



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

MAY 24 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:

Provides Relief of PMS Symptoms

PMS Formula with Indolplex® contains the first and only stable, bioavailable form of DIM (Diindolylmethane) to help support healthy estrogen metabolism. In addition, it features chaste tree berry extract to support the production of progesterone; calcium, magnesium, and vitamin D, which play synergistic roles in supporting health during PMS; and iodine for healthy thyroid function.

on the following product:

YourLife® PMS Symptom Free

Very truly yours,

Leiner Health Products

A handwritten signature in black ink, appearing to read 'W Cochran'.

William Cochran, Manager of Regulatory Affairs

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