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5/24/04

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.

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.

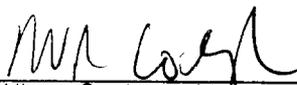
EPO may support hormonal balance which promotes a healthy, balance mood.
EPO may support normal fluid balances during the monthly cycle.

on the following product:

YourLife® Evening Primrose Oil

Very truly yours,

Leiner Health Products



William Cochran, Manager of Regulatory Affairs

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Office of Nutritional Products,
Labeling and Dietary Supplements (HFS-810),
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®