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August 12, 2005

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OFFICE OF SPECIAL NUTRITIONAL PRODUCTS  
LABELING AND DIETARY SUPPLEMENTS  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration (HFS 800)  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

RE: Notification for Certain Types of Statements on Dietary Supplements

Dear Sir or Madam:

As required by Section 403(r)(6)(c) of the Food, Drug and Cosmetic Act, Pharmanex, LLC, 75 West Center Street, Provo, Utah 84601, intends to market a dietary supplement product with the following label and marketing statements on nutritional support:

Product: Cholestin® with Lipidol

Statements:

- Helps maintain existing normal cholesterol levels
- Helps maintain cholesterol levels already in the normal range
- Targets multiple steps in the pathway of cholesterol synthesis
- Lipidol™ offers a unique blend of constituents for cholesterol management
- Promotes healthy cardiovascular function

I certify that the information contained in this notice is complete and accurate and that Pharmanex, LLC, has substantiation that these statements are truthful and not misleading.

Sincerely,

Doug Burke, Ph.D.  
Research Analyst  
Pharmanex, LLC

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