



FEB 22 2001 2 01 MAR 16 A7:16

Ms. Evelyn D. Cadman
Senior Research Scientist
NatureSmart
1500 East 128th Avenue
Thornton, Colorado 80241

Dear Ms. Cadman:

This is in response to your letters of January 12, 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 Maximum Mobility®

“...especially for seniors or anyone with joint concerns”

Bioenergy Nutrients Potassium SR™

“Maintain healthy blood pressure”

“...healthy blood pressure”

“Support your healthy blood pressure”

“...maintain...healthy blood pressure”

“Naturally balance blood pressure”

Bioenergy Nutrients Imperial Garlic®

“...maintain healthy blood pressure and cholesterol levels”

Bioenergy Nutrients Fish Oil

“...maintain healthy blood pressure”

“...keep blood flowing smoothly”

Bioenergy Nutrients FlexiCare™

“Immediate care for joints”

“When you can't wait for your joints to feel better”

“Brings comfort quickly...”

“Promotes a healthy inflammatory response...when the inflammation is in control, it's easier for your body to heal...”

“...support the natural healing process”

“Assist the body's natural response to inflammation”

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Bioenergy Nutrients MetaChrome®

“Promotes blood sugar balance”

Bioenergy Nutrients Flax Seed Oil

“Protect your heart...and your cholesterol levels”

Bioenergy Nutrients MSM

“...help keep the inflammatory response healthy, for comfortable movement”

“Encourages a healthy inflammatory response”

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. 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-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

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, Dallas District Office, Office of Compliance, HFR-SW140

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-811 (file)

HFD-40 (Behrman)

HFD-310

HFD-314 (Aronson)

HFS-605

HFV-228 (Benz)

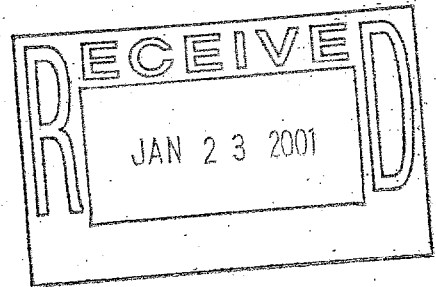
GCF-1 (Nickerson)

f/t:HFS-811:rjm:2/16/01:docname:74149.adv:disc54

NatureSmart

January 12, 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 Potassium SR™

Statement[s] of
nutritional support:

Maintain healthy blood pressure.

Potassium is needed by your heart, kidneys, muscles and nerves to maintain a variety of body functions, most importantly, healthy blood pressure.

Support your healthy blood pressure.

Potassium SR can help to fill in the gaps your diet may leave.

Stay healthy with Potassium SR.

Potassium is an essential mineral needed to maintain a healthy heartbeat and healthy blood pressure.

Naturally balance blood pressure

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 black ink, appearing to read "Evelyn D. Cadman, CN".

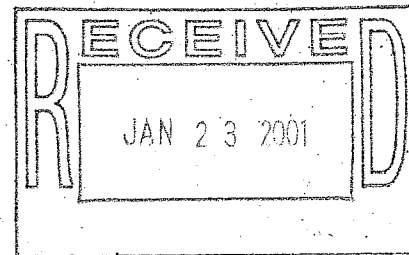
Evelyn D. Cadman, CN
Senior Research Scientist

1500 East 128th Avenue
Thornton, CO 80241
voice: 303.474.2300
fax: 303.474.2700
e-mail: info@naturesmart.net

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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 Imperial Garlic®

Statement[s] of
nutritional support:

Odor-controlled immune support.

Extensive research shows that garlic can boost your immunity.

Research shows garlic can fortify your immune system.

Garlic can help maintain healthy blood pressure and cholesterol levels.

Reinforce the naturally protective action of white blood cells and T-cells.

Strengthen your immune response.

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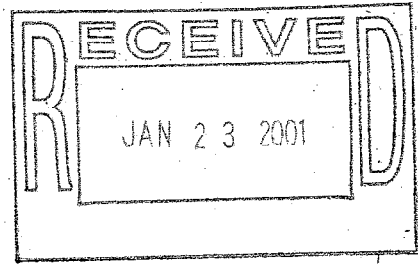
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Name of dietary supplement: Bioenergy Nutrients Fish Oil

Statement[s] of
nutritional support:

Omega-3 fatty acids have been shown to promote the production of beneficial hormone-like substances responsible for regulating many systems within the body – including the immune, hormonal, nervous, cardiovascular and reproductive systems. Fish oil may help regulate your immune, nervous, hormone and reproductive systems.

