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November 19, 2004

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

NOV 23 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:

**Daytime Relief: lack of energy, hot flashes, irritability, mood swings**  
**Nighttime Relief: occasional sleeplessness, night sweats, hot flashes**

**24-hour Relief of Menopause Symptoms**  
**AM/PM Menopause Formula™ is the only natural AM/PM product you can buy that has our unique natural formula to relieve the common menopause symptoms you may experience during the day and at night. AM Formula features standardized ginseng and green tea to give you daytime energy. PM Formula offers theanine and valerian to help you sleep better. Both include time-tested black cohosh for relief of hot flashes, night sweats, and irritability.**

on the following product:

**Your Life® AM/PM Menopause Formula**

Very truly yours,

**Leiner Health Products**

*Kristi Ansnes*

Kristi Ansnes  
Regulatory Affairs Associate

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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®