



NOV - 7 1997

0825 '97 DEC 16 P1:44

Gale Bensussen  
President  
Leiner Health Products  
901 E. 233rd Street  
Carson, California 90745-6204

Dear Ms. Bensussen:

This is in response to your letter of October 10, 1997 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that Leiner Health Products is making the following claims, among others, for point of purchase labeling:

- "...prevent LDL cholesterol from oxidizing (causing arteries to clog)"
- "...stops excessive muscle-cell formation in damaged arteries..."
- "...reduce the progression of a common knee joint affliction"
- "...may help the bones maintain their shape despite the wearing away of cartilage"
- "...maintaining normal urinary flow in many men over 50"
- "...adding potassium to the diet of African-American participants appears to help regulate blood pressure"
- "a daily dose of 1.5 grams nicotinic acid --a form of niacin -- increased "good" cholesterol levels by 20 percent"
- "Problems in pregnancy for women with high blood pressure were lower for those whose diets were rich in magnesium"
- "incidence was lower for nighttime leg cramps for those pregnant women whose diets were rich in magnesium"
- "...confer a sense of well-being in older persons with blood sugar problems" and "...led to better blood sugar balance."
- "Chinese herbalists commonly prescribe ginseng for relief from hot flashes. Some women report that hot flashes are less frequent and intense when ginseng is taken."
- "...offset the distresses which cause stomach discomfort from motion"
- "...a report in the Annals of Internal Medicine showing that cholesterol levels decreased by an average of 9%..."
- "garlic helps reduce cholesterol levels"
- "regular use of cranberry beverage (300 ml per day) reduces the incidence of urinary tract problems in older women"

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Section 403(r)(6) of the act 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 quoted above suggest that the products for which these claims are made in their labeling are intended to treat, cure, mitigate, or prevent disease. These claims do not meet the requirements of section 403(r)(6) of the act. These claims suggests that the products for which these statements are made in their labeling are intended for use as drugs within the meaning of section 201(g)(1)(B) of the act, and that the products 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.

Your submission also states that you are making the following claims on point of purchase labeling:

“Osteoporosis, a bone crippling disease, affects 25 million Americans, 80% are women and 20% (5 million) are men. Calcium and vitamin D are essential for protecting bones”

“The incidence of osteoporosis is expected to rise. The National Osteoporosis Foundation advises men younger than 65 to consume 1,000 mg of calcium daily and over 65 to consume 1,500 mg of calcium daily”

“Studies in women have shown that calcium supplements can reduce bone loss in the hand and arm as much as 50% and have a beneficial effect on the spine”

“In a two-year study at the Nutrition Center on Aging at Tufts, researchers found that postmenopausal women who consumed about 8000 I.U. of vitamin D daily had less than half as much hip bone loss as those who consumed only 200 I.U. daily”

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 section 403(r)(1)(B) of the act. 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 section 201(g)(1)(B) of the act because the product is intended to treat, cure, prevent, or mitigate a disease, osteoporosis.

Page 3 - Ms. Gale Bensussen

Furthermore, FDA has not authorized a health claim for a relationship between vitamin D and osteoporosis. The use of an unauthorized health claim on the label or in the labeling of a food or dietary supplement is a drug claim under section 201(g)(1)(B) of the act because it evidences that the product is intended to treat, cure, prevent, or mitigate osteoporosis.

Please contact us if we may be of further assistance.

Sincerely yours,

James T. Tanner, Ph.D.  
Acting Director  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals  
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, Los Angeles District Office, Compliance Branch, HFR-PA240



RECEIVED  
FEDERAL BUREAU OF INVESTIGATION  
U.S. DEPARTMENT OF JUSTICE

UNITED STATES  
FEDERAL BUREAU OF INVESTIGATION  
U.S. DEPARTMENT OF JUSTICE

NOV 20 1997

0826 '97 DEC 16 P1:44

October 10, 1997

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 "C" Street S.W.  
Washington, D.C. 20204

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 statements on point of purchase labeling:

*Tufts University Diet & Nutrition Letter. October 1996.*

**In a two-year study at the Nutrition Center on Aging at Tufts, researchers found that postmenopausal women who consumed about 8000 I.U. of vitamin D daily had less than half as much hip bone loss as those who consumed only 200 I.U. daily.**

*Tufts University Diet & Nutrition Letter. December 1996.*

**Boston researchers found in an eight-year study that levels approaching twice the RDA of vitamin D may also help reduce the progression of a common knee joint affliction. Precisely how is yet undetermined; it may help maintain the integrity of the knee cartilage or it may help the bones maintain their shape despite the wearing away of cartilage.**

on the following nutrient:

**Vitamin D**

Very truly yours,

**LEINER HEALTH PRODUCTS**

Gale Bensussen, President

cc: Michael Bradley, Director of Regulatory Affairs  
William Cochran, Regulatory Affairs

5309



SELF  
NOTICE

901 E. 24th Street  
Carson, California  
90746-9111  
408-272-0100  
© 1997 LEINER

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October 10, 1997

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 "C" Street S.W.  
Washington, D.C. 20204

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 statements on point of purchase labeling:

*Harvard Health Letter.* November 1996.

