

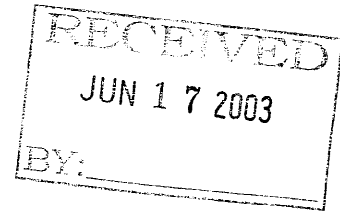
EMORD & ASSOCIATES, P.C.

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May 28, 2003



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**

Fenugreek

Ingredients

Fenugreek extract (trigonella foenum-graecum L) (seed), vitamin C

Text of Statements of Nutritional Support

Support for healthy glycemic response.

Studies suggest that fenugreek seeds help promote healthy glycemic response and post-prandial glucose metabolism.

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

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The fiber content of fenugreek extract plays a role in its ability to moderate metabolism of both glucose and lipids in the digestive tract.

Specifically, galactomannan becomes viscous and thickens the intestinal content, helping to maintain healthy glucose absorption.

Fenugreek also promotes feelings of satiety and may support healthy triglyceride levels.

Pure Encapsulations' concentrated, odorless fenugreek seed extract, standardized for 85% total fiber, provides 70% soluble fiber for optimal support of the glycemic response, lipid metabolism, and potential weight loss.

2. Supplement Brand Name

Beta-glucan

Ingredient

Beta-glucan

Text of Statements of Nutritional Support

Immune support.

Beta 1, 3/1, 6-glucan for advanced immune support.

Absorbed as a whole glucan particle in the Peyers patch of the small intestine, beta-1, 3/1, 6-glucan then binds to specific receptor sites on the surface of macrophages, first-line defense cells in the body.

The long-chained, highly-branches structure of the yeast-derived beta-1, 3/1, 6-glucan allows for optimal binding and activation of macrophages.

Activated macrophages help to promote a healthy immune response.

Using a concentrated, water-soluble version of beta-1, 3/1, 6-glucan, a clinical, double-blind, randomized, placebo-controlled study performed at four university-affiliated medical centers suggested that beta-glucan helped support healthy cytokine activity.

Preclinical studies have reported that beta-1, 3/1, 6-glucan helps to support breast and colon cell health.

Unlike other forms of beta-glucan, purified, whole particle beta-1, 3/1, 6-glucan does not contain mannoprotein and components from the yeast cell wall, allowing for a greater concentration of active ingredient and enhanced absorption.

BetaRight concentrated beta-1, 3/1, 6-glucan provides high potential support for healthy immune cell activity and natural defense.

3. Supplement Brand Name

Beta-sitosterol

Ingredients

Beta-sitosterol (from 150 mg of a phytosterol complex), vitamin C (as ascorbyl palmitate)

Text of Statements of Nutritional Support

Supports prostate health.

Beta-sitosterol naturally occurs as part of a phytosterol complex and has demonstrated the potential to support prostate health.

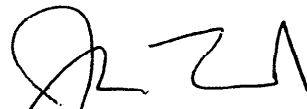
In a 6-month randomized, double-blind, placebo-controlled, multicenter study with 200 male subjects, it was proposed that a mixed phytosterol complex providing beta-sitosterol supported healthy urinary flow.

In an 18-month follow-up trial, beta-sitosterol maintained healthy urinary function.

Beta-sitosterol, derived from a soy-based phytosterol complex, may provide important support for prostate 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,

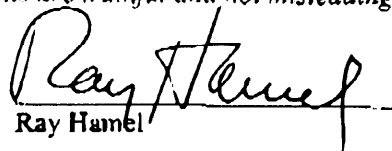


Jonathan W. Emord
Claudia A. Lewis-Eng
Kathryn E. Balmford

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: 5/28/03 —


Ray Hamel