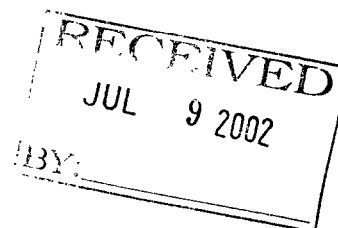


**EMORD & ASSOCIATES, P.C.**

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July 1, 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:

Maitake Products, Inc. ("Maitake"),<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 for the statements presented below. Maitake retains scientific documentation supporting the statements.

**1. Supplement Brand Name**

Mushroom Wisdom™ Super Shiitake

**Supplement Ingredients**

Shiitake (Lentinus edodes) fruit body, Shiitake (Lentinus edodes) 12:1 extract, Maitake (Grifola frondosa) extract (D-fraction® standardized 10%), Vitamin C, Bioperine® (from Piper nigrum).

**Text of Statements of Nutritional Support**

[Shiitake mushroom] was said to boost "chi" (or "qi") within the body's blood circulation and liver function, and enhance immune activity.

<sup>1</sup> The address for Maitake Products, Inc. is P.O. Box 1354, Paramus, NJ 07653

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**2. Supplement Brand Name**

Mushroom Wisdom™ Super Turkey Tail

**Supplement Ingredients**

Turkey Tail (*Coriolus versicolor*) fruit body powder, Turkey Tail (*Coriolus versicolor*) 20:1 extract, Ginger (*Zingiber officinale*) root powder, Maitake (*Grifola frondosa*) extract (D-fraction® standardized 10%), Vitamin C, Bioperine® (from *Piper nigrum*).

**Text of Statements of Nutritional Support**

Turkey Tail (*Coriolus*) belongs to the family Polyporaceae, and its immune-enhancing activities have been extensively studied in Japan since mid-1970's (over 300 clinical studies have been conducted).

**3. Supplement Brand Name**

Mushroom Wisdom™ Super Cordyceps

**Supplement Ingredients**

Cordyceps (*Cordyceps sinensis*) fruit body, Cordyceps (*Cordyceps sinensis*) 12:1:Mycelium extract, Ginger (*Zingiber officinale*) root powder, Maitake (*Grifola frondosa*) extract (D-fraction® standardized 10%), Vitamin C, Bioperine® (from *Piper nigrum*).

**Text of Statements of Nutritional Support**

Well-known for stamina and endurance, this mushroom has gained much attention through the success of Olympic athletes from China.

It has also been known to support healthy sexual function as well as nourishment of lungs and kidneys.

**4. Supplement Brand Name**

Mushroom Wisdom™ Super Royal Agaricus

**Supplement Ingredients**

Agaricus (*Agaricus blazei* Murill) fruit body, Agaricus (*Agaricus blazei* Murill) 12:1 extract, Maitake (*Grifola frondosa*) extract (D-fraction® standardized 10%), Vitamin C, Bioperine® (from *Piper nigrum*).

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

In Japan, its immune enhancing activity has been widely recognized, making this mushroom extremely popular.

#### **5. Supplement Brand Name**

Mushroom Wisdom™ Super Tremella

#### **Supplement Ingredients**

Tremella (*Tremella fuciformis*) fruit body, Tremella (*Tremella fuciformis*) 8:1 extract, Maitake (*Grifola frondosa*) extract (D-fraction® standardized 10%), Vitamin C, Bioperine® (from *Piper nigrum*).

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

Used in ancient times as a Qi and immune tonic, this mushroom is also highly prized as a youthful skin tonic for a healthy complexion.

It is said that Imperial Concubine Yang (719-756), considered to be the most beautiful woman in Chinese history, used it for her facial maintenance.

#### **6. Supplement Brand Name**

Mushroom Wisdom™ Super Reishi

#### **Supplement Ingredients**

Reishi (*Ganoderma lucidum*) fruit body, Reishi (*Ganoderma lucidum*) 14:1 extract, Ginger (*Zingiber officinale*) Root Powder, Maitake (*Grifola frondosa*) extract (D-fraction® standardized 10%), Vitamin C, Bioperine® (from *Piper nigrum*).

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

As a tonic it calms and nourishes the nerve system, strengthens the lungs, protects and stimulates the liver, and supports heart and brain function.

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,

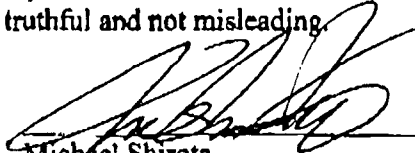
A handwritten signature in black ink, appearing to be 'JW Emord', written over the printed name.

Jonathan W. Emord  
Claudia Lewis-Eng  
Jonathan R. Goodman

**Certification**

I, Michael Shirota, President of Maitake Products, Inc., hereby certify that the information contained in the foregoing notice is complete and accurate and that Maitake Products has substantiation that the statements are truthful and not misleading.

Executed on: June 28, 2002

  
Michael Shirota