**There is a good reason for researchers to suspect that vitamin E may play a role in heart health. As an antioxidant, vitamin E's role is to prevent LDL cholesterol from oxidizing (causing arteries to clog). This article also reports that vitamin E stops excessive muscle-cell formation in damaged arteries and keeps blood clotting in check.**

**Researchers at Tufts University found that 200-800 I.U. of supplemental vitamin E per day consumed by elderly people may support the immune system.**

*New England Journal of Medicine.* May 20, 1993.

**Two large Harvard University epidemiologic studies show a strong association between a high intake of Vitamin E and heart health.**

**Researchers are putting recommendation of vitamin E supplementation on hold pending results from randomized, controlled trials currently testing the value of vitamin E supplementation.**

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Office of Special Nutritionals (HFS-450)  
October 10, 1997  
Page 2

*Lancet*. March 23, 1996.

**The Cambridge Anti-Oxidant Study (CHAOS) examined 2,000 patients over 18 months. The results indicate that vitamin E 400-800 I.U. supplementation may be beneficial for heart health.**

on the following nutrient:

**Vitamin E**

Very truly yours,

**LEINER HEALTH PRODUCTS**

Gale Bensussen, President

cc: Michael Bradley, Director of Regulatory Affairs  
William Cochran, Regulatory Affairs



OFFICE OF SPECIAL NUTRITIONALS

900 L Street  
Carson, California  
90745-0001  
Tel: (310) 590-3000  
Fax: (310) 590-3001

October 10, 1997

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Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 "C" Street S.W.  
Washington, D.C. 20204

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 statements on point of purchase labeling:

**Contributes to prostate well being.**

**Regular use of Saw Palmetto extract can play an important part in maintaining normal urinary flow in many men over 50.**

on the following nutrient:

**Saw Palmetto**

Very truly yours,

**LEINER HEALTH PRODUCTS**

Gale Bensussen, President

cc: Michael Bradley, Director of Regulatory Affairs  
William Cochran, Regulatory Affairs

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REF  
OFF  
NUTR

901 E. 12th Street  
Carson, California  
90745-1000  
415-203-1000  
FAX: 415-203-1001

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0829 '97 DEC 16 P1:44

October 10, 1997

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 "C" Street S.W.  
Washington, D.C. 20204

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 statements on point of purchase labeling:

*Archives of Internal Medicine.* January 8, 1996  
**In a study at John Hopkins, adding potassium to the diet of African-American participants appears to help regulate blood pressure.**

on the following nutrient:

**Potassium**

Very truly yours,

**LEINER HEALTH PRODUCTS**

Gale Bensussen, President

cc: Michael Bradley, Director of Regulatory Affairs  
William Cochran, Regulatory Affairs

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RECEIVED  
OFFICE OF SPECIAL  
NUTRITIONALS

DATE RECEIVED  
CLASSIFICATION  
REGISTRATION NO.  
EXPIRES

'97 OCT 20 2 11

October 10, 1997

0830 '97 DEC 16 P1:44

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 "C" Street S.W.  
Washington, D.C. 20204

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 statements on point of purchase labeling:

*Archives of Internal Medicine*. May 27, 1996.

**A study conducted at the University of Texas Southwestern Medical Center found a daily dose of 1.5 grams nicotinic acid -- a form of niacin -- increased "good" cholesterol levels by 20 percent.**

on the following nutrient:

**Niacin**

Very truly yours,

**LEINER HEALTH PRODUCTS**

Gale Bensussen, President

cc: Michael Bradley, Director of Regulatory Affairs  
William Cochran, Regulatory Affairs

55300



OFFICE OF SPECIAL NUTRITIONALS  
FEDERAL FOOD, DRUG AND COSMETIC ACT

PRELIMINARY  
CONSULTATION  
NOTICE

'97 OCT 20 P 4:44

October 10, 1997

0831 '97 DEC 16 P1:44

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 "C" Street S.W.  
Washington, D.C. 20204

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 statements on point of purchase labeling:

*New England Journal of Medicine.* July 27, 1996.  
**Problems in pregnancy for women with high blood pressure were lower for those whose diets were rich in magnesium.**

*American Journal of Obstetrics and Gynecology.* July 1995.  
**In a study conducted in Sweden, the incidence was lower for nighttime leg cramps for those pregnant women whose diets were rich in magnesium.**

on the following nutrient:

**Magnesium**

Very truly yours,

**LEINER HEALTH PRODUCTS**

  
Gale Bensussen, President

cc: Michael Bradley, Director of Regulatory Affairs  
William Cochran, Regulatory Affairs

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2025-11-19 15:00  
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October 10, 1997

0832 '97 DEC 16 P1:44

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 "C" Street S.W.  
Washington, D.C. 20204

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 statements on point of purchase labeling:

*Diabetes Care.* October 1995.

