

# Manufacturers of Fresh Botanical Extracts

Division of Compliance and Enforcement/ONPLDS Center for Food Safety and Applied Nutrition Food and Drug Administration HFS-810 200 C Street, SW Washington, DC 20204

January 17, 2002

Dear Sir:

This letter is to provide notification, within the prescribed 30 days of marketing, of three new products that Gaia Herbs is adding to our line that contain structure function claims. These products are Liquid Phyto-Caps that are herbal dietary supplements. I have attached a copy of each label that contains the structure function claim as well as other information.

These products are:

- Urinary Support
- Fem-Restore
- Aller-Leaf

Please call at 828-883-5938 if you need addition information or if you have any questions.

Sincerely,

James A. Grant

Regulatory Compliance Officer

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SUGGESTED USE:
Take 2 capsules with a smail amount of warm water every 1-2 hours for 1-2 weeks as needed. Not to be used during pregnancy or laciation. Keep away from children Use only as directed on label. Safety sealed for your protection is Keep bottle capped at all times and store in a cool dry place. Natural separation may occur. This does not affect product quality.

This does not affect product quality.

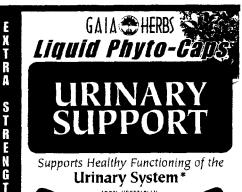
LIQUID PHYTO-CAPS" — Gaia Herbs' patented technology delivers a concentrated full spectrum alcohol-free liquid extract in a 100% vegetaman capsule. Now you can have the supenor bioavailability and fast absorption of a liquid delivery system, from carthed organic and acologically wildcrafted herbs, in a convenient capsule

ECOLOGICALLY WILDCRAFTED

CERTIFIED ORGANIC

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**Urinary System\*** 100% VEGETARIAN

60 LIQUID-FILLED CAPSULES

A DISTARY SUPPLEMENT

## Supplement Facts

Serving Size 1 Capsule Servings Per Container 60

Amount Per 2 Capsules

Amount Per 2 Capsules

Calories 2 Capsules

Calories ConcentrateD extraCTs ofUva Urs solid extract (Arctastaphysis use ursi) 

Buchu leaf (Bacsma betninal)

Prasssewa leaf (Chimaphile unbellibet)

Contis rhaams (Capits chenensis)

Echnacea (Echnacea purpura flowering top.

Echnacea (Echnacea purpura out.

Echnacea purpura seed)

†Daily Value not established

Other ingredients. Vegetable glycerin, vegetable cellulose (capsule)

Certified Organic or Organically Cultivated

University Organically Cultivated

Certified Organic Organically Cultivated

Certified Organically Wildcrafted

Each 2 capsules contain 2,740 mg crude herb equivalent Gaia Herbs Liquid Phyto-Caps " U.S. Patent No. 6,238,696 B1

Gara Herbs, Inc., 108 Island Ford Rd., Brevard, NC 28712 www garaherts com Host by R.E. Carles Manager Co. 1871.

370 mgt 124 mgt 92 mgt 50 mgt

30 mgT

### SUGGESTED USE:

Take 1 capsule with a small amount of warm water 3 times daily between meals. Warm water 3 times daily between meas, Not to be used duning pregnancy or lactation Keep away from children. Use only as directed to label 3-fety sealed for your protection. Keep bottle capped at all times and store in a cood by place. Natural separation may occur. This does not affect product quality.

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AND GRUG ADMINISTRATION. HIS PRODUCT IS NOT INTENDED

ID DIAGNOSE TREAT CURE OR PREVENT ANY DISEASE



GAIA THERBS Liquid Phyto-Caps

Supports Healthy Functioning of the Female Reproductive System\*

100% VEGETARIAN **60** LIQUID-FILLED CAPSULES

IETARY SUPPLEMENT

### Supplement Facts

Servings For Contamor 60

### nt Per 2 Capsule

Calories 20 Calones 20
ALCOHOL FREE CONCENTRATED EXTRACTS OFFraxinus bark (Fraxinus amencana) ●
Red Root (Ceanothus amencanus) ●
Mayappie huxome (Podophylum peletum) ●
Life Root (Senecua aureus) ●
Colleansel intome (Hydrastis canadensis) ▲
Corydaiis root (Carydaiis yanhusuo) ● 60 mgt 40 mgt 30 mgt 20 mgt 20 mgt 16 mgt 16 mgt 16 mgt 14 mgt 10 mgt

Butterbur root (Petasites hybridus) 
Ginger rhizome (Zingiber officinale) 
Lobelia herb/seed (Lobelia inflata) †Daily Value not established.

Other ingredients. Vegetable glycerin, vegetable cellulose (capsule)
▲=Certified Organic or Organically Cultivated
●= Ecologically Wildcrafted

Each 2 capsules contain 2,500 mg crude herb equivalent Gaia Herbs Liquid Phyto-Caps™ U.S. Patent No. 6,238,696 B1

28712  $\mathbf{g}$ Rd . Island Ford 8 Inc., Lot # Best by

Herbs,

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a convenient capsule

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AND DRUG ADMINISTRATION THIS PRODUCT IS NOT INTENDED

TO DIAGNOSE, TREAT, CURE OR PREVENT ANY DISEASE



GAIA THERBS Liquid Phyto-Caps

Supports Healthy Functioning of the **Upper Respiratory System\*** 

> 100% VEGETARIAN 60 LIQUID-FILLED CAPSULES

A DIETARY SUPPLEMEN

## Supplement Facts

Serving Size 1 Capsule Servings Per Container 60

Amount Per 2 Capsules

ALCOHOL FREE CONCENTRATED EXTRACTS OF 132 mgt 132 mgt 106 mgt 100 mgt 36 mgt 16 mgt 14 mgt 8 mgt Turmenc root & leaf (Cucuma longa) • Eyebnight herb (Euphrasia officinalis) • Eyebnight herb (Euphrasia officinalis) 
Attetil leaf (Urtica divoca) 
Bayberry bark (Myrica centera) 
Chinese Skulldag noti (Scutellana baicalensis) 
Goldanseal rhizome (Hydrastis canadensis) 
Arrown flower (Achillea milelolum) 
Calamus rhizome (Acorus calamus)

† Daily Value not established

Other ingredients: Vegetable glycerin, vegetable cellulose

▲=Certified Organic or Organically Cultivated · cologically Wildcrafted

Each 12 capsules contain 2 700 mg crude herb equivalent Gaia Herbs Liquid Phyto-Laps " U.S. Patent No. 6 238 696 B1

Lot # Best b

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Brevaid, NC 28712

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