



8942 '98 NOV 24 P2:40

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- **BLACK COHOSH 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:
BLACK COHOSH 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:
"Black Cohosh contains substances that have an effect similar to
the female hormone estrogen. These estrogenic compounds are used
to help support the female reproductive system and cycle."

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

4) Brand Name: **BLACK COHOSH 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

8989 Rio San Diego Dr., Suite 250, San Diego, CA 92108 • Phone 619/297-8100 • Fax 619/209-6236

LET 2536

Black Cohosh Extract

Description:

Black Cohosh contains substances that have an effect similar to the female hormone estrogen. These estrogenic compounds are used to help support the female reproductive system and cycle.

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. Do not use if you have a heart or liver condition, blood clotting disorder or a history of cancer. May cause vertigo, headache, nausea, impaired vision, vomiting and impaired circulation. Limit use to 6 months.

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

BLACK COHOSH 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

Black cohosh extract (Cimicifuga racemosa
rhizome, std 2.5% triterpene glycosides) 250mg *

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

*Daily Value not established.

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