



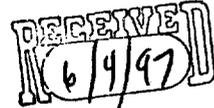
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May 27, 1997

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

Section 403(r)(6) Notification

0162 '97 SEP 19 P1:45



Dear Sir or Madam:

In response to the courtesy letter received on November 19, 1996 from the FDA, suggesting that our previous statement for this product was a drug claim, **LEINER HEALTH PRODUCTS** notifies FDA that it is resubmitting the following restructured statement in accordance with the requirements of section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act:

**Supports Immune System**

**Animal and laboratory studies show that echinacea stimulates the body's own defenses. Scientists discovered that alkaloids like those found in goldenseal help to maintain normal mucous production. These beneficial herbs have been traditionally used during the winter months.**

on the following product:

**Your Life® Echinacea & Goldenseal**

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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