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December 11, 2003

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 "C" Street SW  
Washington, DC 20204

JAN 12 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:

**Heart Health Benefits and Enhanced Antioxidant Protection**

**Vitamin E is one of the most widely accepted vitamins available. Clinical studies demonstrate proven antioxidant abilities in protecting cells against free radical damage for normal heart function. Scientific literature suggests that Alpha Lipoic Acid is a versatile antioxidant that may provide benefits in three ways: 1. Alpha Lipoic Acid can protect key antioxidants, such as vitamin E and vitamin C, in the body. This protection may allow antioxidants to retain more of their power and may give the body more sustained nutritional defense. 2. Alpha Lipoic Acid's metabolic action may help energize cells to stay at their peak. 3. Alpha Lipoic Acid is universally soluble, to act both in and outside the cell for added antioxidant protection. Vitamin E is a powerful antioxidant which helps prevent damage to the cells and supports heart cell health. Alpha Lipoic Acid is an antioxidant with metabolic activity that can help repower and protect antioxidants (Vitamin C and Vitamin E) for sustained cell protection. Rice Bran Oil is a natural source of Tocotrienols (Vitamin E-like compounds) for enhanced antioxidant activity.**

on the following product:

**YourLife® Advanced E with Alpha Lipoic Acid**

Very truly yours,

**Leiner Health Products**

William Cochran, Manager of Regulatory Affairs

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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™  
*Savon™*  
*Shaw's*  
*ShopKo®*  
Spring Valley®  
TARGET®  
TOP CARE®  
TRUNATURE®  
Wegmans®