



**Zenith Goldline**  
P H A R M A C E U T I C A L S

**Regulatory Affairs**

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November 1, 2000

Attention: Mr. John B. Foret, Director  
Division of Compliance and Enforcement  
Office of Special Nutritionals  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street, SW (HFS-450)  
Washington, D.C. 20204

Dear Mr. Foret:

We acknowledge receipt of your letter in response to our correspondence, referencing Section 6 of the Dietary Supplement Health and Education Act of 1994. Alternative language was reviewed with Ms. Linda McCollum of your division and considered acceptable; therefore, we wish to advise that we will be revising our labeling at next printing.

This letter will serve as a 30 day notification pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 that Zenith Goldline Pharmaceuticals, Inc. intends to use using the following statement on our Cholesterol Formula Tablets, Evening Primrose Oil Softgels, Fish Oil Concentrate Softgels, Garlic Oil Softgels and Green Tea Extract softgels supplements under one or more of the following brand names:

“Goldline”, “Goldline Naturals™”, “PharmaSelect”:

Helps maintain cholesterol levels that are already within the healthy range

The above statement will be accompanied by the required disclaimer pursuant to Section 6 of the Dietary Supplement Health and Education Act.

Sincerely,

Karen A. Rocco, RAC  
Director, Global Regulatory Affairs

KAR/  
Attachment

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