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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:

**Helps Reduce Hot Flashes & Night Sweats**  
**A natural approach to relieving menopausal symptoms**

**Extra Strength estro Vital Nutrients™ supplies a more complete natural approach to relieving menopausal symptoms, providing:**

- **Black Cohosh and Isoflavones are natural sources of phytoestrogens that help reduce hot flashes and night sweats. Benefits backed by clinical research.**
- **Isolase™ enzymes help increase isoflavone absorption**
- **Stress reducing herbal blend may help even out mood swings, reduce irritability and improve mental clarity**
- **Calcium develops healthy bones**
- **Vitamin B-6, E and folic acid to promote heart health**

on the following product:

**Extra Strength estro Vital Nutrients™**

Very truly yours,

**Leiner Health Products**

Kristi Ansnes  
Kristi Ansnes  
Regulatory Affairs Associate

975 0162 LET 14931



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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®