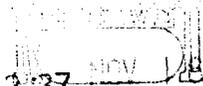




8897 '98 NOV 24 P2:37



October 30, 1998

Office of Special Nutritionals  
HFS-450 Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
200 C St.SW  
Washington DC 20204

Statement of Nutritional Support- **MELATONIN**  
Pursuant to 21 CFR Part 101.93, American Specialty Health &  
Wellness (ASHW) files the following Statement of Nutritional  
Support for the Dietary Supplement marketed as: **MELATONIN**

- 1) Name and Address of Distributor: ASHW 8989 Rio San Diego Dr.  
Ste. 250, San Diego CA 92108
- 2) Text of Nutritional Support Statement being Made:  
"Melatonin is a hormone that affects sleep and other bodily  
functions. Recent scientific research is investigating  
melatonin's usefulness in normal sleep, supporting a healthy  
immune system and recovery from jet lag."
- 3) Name of dietary ingredient(s): See Attached Product Label
- 4) Brand Name: **MELATONIN**
- 5) Substantiation information on file at the company office. The  
corporate officer who can certify same is Dr. Doug Metz, Vice  
President.

Yours truly,

A handwritten signature in cursive script, appearing to read "Doug Metz".

Dr. Doug Metz  
Vice President

97S-0162

LET 2491

# Melatonin

## Description:

Melatonin is a hormone that effects sleep and other bodily functions. Recent scientific research is investigating melatonin's usefulness in normal sleep, supporting a healthy immune system and recovery from jet lag.

These statements have not been evaluated by the Food and Drug Administration (FDA). This product is not intended to diagnose, treat, cure or prevent any disease.

**Directions For Use:** Take 1 capsule per day.

**Storage:** Keep tightly closed in a cool, dry place.

**Caution/Warning:** As with any supplement, herb or medication, do not use it while pregnant or lactating, or provide it to a child without consulting a physician. If you suffer from sleep disorders, cancer or immune disorders, do not use this product without first consulting your physician.

**Note:** This product is regulated by the FDA as a dietary supplement. If you have any questions about how you feel while taking this supplement, contact your physician. If you are taking any medication, have any disease or illness, consult your physician before taking this product. Do not stop or change prescribed medication without the permission or prescription of your physician.

DISTRIBUTED BY AMERICAN SPECIALTY HEALTH & WELLNESS™  
PO BOX 509040, SAN DIEGO, CA 92150-9040

# MELATONIN

## DIETARY SUPPLEMENT

60 CAPSULES

*Premium Products for Your Health & Wellness™*

## Supplement Facts

Serving Size: 1 Capsule – Servings Per Container: 60

	Amount Per Serving:	% Daily Value
Melatonin	3mg	*

**Other Ingredients:** Gelatin, cellulose, calcium phosphate hydrous, stearic acid, magnesium stearate and silicon dioxide.

\*Daily Value not established

Melatonin is free of wheat, corn, dairy, sucrose, starch, salt and yeast.