



August 10, 1998

1703 '98 SEP -3 P2:14

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

9/24/98

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:

Digestive Enzyme

Papaya is known for its ability to aid digestion. Papain, a naturally occurring proteolytic enzyme, is found in papaya fruit. It has been historically used to support the digestive process.

on the following products:

**YourLife® Chewable Papaya
Safeway® Chewable Papaya**

Very truly yours,

Leiner Health Products

A handwritten signature in cursive script, appearing to read 'Gale Bensussen', written over a horizontal line.

Gale Bensussen, President

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