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July 20, 1998

Office of Special Nutritionals (HFS-450) 8993 '98  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 "C" Street SW  
Washington, DC 20204

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8/3/98

**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:

**Women's Herbal Support for Estrogen Balance**

**Black Cohosh is a perennial herb native to eastern North America with a long history in traditional Chinese use as well as European acceptance. Black Cohosh is a key herb that affects estrogen balance. Research suggests that women as they age may benefit from Black Cohosh. It has been used traditionally to help support normal menstrual cycles in women of childbearing years.**

on the following product:

**YourLife® Black Cohosh Tablets**

Very truly yours,

**Leiner Health Products**

  
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Gale Bensussen, President

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

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