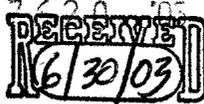




Shaklee Corporation  
Forrest C. Shaklee Research Center



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24 June 2003

Office of Special Nutritionals (HFS-810)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

**Re: Section 403(r)(6) Notification**

Dear Sir or Madam:

In accordance with the requirements of section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act, Shaklee Corporation hereby notifies FDA that it has begun using the following statements:

- Cholesterol Regulation Complex (product name)
- Helps retain normal cholesterol levels
- Promotes cardiovascular health
- Supports heart health
- Helps inhibit absorption of dietary cholesterol
- In a clinical study, the phytopeptides and phospholipids in Cholesterol Regulation Complex increased HDL ("good") cholesterol by 26% after two months and 37% after three months
- Increases HDL cholesterol levels
- Cholesterol Regulation Complex can help you retain normal cholesterol levels, along with a low-fat diet and exercise.
- N-acetylcysteine supports the body's natural antioxidant defenses, which help prevent LDL oxidation.

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- N-acetylcysteine contributes a key precursor for the production of glutathione, a powerful antioxidant that helps protect against oxidative stress.
- Does not interrupt production of Coenzyme Q<sub>10</sub>, a nutrient important to heart health because it helps cells produce energy

which contain the statutory statement, on the label and labeling for the following product:

**Cholesterol Regulation Complex Dietary Supplement**

I certify that the foregoing is complete and accurate, and that Shaklee Corporation has substantiation that the statements are truthful and not misleading.

Sincerely,



Jack Hegenauer, Ph. D.  
Director,  
Innovation & Health Sciences

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