



901 E. 233rd Street  
Carson, California  
90745-6204  
310/835-8400  
Fax 310/835-6615

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

**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:

**Supports Healthy Mood and Emotional Well-Being  
Promotes Joint Health, Mobility and Comfort  
Supports Liver Health**

**SAM-e is a natural compound present in all living cells and is involved in many important biochemical reactions in the body.  
SAM-e helps to maintain healthy mood and emotional well-being.  
SAM-e helps to promote healthy cartilage formation which may enhance joint comfort and mobility.  
SAM-e helps to support a healthy liver.**

on the following product:

**Your Life® SAM-e 400 mg**

Very truly yours,

**Leiner Health Products**

A handwritten signature in cursive script that reads 'Kristi Ansnes'.

Kristi Ansnes  
Regulatory Affairs Associate

97S 0162

LET 14938



Office of Nutritional Products,  
Labeling and Dietary Supplements (FIFs-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®