

**EMORD & ASSOCIATES, P.C.**

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MAR 19 2002

March 14, 2002

**VIA UPS NEXT DAY AIR**

Dr. Robert Moore - Chief  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C. Street, S.W.  
Washington, DC 20204

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

Dear Dr. Moore:

Pure Encapsulations, Inc.,<sup>1</sup> in accordance with 21 U.S.C. § 343(r) and 21 CFR § 101.93, hereby submits an original and two copies of its structure/function claim notification within 30 days of first marketing its products with the statements presented below. Pure Encapsulations retains scientific documentation supporting the statements.

**1. Supplement Brand Name**

OsteoBalance™

**Supplement Ingredients**

Calcium (microcrystalline hydroxyapatite), calcium (citrate/malate), equisetum arvense (horsetail) extract (root), magnesium (aspartate), manganese (aspartate), zinc (picolinate), copper (glycinate), boron (glycinate), vitamin C (ascorbyl palmitate), vitamin D<sub>1</sub>.

**Text of Statements of Nutritional Support**

This formula also includes a comprehensive profile of important bone building nutrients.

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<sup>1</sup> The address for Pure Encapsulations, Inc. is 490 Boston Post Rd., Sandbury, MA 01776.

Calcium citrate/malate has excellent bioavailability and provided bone mass support for women with low dietary calcium intake in a two-year double-blind placebo-controlled trial.

In a separate two-year trial, calcium MCHA maintained healthy bone mineral content in volunteers.

One study demonstrated that concomitant supplementation of the trace minerals zinc, copper, and manganese with calcium citrate/malate helped to promote proper bone metabolism in subjects.

Magnesium supports healthy bone mineral density and boron plays an important role in reducing urinary calcium and magnesium excretion

Like boron, vitamin D reduces urinary calcium loss but is also a key nutrient because it enhances calcium absorption.

OsteoBalance provides a high calcium osteoporosis support formula with additional nutritional factors that promote optimal calcium absorption and retention and enhance healthy bone mineralization.

## **2. Supplement Brand Name**

Ultra-Synergist E™

### **Supplement Ingredients**

Natural vitamin E (from mixed tocopherols), providing: d-alpha tocopherol (min), d-beta tocopherol (typical), d-gamma tocopherol (min), d-delta tocopherol (typical).

### **Text of Statements of Nutritional Support**

[Alpha and gamma tocopherols] offer important anti-oxidant support for lipid membranes.

Long-term supplementation with d-alpha tocopherol supports prostate health, as indicated in a recent study.

In a separate case-control study, high intake of gamma tocopherol was also positively associated with prostate health.

Both alpha and gamma tocopherols support arterial smooth muscle cells.

In an in vitro investigation of human macrophage and epithelial cells, gamma tocopherol supported healthy prostaglandin metabolism.

An additional trial revealed that a mixture of alpha, gamma and delta isomers was more effective than any single tocopherol in promoting healthy platelet function.

Pure Encapsulations Ultra-Synergist E™ provides a powerful spectrum of mixed tocopherols with high alpha and gamma fractions for optimal antioxidant support, prostate health, and cardiovascular function.

3. Supplement Brand Name

Chitosan LipoSan Ultra™

Supplement Ingredients

Chitosan (90% pure) (shellfish)

Text of Statements of Nutritional Support

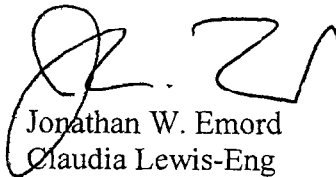
Chitosan dissolves into a gelled form that entraps fat.

Chitosan LipoSan Ultra™ is an innovative chitosan with advanced fat-binding ability and rapid solubility, with natural succinic acid to help maintain its properties.

LipoSan Ultra™ provides advanced solubility chitosan for optimal binding of fat.

In accordance with 21 U.S.C. § 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 Lewis-Eng  
Jonathan R. Goodman

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: March 15, 2002

Ray Hamel  
Ray Hamel