



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

RECEIVED  
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:

**Mood Enhancer**

**St. John's Wort is one of the most popular and widely used herbs in Europe. Hypericin, the active ingredient in St. John's Wort, may inhibit the breakdown of specific neurotransmitters and may lead to a feeling of mood elevation.**

on the following product:

**YourLife® St. John's Wort**

Very truly yours,

**Leiner Health Products**

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

William Cochran, Manager of Regulatory Affairs

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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  
Osco®  
PHARMACIST FORMULA®  
BODYCOLOGY™  
SAFEWAY SELECT™  
Sav•on™  
*Shaw's*  
*ShopKo*®  
Spring Valley®  
TARGET®  
TOP CARE®  
TRUNATURE®  
Wegmans®