**Ginseng has been shown to elevate mood, increase energy, and confer a sense of well-being in older persons with blood sugar problems. This tended to support positive lifestyle changes, which in turn led to better blood sugar balance.**

*Primary Care of the Mature Woman.* June 1994.

**Chinese herbalists commonly prescribe ginseng for relief from hot flashes. Some women report that hot flashes are less frequent and intense when ginseng is taken.**

on the following nutrient:

**Ginseng**

Very truly yours,

**LEINER HEALTH PRODUCTS**

Gale Bensussen, President

cc: Michael Bradley, Director of Regulatory Affairs  
William Cochran, Regulatory Affairs

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REC-11  
C/F  
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9011 21st St  
Carson, California  
90745-0913  
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Fax: 410-614-0317

'97 OCT 20 P 11

October 10, 1997

0833 '97 DEC 16 P1:44

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 "C" Street S.W.  
Washington, D.C. 20204

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 statements on point of purchase labeling:

**Ginger is a root which has worldwide usage as an aid to normal digestive activity. As a supplement, its unique aromatic compounds can help to offset the distresses which cause stomach discomfort from motion.**

**Standardized extracts use marker ingredients to help ensure that the proper ingredients needed for the herbs functions are present at the level required to provide that function.**

on the following nutrient:

**Ginger**

Very truly yours,

**LEINER HEALTH PRODUCTS**

Gale Bensussen, President

cc: Michael Bradley, Director of Regulatory Affairs  
William Cochran, Regulatory Affairs

55311



OFFICE OF SPECIAL NUTRITIONALS

DATE: 10/10/97  
TIME: 10:44 AM  
BY: [illegible]

'97 OCT 20 P 11

October 10, 1997

0834 '97 DEC 16 P1:44

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 "C" Street S.W.  
Washington, D.C. 20204

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 statements on point of purchase labeling:

*The Johns Hopkins Medical Letter Health After 50.* August 1994.  
Collecting data from five previous studies, researchers at New York Medical College published a report in the *Annals of Internal Medicine* showing that cholesterol levels decreased by an average of 9% among those participants taking garlic supplements compared to those taking placebos (dummy substances)

Research indicates that consumption of garlic helps reduce cholesterol levels.

Scientific studies suggest that frequent inclusion of garlic in the diet may offer another means to help maintain good health.

on the following nutrient:

**Garlic**

Very truly yours,

**LEINER HEALTH PRODUCTS**

Gale Bensussen, President

cc: Michael Bradley, Director of Regulatory Affairs  
William Cochran, Regulatory Affairs

55311



UNITED STATES  
DEPARTMENT OF  
HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

991 E. 13th Street  
Carson, California  
90745-6004  
Telephone: (310) 591-3000

'97 OCT 20 9 47

0835 '97 DEC 16 P1:44

October 10, 1997

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 "C" Street S.W.  
Washington, D.C. 20204

**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 statements on point of purchase labeling:

*Journal of the American Medical Association.* March 9, 1994

**In a 6-month study of 153 elderly women, researchers concluded that regular use of cranberry beverage (300 ml per day) reduces the incidence of urinary tract problems in older women. The effect appeared after 4 to 8 weeks of using the beverage.**

**Cranberry juice has been used historically to help maintain normal function of the urinary tract.**

**Constituents naturally present in cranberries minimize undesirable adhesions to the wall of the bladder.**

on the following nutrient:

**Cranberry**

Very truly yours,

**LEINER HEALTH PRODUCTS**

Gale Bensussen, President

cc: Michael Bradley, Director of Regulatory Affairs  
William Cochran, Regulatory Affairs

55311



OFFICE OF  
SPECIAL  
NUTRITIONALS

UNITED STATES  
FOOD & DRUG  
ADMINISTRATION  
WASHINGTON, DC

October 10, 1997

97 OCT 20 2:44

0836 '97 DEC 16 P1:44

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 "C" Street S.W.  
Washington, D.C. 20204

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 statements on point of purchase labeling:

*Harvard Health Letter.* September 1996  
Osteoporosis, a bone crippling disease, affects 25 million Americans, 80% are women and 20% (5 million) are men. Calcium and vitamin D are essential for protecting bones.

*Tufts University Diet & Nutrition Letter.* November 1996.  
The incidence of osteoporosis is expected to rise. The National Osteoporosis Foundation advises men younger than 65 to consume 1,000 mg of calcium daily and over 65 to consume 1,500 mg of calcium daily.

*The Johns Hopkins Medical Letter.* August 1994.  
Studies in women have shown that calcium supplements can reduce bone loss in the hand and arm as much as 50% and have a beneficial effect on the spine.

on the following nutrient:

**Calcium**

Very truly yours,

**LEINER HEALTH PRODUCTS**

Gale Bensussen, President

cc: Michael Bradley, Director of Regulatory Affairs  
William Cochran, Regulatory Affairs

55309