

Manufacturers of Fresh Botanical Extracts

John B. Foret
Director
Division of Compliance and Enforcement/ONPLDS
Center for Food Safety and Applied Nutrition
Food and Drug Administration HFS-810
5100 Paint Branch Parkway
College Park, Maryland 20740

APR 1 0 2002

April 3, 2002

Dear Sir:

This letter is in response to your letter of March 26, 2002 in regard to our name and structure function claim as follows:

Cholesterol Vital Balance Supports Healthy Cholesterol Metabolism

You stated this name and claim might imply a disease claim and therefore did not meet the requirements of 21 U.S.C. 343(r)(6). For this reason we are changing the name and structure function claim. We used as guidance the section which you referenced in the preamble to the January 6, 2000 final rule on structure function claims which discusses cholesterol (65 FR 1000 at 1018). We used the suggestions contained in this section to avoid any implication of a disease claim. The name and structure function claim are as follows:

Cholesterol Vital Maintenance

Helps maintain cholesterol levels already in a normal range.

We feel that this does meet the requirements of 21 U.S.C. 343(r)(6) as required for dietary supplements. Please call at 828-883-5938 if you need addition information or if you have any questions.

Sincerely,

James A. Grant

James Cl. Gran

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Regulatory Compliance Officer

108 Island Ford Road • Brevard, NC 28712 (828) 884-4242 tel • (828) 883-5999 fax • (800) 831-7780 orders 80201



SUGGESTED USE:
Take 2 capsules with a small emount of warm water 2 times daily between meals. Not to be used during pragmency or factation. Keep away from children. Lise only as directed on label. Safety sealed for your protection accord by place. Neutral separation may occur. The does not affect product quality.

EXTRA

STRENGTH

The does not affect product quarry.

LIQUID PMYTO-CAPS** — Gale Herbs' patented technology delivers a concentrated till spectrum school-three liquid extract in a 100% vegetarian capsule. Now you can have the superior bioevallability and fast absorption of a liquid delivery system, from certified organic and ecologically wildcrafted herbs, in a convenient capsule.

ECOLOGICALLY WILDCRAFTED

"THIS STATEMENT HAS NOT BEEN PUBLIATED BY THE POOD AND ORIGI ADMINISTRATION. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE OF PREVENT ANY OBSEASE.





Helps Maintain Cholesterol Levels Already in a Normal Range*



DIETARY SUPPLEMENT

Supplement Facts

Serving Size 1 Capeals Servings Per Container 60

Calories 28

ALCOHOL FREE CONCENTRATED EXTRACTS OF:

ALCOROU, FREE CORGENTRATED EXTRACTS OF:
Perchetone
Artichoka leef (Cynare sootymus) & 200 mgt
Coleus root (Coleus forstbridf) © 150 mgt
150 mgt
Ulgugus wesh (Commisphore malaul) © 150 mgt
Wild Yarn rhacome (Dioscores villosa) © 22 mgt
Polecosanol
Greeter Celendine tops & roots (Chelidonsun malas) © 8 mgt

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Thomy venue full venue members (Vegetable dysenin, vegetable cellulote (coptule).

A - Certified Orgetic of Organesity Cultivated

Cescologically Wilderstad

Each 2 cessuales counted 3,860 mg crade herh equivalent.

San Herbs Liquid Phytio-Caps ** U.S. Petert No. 5,238,566 B1

Bravard, NC 28712

Herbs, Inc., 108 Island Ford Rd., I www.guisheds.com