



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

July 1, 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

JUL 11 1997

0200 '97 SEP 19 P1:50

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 statements:

**Relaxation**

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

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

on the following product:

**Your Life® Kava Kava**

Very truly yours,

**LEINER HEALTH PRODUCTS**

Gale Bensussen, President

cc: Michael Bradley, Director of Regulatory Affairs  
William Cochran, Regulatory Affairs

975-0162

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