Improve cardiovascular health with omega-3s

Fish oil boosts your cardiovascular health and is wonderful for your whole body.

Studies show that fish oil may help you maintain healthy blood pressure. It may also promote relaxed capillaries and help keep blood flowing smoothly.

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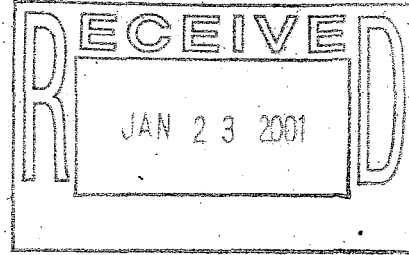
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This Notification is filed pursuant to § 403(r)(6) of the Federal Food Drug and Cosmetic Act (FDC Act), 21 U.S.C. § 343 (r)(6).

Name of dietary supplement: **Bioenergy Nutrients FlexiCare™**

Statement[s] of
nutritional support:

Speed recovery time in joints.

Immediate care for joints.

When you can't wait for your joints to feel better.

Brings comfort quickly, safely and naturally

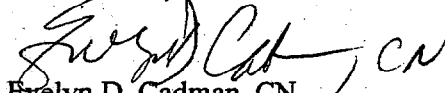
Promotes a healthy inflammatory response throughout your body. When inflammation is in control, it's easier for your body to heal in a natural, healthy way.

Soothe the body and support the natural healing process.

Assist the body's natural response to inflammation

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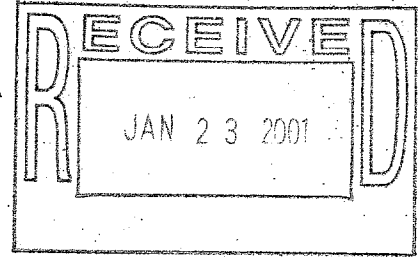

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21 U.S.C. § 343 (r)(6).

Name of dietary supplement: Bioenergy Nutrients MetaChrome®

Statement[s] of
nutritional support: For healthy weight maintenance.

Build a better body.

Trim fat and increase lean muscle mass.

Promotes blood sugar balance.

Lose fat, gain muscle

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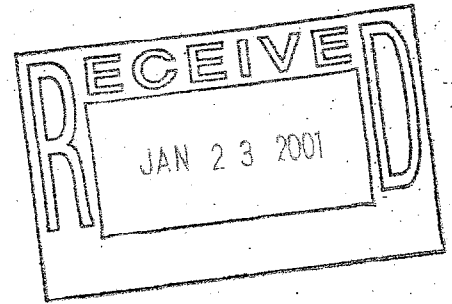
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Name of dietary supplement: Bioenergy Nutrients Flax Seed Oil

Statement[s] of nutritional support: Protect your heart, your immunity and your cholesterol levels.

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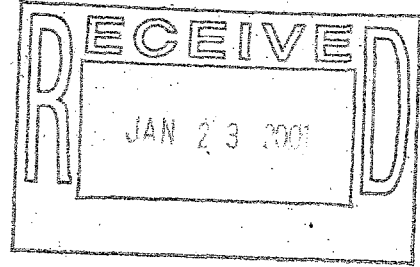
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Name of dietary supplement: Bioenergy Nutrients Maximum Mobility®

Statement[s] of
nutritional support:

High-powered joint protection.

Walk, run, work and play with greater comfort and ease.

Designed especially for seniors or anyone with joint concerns.

Help you move in comfort.

Enjoy total joint support.

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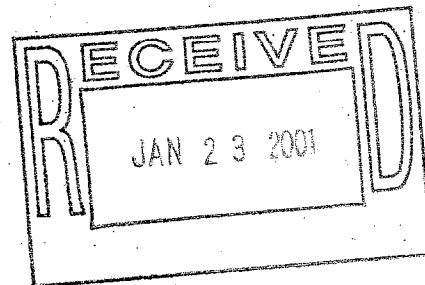
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Name of dietary supplement: Bioenergy Nutrients MSM

Statement[s] of
nutritional support:

Nourish joints for easy movement.

Provides the key to stronger joints... for powerful results your joints can feel.

Build strong connective tissues, like cartilage, tendons and ligaments, the pieces and parts that keep joints functioning smoothly.

MSM can even help keep the inflammatory response healthy, for comfortable movement.

Encourages a healthy inflammatory response.

Strengthens connective tissue.

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