

EMORD & ASSOCIATES, P.C.

1050 SEVENTEENTH STREET, N.W.

SUITE 600

WASHINGTON, D.C. 20036

TELEPHONE: (202) 466-6937  
TELECOPIER: (202) 466-6938

OCT -6 P 3:01

September 28, 1998



**VIA UPS NEXT DAY AIR**

Dr. Elizabeth Yetley  
Office of Special Nutritionals (HFS-450)  
Food and Drug Administration  
200 C Street, S.W.  
Washington, D.C. 20204

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

Dear Dr. Yetley:

Mycology Research Laboratories, Ltd.,<sup>1</sup> by counsel and in accordance with 21 U.S.C. § 343(r) and 21 CFR § 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. Mycology Research Laboratories, Ltd. retains scientific documentation supporting the statements.

1. **Supplement Brand Name**

Ginger-MRL

**Ingredients**

Ginger

**Text of Statements of Nutritional Support**

- Provides nutritional support for proper digestion.

2. **Supplement Brand Name**

Green Tea- MRL

<sup>1</sup> The address for Mycology Research Laboratories, Ltd., is Bank House, Saltsgrounds Road, Brough, East Yorkshire, HU151EF, England.

97S - 0162

61433  
LET 2236

Ingredients

Green Tea

Text of Statements of Nutritional Support

- Contains catechins that have been shown to support the immune system.

3. Supplement Brand Name

Melatonin-MRL

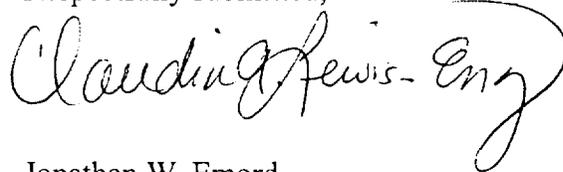
Ingredients

Text of Statements of Nutritional Support

- Supports the body's normal sleep/wake cycle.

In accordance with 21 USC § 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 faced type: "[This statement has or 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

Attachment

**Certification**

I, William Ahern, President of Mycology Research Laboratories, Ltd., hereby certify that the information contained in the foregoing notice is complete and accurate and that Mycology Research Laboratories, Ltd., has substantiation that the statements are truthful and not misleading.

Executed on: 9/28/98.

  
\_\_\_\_\_  
William Ahern