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 www.Jarrow.com

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RECEIVED  
 6/14/03

May 28, 2003

Food and Drug Administration  
 Center for Food Safety and Applied Nutrition  
 Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-810)  
 5100 Paint Branch Parkway  
 College Park, Maryland 20740  
 Reference phone #301-436-2373

Dear CFSAN:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section of 101.93 of FDA's regulations, we hereby notify you that we are using the following statement(s):

**(1) Name of Address of distributor:**

Jarrow Formulas, 1824 South Robertson Blvd., Los Angeles, CA 90035

**(2) Text of the statement(s):**

CholesTame<sup>TM</sup> is a comprehensive combination of nutrients that affect cholesterol metabolism.

Policosanols are a family of aliphatic alcohols found in rice bran wax and they affect cholesterol biosynthesis in the liver. Plant Sterols are known to interfere with the absorption of dietary cholesterol by blocking cholesterol receptor sites. CholesTame<sup>TM</sup> supplies 30 mg of Co-Q10 per serving because Policosanols may reduce the body's biosynthesis of Coenzyme Q10. Artichoke leaf extract is rich in cynarines which supports the actions of policosanols. Alpha Lipoic Acid (ALA), Grape Seed and Taurine provide antioxidant protection against free radicals, particularly against oxidation of cholesterol, and supports the metabolism of lipoproteins. ALA also supports glucose metabolism by promoting glucose uptake into cells. Guggul is an Ayurvedic extract that improves HDLs. Pantethine is involved in lipid and carbohydrate metabolism by supporting the synthesis of Coenzyme A. Lutein is an effective carotenoid antioxidant that is important for protecting HDLs.

As part of a regimen that includes a diet low in saturated fat and high in fiber and vegetables plus physical exercise, CholesTame's formula promotes healthy cholesterol metabolism and healthy HDL levels.

**(3) Name of the dietary ingredient(s) if not provided in the text of the statement:**

Policosanols (*Rice bran wax*) (Derived from 45mg rice bran wax 22% extract) • Plant Sterols • Coenzyme Q10 (*Ubiquinone*) • Artichoke Leaf Extract (*Cynara scolymus*) (2% cynarine) • Alpha Lipoic Acid • Grape Seed Extract (*Vitis vinifera*) (95% polyphenols) • Pantethine (coenzyme vit. B5) • Lutein (*Tagetes erecta*) • Taurine

**(4) Name of the dietary supplement(s)**

Cholestame<sup>TM</sup> 90 tablets

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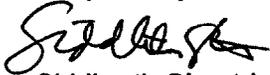
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**(5) The following disclaimer appears on the label in bold:**

**These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.**

These claims are limited to, and a result of, what we believe to be a substantial body of scientific evidence supporting the functional role of these nutrients.

Respectfully submitted,



Siddharth Shastri, CCN  
Vice President, Product Development