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1550 '98 OCT -6 P2:59

September 22, 1998

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

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OCT - 2 1998

**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:

**Promotes Healthy Brain Function**

DHA (Docosahexaenoic Acid) is naturally produced by the body, but may require supplementation to reach proper levels. DHA is required for normal brain development and is the primary structural fatty acid in the gray matter of the brain and retina of the eye. DHA is necessary for proper mental and visual functioning. Research suggest that DHA may be important for signal transmissions among cells in the brain, eye and nervous system.

In the United States DHA levels can be low as a result of poor dietary habits. DHA dietary supplement may help raise DHA levels in the blood when taken regularly on the following product:

on the following products:

**YourLife® DHA**  
**Safeway® DHA**

Very truly yours,

**Leiner Health Products**

  
Gale Bensussen, President

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