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DEC 23 2003

Nancy Steely, N.D.
Director of Research
Your Vitamins from Andrew Lessman
430 Parkson Road
Henderson, Nevada 89015

Dear Dr. Steely:

This is in response to your letters of November 03, 2003 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 submissions state that Your Vitamins from Andrew Lessman is making the following claims, among others, for the following products:

Calcium Intensive Care

“...may reduce the risk of osteoporosis later in life

ProCaps CholestaCare

“...support heart health by helping to reduce Total Cholesterol and LDL Cholesterol levels”

“Phytosterols help to control your Total Cholesterol and LDL Cholesterol levels”

...plant sterol esters necessary to positively affect their Cholesterol levels”

These claims are not claims subject to 21 U.S.C. 343(r)(6), but instead are claims subject to 21 U.S.C. 343(r)(1)(B). FDA has authorized health claims on the relationships between plant sterol esters and stanol esters and the risk of coronary artery disease (see 21 CFR 101.83)¹ and between calcium and the risk of osteoporosis (see 21 CFR 101.72). A dietary supplement that meets the eligibility and message requirements set forth in these regulations may bear a claim for the relationship between plant sterol esters and stanol esters and the risk of coronary artery disease or the relationship between calcium and the

¹ On February 14, 2003, FDA issued a letter announcing that it intended to exercise enforcement discretion, pending publication of a final rule regarding expanded use of the sterol/stanol ester health claim, with respect to certain requirements of the health claim. A copy of that letter can be found at <http://www.cfsan.fda.gov/~dms/ds-ltr30.html>.

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Page 2 - Dr. Nancy Steely

risk of osteoporosis in its labeling. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.83 or 21 CFR 101.72 would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, failure to make a claim in accordance with the requirements in 21 CFR 101.83 or 21 CFR 101.72 subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, coronary artery disease or osteoporosis. If your products meets the eligibility requirements to bear the health claims authorized in 21 CFR 101.83 or 21 CFR 101.72 in its labeling and the claims themselves meet the message requirements set forth in the regulations, they would qualify to bear the authorized health claims in their labeling.

Please contact us if you require further assistance.

Sincerely yours,



Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
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, San Francisco District Compliance, HFR-PA140

Page 3 - Dr. Nancy Steely

cc:

all w/copy incoming

HFA-224

HFA-305 (docket 97S-0163)

HFS-800 (file)

HFS-810

HFS-811 (Moore w/original incoming)

HFD-40 (Behrman)

HFS-607

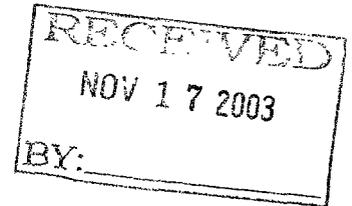
HFV-228 (Benz)

GCF-1 (Nickerson)

f/t:HFS-811:rjm:11/26/02:docname:86526.adv:disc80



November 03, 2003



Director
Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street S.W.
Washington, DC 20204

SENT VIA CERTIFIED MAIL – RETURN RECEIPT REQUESTED
ARTICLE #: 7099 3400 0016 4139 9508

RE: PROCAPS CHOLESTACARE

Dear Sir / Madam:

This is a 30-day notification of a statement of nutritional support for a dietary supplement. The product name is **ProCaps CholestaCare**. The structure / function claims on all sizes and configurations of this product are identical. They are as follows:

ProCaps CholestaCare is an effective natural formula designed to support heart health by helping to reduce Total Cholesterol and LDL Cholesterol levels. The Food and Drug Administration now recognizes that phytosterol esters, like those contained in **ProCaps CholestaCare**, provide a natural means of supporting heart health. Phytosterols help to control your Total Cholesterol and LDL Cholesterol levels. Although naturally present in fruits, vegetables and grains, most Americans do not consume adequate amounts of these foods to achieve the recommended levels of the plant sterol esters necessary to positively affect their Cholesterol levels. Scientific evidence establishes that including adequate amounts of plant sterol esters in the diet helps to lower Total Cholesterol and LDL Cholesterol levels, which is important for heart health since high Total Cholesterol and high LDL Cholesterol levels are associated with an increased risk of developing coronary heart disease. According to the US Food and Drug Administration, consuming at least 650 mgs per serving of plant sterol esters twice daily with meals for a daily total intake of at least 1.3 g (1,300 mg), as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of **ProCaps CholestaCare** supplies 650 milligrams of plant sterol esters.

Respectfully Submitted,

Nancy Steely, ND
Director of Research

86526



November 03, 2003

RECEIVED
NOV 17 2003
BY:

Director
Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street S.W.
Washington, DC 20204

SENT VIA CERTIFIED MAIL – RETURN RECEIPT REQUESTED
ARTICLE #: 7099 3400 0016 4139 8440

RE: CALCIUM INTENSIVE CARE

Dear Sir / Madam:

This is a 30-day notification of a statement of nutritional support for a dietary supplement. The product name is **Calcium Intensive Care**. The structure / function claims on all sizes and configurations of this product are identical. They are as follows:

Although also important for men, this formula is particularly useful for women who need to consume extra Calcium to build and maintain a healthy skeleton; especially for teens and young adults for whom adequate Calcium intake and a healthy diet may reduce the risk of osteoporosis later in life.

Respectfully Submitted,

Nancy Steely, ND
Director of Research

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COPY

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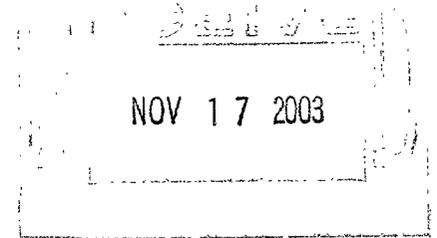
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