



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

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NOV 30 2004

Kristi Ansnes
Regulatory Affairs Associate
Leiner Health Products
901 E. 233rd Street
Carson, California 90745-8400

Dear Ms. Ansnes:

This is in response to your letters of November 19, 2004 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 letter states that the product **Your Life Vitamin E 400 I.U. plus Fish Oil 250 mg** will use the claim "Helps maintain healthy cholesterol levels."

In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. Therefore, because the claim you are making for this product represents that the product is intended to affect blood cholesterol but does not also include a statement about it being intended to affect blood cholesterol that is already in the normal ranges, it is an implied disease claim.

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 statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is 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, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

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Page 2 - Ms. Kristi Ansnes

Your submissions also state that Leiner Health Products is making claim about the relationship between calcium and the risk for developing osteoporosis for the products **Your Life Calcium 600 mg with Soy Isoflavones & Vitamin D, Your Life Calcium, Phosphorus with Vitamin D, and Your Life Coral Calcium.**

A statements about a relationship between calcium and osteoporosis is not a claim subject to 21 U.S.C. 343(r)(6), but a claim subject to 21 U.S.C. 343(r)(1)(B). FDA has authorized a health claim on the relationship between calcium and osteoporosis (see 21 CFR 101.72). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between calcium and osteoporosis. 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 101.72 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 101.72 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, osteoporosis.

Please contact us if we may be of further assistance.

Sincerely yours,

for Susan J. Walker, M.D.

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-310
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Los Angeles District Office, Office of Compliance, HFR-PA140



901 E. 233rd Street
Carson, California
90745-6204
310/835-8400
Fax 310/835-6615

November 19, 2004

Office of Nutritional Products,
Labeling and Dietary Supplements (HFS-810),
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Brush Pkwy.
College Park, MD 20740

NOV 23 2004

Section 403(r) (6) Notification

Dear Sir or Madam:

In accordance with the requirement of section 403(r) (6) of the Federal Food, Drug and Cosmetic Act, **Leiner Health Products** notifies the FDA that it has begun using the following phrase and statement:

**Heart Health
Helps Maintain Healthy Cholesterol Levels**

Vitamin E with Fish Oil is a unique combination of two powerful supplements in one convenient dose. Vitamin E helps maintain healthy heart and circulatory functions. Fish Oil also contributes to heart and vascular health and promotes healthy brain functions.

on the following product:

Your Life® Vitamin E 400 I.U. plus Fish Oil 250 mg

Very truly yours,

Leiner Health Products

A handwritten signature in cursive script that reads 'Kristi Ansnes'.

Kristi Ansnes
Regulatory Affairs Associate

90186



Office of Nutritional Products,
Labeling and Dietary Supplements (HFS-810),
Center for Food Safety and Applied Nutrition
Food and Drug Administration
(Continued)

The following brands also use the above statement:

Albertson's
BI-MART
BIO BALANCE®
COUNCIL LABS®
CVS®
ECKERD®
equate®
Hannaford®
HealthLine
health PRIDE
Kash n' Karry
KIRKLAND Signature™
Kroger®
Longs
MARC'S
Member's Mark
MEIJER™

Nature's Origin®
NATURE'S VALLEY™
NATURITE®
NUTRA CHOICE
NUTRI-BLEND
Oscor®
PHARMACIST FORMULA®
BODYCOLOGY™
SAFEWAY SELECT™
Savon™
Shaw's
ShopKo®
Spring Valley®
TARGET®
TOP CARE®
TRUNATURE®
Wegmans®



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Helps Support Your Body through Natural Changes

Isoflavones are phytoestrogens, nutrients from plants with estrogen-like chemical structures. Studies show that isoflavones may help maintain healthy bones, already healthy cholesterol levels and good cardiovascular health. Studies have also shown that soy isoflavones may benefit men's health by contributing to good prostate health. Calcium 600 mg + Soy Isoflavones is an ideal complex for bone health. Regular exercise and a healthful diet with adequate calcium are essential in achieving peak bone mass in teenagers and young adults and maintaining bone health during adulthood. Individuals who do not store enough calcium throughout their lives have an increased risk for developing osteoporosis. Vitamin D assists in the absorption of calcium.

Soy isoflavones are natural plant nutrients that help your body support bone health. Soy isoflavones also help promote good menopausal health.

on the following product:

Your Life® Calcium 600 mg with Soy Isoflavones & Vitamin D

Very truly yours,

Leiner Health Products

A handwritten signature in black ink that reads 'Kristi Ansnes'.

Kristi Ansnes
Regulatory Affairs Associate

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Nature's Origin®
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NATURITE®
NUTRA CHOICE
NUTRI-BLEND
Oscor®
PHARMACIST FORMULA®
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SAFEWAY SELECT™
Savon™
Shaw's
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Promotes Stronger Bones than Calcium Alone

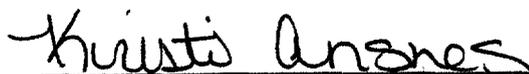
Studies have shown that taking Phosphorus along with Calcium promotes stronger bones than calcium alone in healthy people. Phosphorus assists the body in retaining Calcium, while Vitamin D helps increase the absorption of both Calcium and Phosphorus. Regular exercise and a healthful diet with adequate calcium are essential in achieving peak bone mass in teenagers and young adults and maintaining bone health during adulthood. Individuals who do not store enough calcium throughout their lives have an increased risk for developing osteoporosis. While adequate calcium intake is important, daily intakes above 2000 mg are not likely to provide any additional benefit.

on the following product:

Your Life® Calcium, Phosphorus with Vitamin D

Very truly yours,

Leiner Health Products



Kristi Ansnes
Regulatory Affairs Associate

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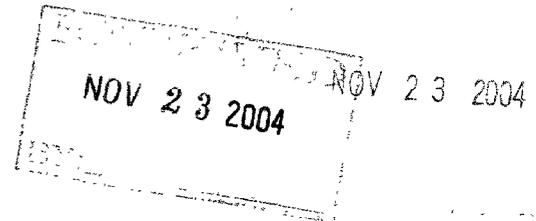
Nature's Origin®
NATURE'S VALLEY™
NATURITE®
NUTRA CHOICE
NUTRI-BLEND
Oscor®
PHARMACIST FORMULA®
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Calcium intake is critical for supporting bone health. Regular exercise and a healthful diet with adequate calcium are essential in achieving peak bone mass in teenagers and young adults and maintaining bone health during adulthood. Individuals who do not store enough calcium throughout their lives have an increased risk for developing osteoporosis. Extra strength coral calcium provides rich trace minerals from fossilized stony coral and mineral plant life. Extra strength coral calcium supports healthy bones and teeth, and promotes heart, nerve and muscle function.

on the following product:

Your Life® Coral Calcium

Very truly yours,

Leiner Health Products

A handwritten signature in cursive script that reads 'Kristi Ansnes'.

Kristi Ansnes
Regulatory Affairs Associate

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