



AUG 18 2004

William Cochran  
Manager of Regulatory Affairs  
Leiner Health Products  
901 E. 233<sup>rd</sup> Street  
Carson, California 90745-6204

Dear Mr. Cochran:

This is in response to your letters of May 17, 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 letters state that the following statements will made for the following products:

YourLife Advanced Strength  
Odor Controlled Garlic  
YourLife Evening Primose Oil

“[R]egulate cholesterol levels”  
“Natural source of gamma linolenic acid...influence...blood pressure....”

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. The same principle applies to claims about the control of blood pressure; that is, a claim that does not establish that the claims are about blood pressure that is already within normal limits implies that the product is intended to treat elevated blood pressure (hypertension), which is a disease. Therefore, because the claims you are making for these products represent that the products are intended to affect blood cholesterol and blood pressure but do not also include a statement about them being intended to affect blood cholesterol and blood pressure that are already in the normal ranges, they are implied disease claims.

You also submitted a notification for the product YourLife Soy Isoflavones stating that it would use the claim “[M]ay help offset bone loss associated with during the transition into menopause.” This is an implied disease claim to treat osteoporosis, a disease.

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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, 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, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'S. Walker', with a long horizontal flourish extending to the right.

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-PA240



May 17, 2004

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



**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:

**Helps Maintain a Healthy Heart & Regulate Cholesterol**

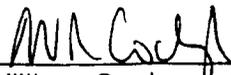
**Clinical research has shown that consumption of garlic may help promote healthy heart function and regulate cholesterol levels. The enteric coating may help the Garlic to fully absorb in the intestine where the beneficial ingredients in garlic can best help regulate heart health.**

on the following product:

**YourLife® Advanced Strength Odor Controlled Garlic**

Very truly yours,

**Leiner Health Products**

  
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William Cochran, Manager of Regulatory Affairs

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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™  
Sav-on™  
Shaw's  
ShopKo®  
Spring Valley®  
TARGET®  
TOP CARE®  
TRUNATURE®  
Wegmans®



May 17, 2004

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

5/24/04

**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:

**PMS Support**

The Evening Primrose is native to North America and has been used in herbal medicine for centuries. The flowers produce large quantities of small brown seeds from which nutrient-rich oil is extracted. The oil is a natural source of Linoleic Acid (LA) and Gamma Linolenic Acid (GLA). LA is an essential fatty acid, and GLA is a specialized omega-6 fatty acid. Evening Primrose Oil may help the body to regulate the hormone-like compounds associated with premenstrual conditions.

NATURAL SOURCE OF GAMMA LINOLENIC ACID (GLA) GLA may regulate the nervous system and influence many critical body functions such as the reproductive cycle, blood pressure, and blood clotting. LINOLEIC ACID (LA) An essential fatty acid, must be present in the diet to maintain health.

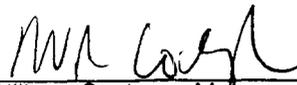
EPO may be beneficial for breast discomfort.  
EPO may support hormonal balance which promotes a healthy, balance mood.  
EPO may support normal fluid balances during the monthly cycle.

on the following product:

**YourLife® Evening Primrose Oil**

Very truly yours,

**Leiner Health Products**

  
\_\_\_\_\_  
William Cochran, Manager of Regulatory Affairs

88429



Office of Nutritional Products,  
Labeling and Dietary Supplements (HFS-810),  
Food and Drug Administration  
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ECKERD®  
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KIRKLAND Signature™  
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NUTRI-BLEND  
Oscor®  
PHARMACIST FORMULA®  
BODYCOLOGY™  
SAFEWAY SELECT™  
Sav•on™  
Shaw's  
ShopKo®  
Spring Valley®  
TARGET®  
TOP CARE®  
TRUNATURE®  
Wegmans®



May 17, 2004

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

5/24/04

**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:

**Menopause Support**

**Studies suggest that soy isoflavones may promote optimal hormonal balance, help relieve hot flashes and night sweats and may help offset bone loss associated with during the transition into menopause. Additionally scientists believe that soy isoflavones are the main contributors to heart health benefits of soy protein.**

on the following product:

**YourLife® Soy Isoflavones**

Very truly yours,

**Leiner Health Products**

A handwritten signature in black ink, appearing to read 'W. Cochran', is written over a horizontal line.

William Cochran, Manager of Regulatory Affairs

88429

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:

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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™  
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NUTRI-BLEND  
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SAFEWAY SELECT™  
Sav-on™  
Shaw's  
ShopKo®  
Spring Valley®  
TARGET®  
TOP CARE®  
TRUNATURE®  
Wegmans®