an important component of hemoglobin, a protein in red blood cells that deliver oxygen to tissues throughout the body.
- It is also a part of myoglobin, a protein that helps muscle cells store oxygen, and ferritin, the body's main iron storage protein found in the intestines, liver and spleen.
- Iron bound to ferritin is readily mobilized to meet the body's demands.
- The intestinal mucosal tissue tightly controls the release of ferrochel, supporting the safety profile of this iron amino acid chelate.
- In a double blind, randomized, placebo-controlled trial, iron supplementation supported healthy ferritin levels and enhanced energy and well-being in female subjects.
- A recent report emphasizes the importance of maintaining healthy serum ferritin for optimal performance in elite female athletes.
- In another randomized trial, iron supplementation or a high iron diet supported mental health and moderated fatigue in women of childbearing age.

- Combined iron and folic acid supplementation supported healthy hemoglobin levels better than iron alone in another double blind randomized study involving women.
- Vitamin B12 is also essential for and intricately connected to the crucial roles of iron and folic acid in erythropoiesis, or red blood cell formation.
- OptiFerin contains Ferrochel® Iron bio-glycinate, a highly specialized iron amino acid chelate, combined with folic acid and vitamin B₁₂ as cofactors to support hemoglobin and red blood cell function as well as ferritin for healthy iron stores.

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,

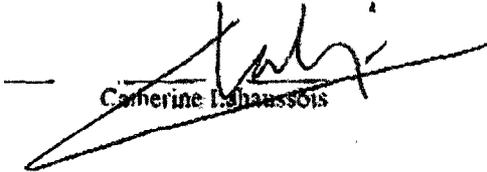


Jonathan W. Emord
Claudia A. Lewis-Eng
Karl M. Nobert

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: 5-17-05


Catherine Lahaussais