



September 30, 2004

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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
5100 Paint Brush Pkwy.
College Park, MD 20740

OCT 18 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:

PMS Support

GLA may regulate the nervous system and influence may critical body functions such as the reproductive cycle. It may also help retain already normal healthy blood pressure.

Linoleic Acid (LA), an essential fatty acid, must be present in the diet to maintain health.

Evening Primrose Oil may be beneficial for breast discomfort

Evening Primrose Oil may support hormonal balance which promotes a healthy, balanced mood

Evening Primrose Oil may support normal fluid balances during the monthly cycle

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 the body to regulate the hormone-like compounds associated with premenstrual conditions.

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on the following product:

YourLife® Evening Primrose Oil

Very truly yours,

Leiner Health Products

Kristi Ansnes
Regulatory Affairs Associate



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