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July 8, 2002

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 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:

Blocks Calories from Bread, Pasta, Potatoes & Other Starchy Foods

Starch Away™ is a new diet aid that's safe, natural and easy: Just take 1-2 delicious citrus soft chews a few minutes before a meal that contains a "starch" (bread, potatoes, pasta, grain – even French fries contain starch) and you can block the digestion of starch calories.

**Starch Away™** is also a perfect alternative for people who want to follow an all protein diet, but don't want to give up starch.

Starch Away™ is safe and stimulant free (contains no ephedra or caffeine). Starch Away™ is NOT an appetite suppressant or meal replacement. It's a whole new approach to dieting!

**Starch Away™** contains Phaseolamin, an active natural ingredient that inhibits amylase from converting starch to sugar, thereby blocking the body's intake of starch carbohydrate calories. Without the starch-to-sugar conversion, the starch is safely eliminated from the body before it is converted to sugar and can be stored as fat.

on the following product:

Starch Away™

Very truly yours,

Leiner Health Products

William Cochran, Manager of Regulatory Affairs

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