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January 13, 1998

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

Section 403(r)(6) Notification

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:

Helps Regulate Cholesterol

Research indicates that consumption of garlic helps regulate cholesterol levels, as well as maintain normal blood pressure levels. Scientific studies suggest that the frequent inclusion of garlic in the diet may offer another means to help maintain good health.

on the following product:

Your Life® Daily Garlic

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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