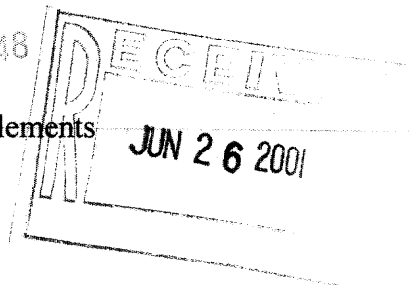




Mr. John B. Foret, Director 7089 '01 JUL 31 P2:48  
Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling and Dietary Supplements  
Center for Food Safety and Applied Nutrition  
Public Health Service  
Food and Drug Administration  
200 C Street SW  
Washington DC 20204



76553

June 19, 2001

Dear Mr. Foret:

This letter is to follow-up from our letter to you dated June 18, 2001. Thank you for bringing to our attention the verbiage of our original claim for one of our products, Colest-Oil. We have made necessary corrections and have enclosed a notification letter for the new claim that will appear on our new packaging for this item. Along with this letter for Colest-Oil, we have enclosed notification letters for five other products for your review.

Your time and assistance are greatly appreciated. We look forward to hearing any comments or suggestions you may have for us.

Sincerely,  
*Anna Tucci*  
Anna Tucci  
Executive Vice-President  
Aboca USA, Inc.

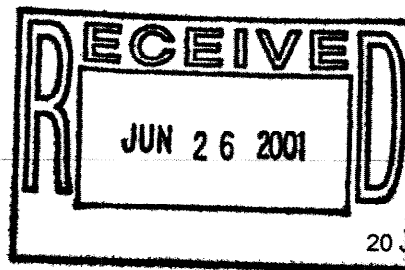
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Aboca USA, Inc.

126 South Spokane Street, Suite C • Seattle, WA 98134 • www.abocausa.com • Fax 206-624-7702 • 206-624-7542



Office of Special Nutritionals,  
 Center for Food Safety and Applied Nutrition,  
 Food and Drug Administration  
 200 C St. SW.  
 Washington DC - 20204



20 June 2001

Aboca USA Inc., located at 126 South Spokane Street/Suite C, Seattle – Washington 98134, submits the following notification of marketing in the United States of a dietary supplement imported from Italy. Aboca will sell the product to medical practitioners, primarily in the Pacific Northwest.

**NOTIFIES**

The marketing of the following Dietary Supplement:

**Brand Name:** COLEST-OIL  
**Presentation:** 60 Capsules 28.3 g  
**Name and address of the manufacturer:** Aboca S.s., Loc. Aboca 20, I-52037 Sansepolcro - ITALY  
**Name and address of the distributor:** Aboca USA Inc., 126 South Spokane Street/Suite C, Seattle Washington 98134

**TEXT OF THE STATEMENT:** **Helps to maintain cholesterol levels that are already within the normal range.**

**Text of the disclaimer:** This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent disease.

**DIETARY INGREDIENTS (Amount per Serving – 3 Capsules):**  
 Fish Oil 0.72 mg;  
 Guggul oleo-gum resin extract, (1:10) in flaxseed oil 0.33 mg;  
 Garlic bulb extract, (1:10) in flaxseed oil 0.11 mg;

**Other ingredients:** Gelatin (Capsule), essential oil of rosemary.

I Anna Tucci, Executive Vice-President and General Manager of Aboca USA, certify that all the information presented and contained in this notice is complete and accurate, and that Aboca USA has substantiation that the statement is truthful and not misleading.

*Anna Tucci*  
 Anna Tucci  
 Executive Vice-President  
 Aboca USA

76553

Colest-oil

Dietary Supplement

Colest-oil

Helps to maintain cholesterol level that are already within the normal range\*

Net Wt 1 oz (28.3 g) 60 Capsules



**WARNING:** Do not take if you are pregnant or nursing. For other contraindications and cautions, please consult your health care practitioner.

Keep out of reach of children

**MADE IN ITALY**

This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent disease.

Manufactured by:  
Aboca s.p.a. Loc. Aboca 20  
I-52037 Sansepolcro - Italy  
Distributed by:  
Aboca Usa Inc., 126 South Spokane  
Street/Suite C, Seattle - Washington  
98134 USA  
www.abocausa.com



**SUGGESTED USE:**  
Take 3 capsules with lunch and 3 with dinner or as directed by a qualified expert.

**Supplement Facts**

Serving size: 3  
Servings per container: 20

Amount Per Serving  
Total Calories: 11.42  
Calories from Fat: 10.72

	mg	% Daily Value+
<b>Total Fat</b>	1.19	1.8
Saturated Fat	0.07	0.35
Monounsaturated Fat	0.11	*
Polysaturated Fat	1.01	*
<b>Cholesterol</b>	0	*
<b>Fish Oil</b>	0.72	*
Eicosapentaenoic acid	0.15	*
Docosahexaenoic acid	0.57	*
<b>Guggul oleo-gum-resin extract (1:10) in flaxseed oil</b>	0.39	*
<b>Garlic bulb extract (1:10) in flaxseed oil</b>	0.11	*

Other ingredients: gelatin (capsule), essential oil of rosemary. This product contains no artificial excipients, colorings, flavorings, preservatives, GMO free.

\*% Daily Value not established  
+Percent Daily values are based on a 2,000 calories diet. Your daily values may be higher or lower depending on your calorie needs.

Best before  
BATCH n°  
Keep in a dry cool place