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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

0160 '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 statements in accordance with the requirements of section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act:

**Uterine Health**

**In traditional Asian medicine, Dong Quai is an important herbal tonic for women. Dong Quai, with its aromatic compounds, coumarins and essential oils has long been used to help maintain uterine muscle tone and strength. Dong Quai is a traditionally used herb associated with the monthly cycle.**

on the following product:

**Your Life® Dong Quai**

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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