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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 - **VALERIAN EXTRACT**  
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: **VALERIAN EXTRACT**

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:  
"Valerian root is an herb that is used for its non-addictive  
relaxing and calming effect. It may be helpful in promoting a  
full night's sleep."

3) Name of dietary ingredient(s): See Attached Product Label

4) Brand Name: **VALERIAN EXTRACT**

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

LET2489

# Valerian Extract

## Description:

Valerian root is an herb that is used for its relaxing and calming effect. It may be helpful in promoting a full night's sleep.

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.

**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

## VALERIAN EXTRACT 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
Valerian extract (Valeriana officinalis root, std 0.8% valerianic acid)	100mg	*

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

\*Daily Value not established.

Valerian Extract is free of wheat, corn, soy, dairy, sucrose, starch, salt and yeast.