



1042 '01 APR 13 P3:21

MAR 30 2001

Ms. Evelyn D. Cadman, DN
Senior Research Scientist
NatureSmart
1500 East 128th Avenue
Thornton, Colorado 8024 1

Dear Ms. Cadman:

This is in response to your letters of March 8, 2001 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that **NatureSmart** is making the following claims, among others, for the following products:

Bioenergy Nutrients Lecithin Granules

“Maintain healthy cholesterol...”

Bioenergy Nutrients Contrinol®

“For better bladder control”

“Support healthy bladder control”

“Helps you stay continent.. **and** confident”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, cure, or mitigate diseases, namely hypercholesterolemia and disorders of the bladder related to incontinence. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-3 10, 7520 Standish Place, Rockville, Maryland 20855.

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Please contact us if we may be of further assistance.

Sincerely,

for Robert Moore
for John B. Foret

Director

Division of Compliance and Enforcement

Office of Nutritional Products, Labeling
and Dietary Supplements

Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Denver District Office, Office of Compliance, HFR-SW240

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cc:

HFA-224

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-810 (Foret)

HFS-8 11 (Moore, w/original incoming)

HFD-40 (Behrman)

HFD-3 10

HFD-3 14 (Aronson)

HFS-607 (Bayne-Lisby)

HFV-228 (Benz)

GCF- 1 (Nickerson)

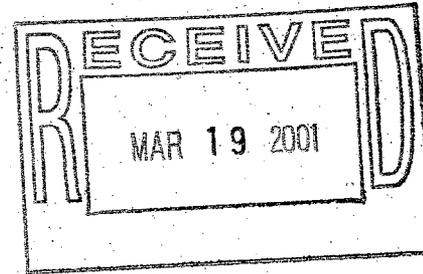
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NatureSmart

March 8, 2001

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, DC 20204



NOTIFICATION OF STATEMENTS OF NUTRITIONAL SUPPORT

This Notification is filed pursuant to § 403(r)(6) of the Federal Food Drug and Cosmetic Act (FDC Act), 21 U.S.C. § 343 (r)(6).

Name of dietary supplement: **Bioenergy Nutrients Contrinol®**

Statement[s] of
nutritional support:

For better bladder control.

Support healthy bladder control.

Helps you stay continent... and confident.

Supports a healthy bladder muscle.

Horsetail and wild-crafted white poplar bark interact to support the health of the bladder and walls of the urinary tract.

Dogwood berry and schisandra berry may help balance body fluids and support urinary health.

I certify that the information contained in this notice is complete and accurate, and that we have substantiation that the statement[s] is [are] truthful and not misleading. Two copies of this notification are enclosed with this original.

NatureSmart, Inc.

A handwritten signature in cursive script that reads "Evelyn D. Cadman, CN".

Evelyn D. Cadman, CN

Senior Research Scientist

1500 East 128th Avenue

Thornton, CO 80241

voice: 303.474.2300

fax: 303.474.2700

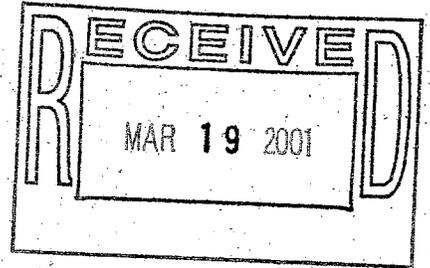
e-mail: info@naturesmart.net

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March 8, 2001

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, DC 20204



NOTIFICATION OF STATEMENTS
OF NUTRITIONAL SUPPORT

This Notification is filed pursuant to § 403(r)(6) of the Federal Food Drug and Cosmetic Act (FDC Act), 21 U.S.C. § 343 (r)(6).

Name of dietary supplement: Bioenergy Nutrients Lecithin Granules

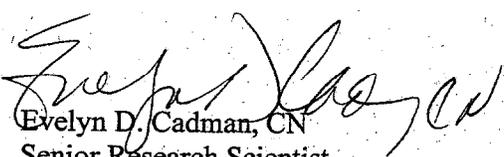
Statement[s] of nutritional support: Maintain healthy cholesterol and memory.

Support healthy-levels of phosphatidylcholine and phosphatidylserine.

Two tablespoons of Lecithin Granules a day can boost your memory.

I certify that the information contained in this notice is complete and accurate, and that we have substantiation that the statement[s] is [are] truthful and not misleading. Two copies of this notification are enclosed with this original.

NatureSmart, Inc.


Evelyn D. Cadman, CN
Senior Research Scientist

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Thornton, CO 80241
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