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July 6, 1999

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

Glucosamine/MSM

Text of Statements of Nutritional Support

Support for healthy joint function and tissues.

Glucosamine sulfate and MSM provide intrinsic compounds essential for healthy cartilage formation.

MSM has also been attributed with enhancing proper immune cell activity, thereby supporting tissues surrounding the joints.

These important cartilage matrix constituents are complemented with additional factors for supporting a healthy immune response.

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

In studies, ginger promotes healthy prostaglandin and leukotriene biosynthesis.

Curcumin helps regulate neutrophil function and scavenge free radicals such as nitric oxide.

Pure Encapsulations Glucosamine/MSM with Joint Herbs offers comprehensive joint function support, building healthy cartilage while maintaining healthy joint tissue.

2. Supplement Brand Name

Maitake Mushroom

Text of Statements of Nutritional Support

Promotes healthy blood glucose and immune function.

Maitake has been shown to promote proper lipid metabolism in the liver and healthy levels of total cholesterol.

Maitake encourages healthy cardiovascular functioning.

Studies also suggest that maitake may contain substances that offer glucose support.

Maitake mushroom helps to promote optimal immune support and overall excellent health.

3. Supplement Brand Name

M/R/S Mushroom Formula

Text of Statements of Nutritional Support

Polysaccharides from shitake, reishi, and maitake are believed to be among the most nutritionally effective for enhancing healthy immune function.

Wide-ranging health properties of mushroom supplementation include liver, cardiovascular, blood sugar, and cellular health support.

Pure Encapsulations M/R/S Mushroom Formula provides a dynamic combination of shitake, reishi, and maitake for promoting optimal immune system health and exceptional broad-spectrum physiological support.

4. Supplement Brand Name

Reishi Mushroom

Text of Statements of Nutritional Support

Promotes optimal immune cell responses.

Reishi polysaccharides and triterpenes have proved to be important for maintaining healthy cells in the body. They do this by promoting optimal immune cell responses and proper enzyme activity in cells, including liver cells.

Polysaccharides may also support healthy levels of intracellular cholesterol.

The remaining compounds further support immune function.

Pure Encapsulations Reishi Mushroom is standardized to contain 10% polysaccharides and 4% triterpenes, providing high-potential broad-range nutritional support, including maintenance of healthy body cells.

5. Supplement Brand Name

Shitake Mushroom

Text of Statements of Nutritional Support

Exceptional liver, heart and immune system **support**.

It helps enhance the body's natural defense system and provides a healthy environment for cells.

Lentinan has been shown to **support** normal liver cell health.

Shitake has the ability to promote healthy enzyme activity in the heart, positively influencing cardiovascular function.

Shitake has demonstrated the ability to support healthy levels of free cholesterol.

Pure Encapsulations Shitake Mushroom is standardized to contain 6% polysaccharides, provides exceptional support for the liver, heart and immune system.

6. Supplement Brand Name

Cognitive Factors

Text of Statements of Nutritional Support

Advanced support for cognitive function.

In studies vinpocetine promotes healthy blood flow, glucose transport and healthy red blood cell function in the brain, maintaining optimal cognitive ability.

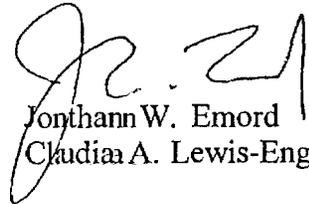
Ginkgo biloba was included in this formula to provide time-tested nutritional support enhancing benefits for the flow of oxygen and blood to the brain and promoting normal transmission of nerve impulses.

Ginkgo has the ability to support healthy capillaries and blood vessels, promote proper platelet function, and act as a free radical scavenger.

This powerful combination of vinpocetine and Ginkgo biloba provides high potential cognitive support.

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



Jonthann W. Emord
Cludia A. Lewis-Eng

Attachment

CeCertification

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: July 6, 1999

Raymond F. Hamel