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July 29, 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:

**Daytime Relief: lack of energy, hot flashes, irritability, mood swings**  
**Nighttime Relief: occasional sleeplessness, night sweats, hot flashes**

**24-hour Relief of Menopause Symptoms**

**AM/PM Menopause Formula™ is the only natural AM/PM product you can buy that has our unique natural formula to relieve the common menopause symptoms you may experience during the day and at night.**

**AM Formula features standardized ginseng and green tea to give you daytime energy.\* PM Formula offers theanine and valerian to help you sleep better.\* And both include time-tested black cohosh for relief of hot flashes, night sweats, and irritability.**

on the following product:

**Menopause Formula™**

Very truly yours,

**Leiner Health Products**

  
William Cochran, Manager of Regulatory Affairs

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