



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

March 14, 1997

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

0054 '97 SEP 19 P1:32

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:

**Relaxation**

**Kavalactones (the active compounds in kava) may result in a calming feeling which may result in a calming feeling which may promote a relaxing effect on the body.**

**Kavalactones act as muscle relaxants that in some people promotes a feeling of serenity.**

on the following product(s):

**Your Life® Kava Kava**

Very truly yours,

**LEINER HEALTH PRODUCTS**

Gale Bensussen  
President

975-0162

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