



8917 '98 NOV 24 P2 38  
NOV 16 1998

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- **ASTRAGULUS 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:  
**ASTRAGULUS 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:  
"Astragalus, also known as milk-vetch root is considered a  
general tonic. The root of the plant is used to support a  
healthy immune system, promote healing, and counteract fatigue.  
General tonics such as astragalus are believed to enhance the  
body's ability to cope and adapt to stressful conditions."
- 3) Name of dietary ingredient(s): See Attached Product Label
- 4) Brand Name: **ASTRAGULUS 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,

Dr. Doug Metz  
Vice President

97S - 0162

Also see docket 97S-0163

62292

LET 2511

# Astragalus Extract

## Description:

Astragalus, also known as milk-vetch root, is considered a general tonic. The root of the plant is used to support a healthy immune system, promote healing and counteract fatigue. General tonics such as astragalus are believed to enhance the body's ability to cope and adapt to stressful conditions.

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

## ASTRAGALUS EXTRACT DIETARY SUPPLEMENT

30 CAPSULES

*Premium Products for Your Health & Wellness™*

### Supplement Facts

Serving Size: 1 Capsule – Servings Per Container: 30

Amount Per Serving: % Daily Value

Astragalus extract (Astragalus membranaceus root, std 16% astragalosides)	450mg	*
---	-------	---

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

\*Daily Value not established

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