

EMORD & ASSOCIATES, P.C.

BURKE PROFESSIONAL CENTER  
5282 LYNNGATE COURT  
BURKE, VIRGINIA 22015

1015 '02. OCT 13 P1 59

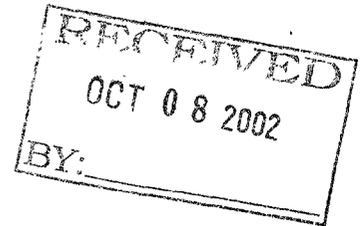
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WASHINGTON, D.C. 20036

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WEB SITE: www.emord.com  
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October 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.,<sup>1</sup> 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)**

Lesstanol™ 20 mg  
Policosanol 20 mg (from sugar cane wax) providing 1-octacosanol, 1-triacontanol, 1-hexacosanol, 1-tetracosanol, 1-nonacosanol, 1-dotriacontanol, 1-tetratriacontanol, and 1-heptacosanol. Hypoallergenic plant fiber added to complete capsule volume requirement.

**Text of Statements of Nutritional Support**

*Supports healthy lipid metabolism in some individuals.*

*Policosanol supports cardiovascular health.*

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

*Policosanol may act by providing antioxidant protection, promoting healthy platelet function, and supporting healthy lipid metabolism.*

*Policosanol may support healthy triglyceride metabolism in some individuals.*

*Policosanol is a well-tolerated mixture of long-chain aliphatic alcohols derived from sugar cane wax, promoting healthy lipid metabolism, platelet function, and antioxidant protection for healthy cardiovascular function.*

## **2. Supplement Brand Name (ingredient)**

Lesstanol™ 10mg

Policosanol 10 mg (from sugar cane wax) providing 1-octacosanol, 1-triacontanol, 1-hexacosanol, 1-tetracosanol, 1-nonacosanol, 1-dotriacontanol, 1-tetratriacontanol, and 1-heptacosanol. Hypoallergenic plant fiber added to complete capsule volume requirement.

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

*Supports healthy lipid metabolism in some individuals.*

*Policosanol supports cardiovascular health.*

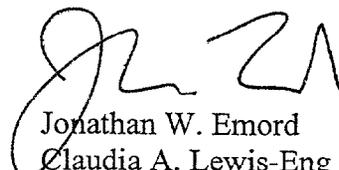
*Policosanol may act by providing antioxidant protection, promoting healthy platelet function, and supporting healthy lipid metabolism.*

*Policosanol may support healthy triglyceride metabolism in some individuals.*

*Policosanol is a well-tolerated mixture of long-chain aliphatic alcohols derived from sugar cane wax, promoting healthy lipid metabolism, platelet function, and antioxidant protection for healthy cardiovascular 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

OCT-02-02 03:28PM FROM-PURE ENCAPSULATIONS

978-443-4230

T-937 P.03/03 F-912

**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: 10/2/02

Ray Hamel  
Ray Hamel