

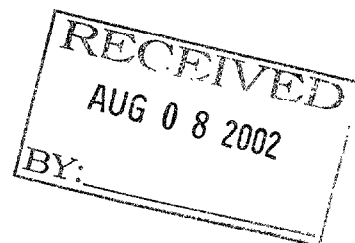
EMORD & ASSOCIATES, P.C.

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August 7, 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)

ClearDetox™

l-glutathione, n-acetyl-l-cysteine, methylsulfonylmethane, alpha lipoic acid (thioctic), silybum marlanum (milk thistle fruit extract), cynara scolymus (artichoke leaf extract), curcuma longa (turmeric root extract), chelidonium majus (greater celandine whole plant extract), berberis vulgaris (barberry bark extract), stevia, ascorbyl palmitate, rice protein concentrate, natural flavors, Lo Han (Momordica grosvenori fruit extract))

Text of Statements of Nutritional Support

975 0162

LET

10882

Nutritional support for detoxification

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

ClearDetox™ is an innovative, hypoallergenic beverage, formulated specifically to support detoxification and liver health.

As a critical component of the Krebs cycle, alpha-lipoic acid supports aerobic energy production.

In addition, it supports healthy liver function by scavenging free radicals and regenerating other antioxidants such as vitamins C and E.

This formula provides a synergistic combination of standardized milk thistle, artichoke, turmeric, greater celandine, and barberry extracts to support hepatic function by increasing bile flow, preserving glutathione concentrations, and promoting healthy turnover of liver tissue.

ClearDetox™ delivers broad-spectrum nutritional support for detoxification and the maintenance of healthy liver function.

2. Supplement Brand Name (ingredient)

Dairyzimes™

proprietary blends of lactase and proteases, hypo-allergenic plant fiber

Text of Statements of Nutritional Support

Intestinal support formula

Support for digestion of dairy foods

In addition to providing lactase, Dairyzimes™ delivers protease enzymes that assist digestion of acid-stable proteins such as beta-lactoglobulin, enhancing overall digestion of dairy products.

Dairyzimes™ provides a unique mixture of lactase and protease enzymes to help digest multiple constituents of milk and dairy products.

Dairyzimes™ is an innovative blend of lactase and proteases designed to support digestion of both lactose and proteins in dairy products.

3. Supplement Brand Name (ingredient)

Super CitriMax Plus™

garcinia cambogia fruit extract, chromium (polynicotinate), gymnema sylvestre leaves extract, ascorbyl palmitate

Text of Statements of Nutritional Support

Weight management support

Broad spectrum support for healthy weight and lean body composition

The results indicate enhanced healthy weight support, healthy serotonin levels, and improved body mass index.

ChromeMate supports healthy weight in combination with exercise.

ChromeMate promoted healthy body composition in overweight women.

Gymnema sylvestre promotes healthy glucose metabolism, providing a favorable effect on energy utilization.

Super CitriMax Plus™ is an all-natural formula with unique and broad-spectrum support for healthy weight and lean body composition.

4. Supplement Brand Name (ingredient)

Control C/P™

flower pollen extract, lipid-free pumpkin seed extract (Cucurbita pepo L)

Text of Statements of Nutritional Support

Support for healthy urinary and bladder function.

Lignan compounds modulate enzymatic activity in both men and women to promote healthy urinary and bladder function.

Lignans target the enzyme 5-alpha reductase, maintaining healthy levels of dihydrotestosterone for prostate and male urinary health.

This enzyme converts testosterone to estradiol in women. A decrease in this conversion helps maintain healthy testosterone levels in women for strengthening pelvic muscles and bladder function.

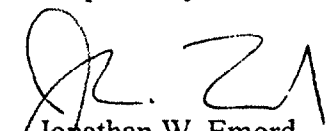
Cernitin flower pollen extract maintains healthy leukotriene and prostaglandin production in vitro and may play a role in supporting urethra smooth muscle function.

Cernitin is also a promising urinary support extract for women.

Pure Encapsulations Control C/P™ provides a unique pumpkin seed and Cernitin™ flower pollen combination to promote healthy male and female urinary and bladder function.

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,

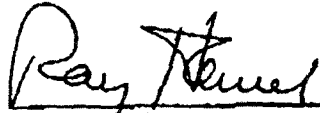


Jonathan W. Emord
Claudia A. Lewis-Eng
Michelle C. Gayeski

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: 7/30/02


Ray Hamel