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1325 '04 APR -8 P1:49
FEB - 3 2004

February 2, 2004

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**

DMG

Ingredients

N₁ N-Dimethylglycine (free-form) (DMG), Vitamin C (as ascorbyl palmitate), and hypo-allergenix plant fiber added to complete capsule volume requirement

Text of Statements of Nutritional Support

The use of DMG in supporting healthy neurological function in children has been studied for more than twenty years, as reported by one research institution.

In accordance with 21 U.S.C. § 343(r)(6) and 21 C.F.R. § 101.93(c), the above statement will be followed by an asterisk that will be cross-referenced to another

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

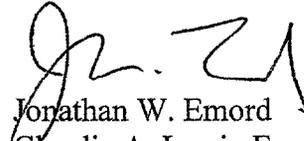
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asterisk on the very same panel or page next to which the following statement will appear in a box in bold face type: **“This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”**

Respectfully submitted,



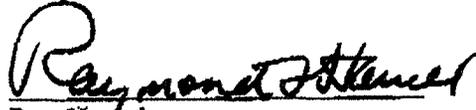
Jonathan W. Emord
Claudia A. Lewis-Eng
Kathryn E. Balmford

cc: Ray Hamel

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: 1/28/04


Ray Hamel