

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

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773 A. E.,

December 6, 2002

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:

COLEST-OIL **Brand Name:** 

2.49 Oz (70.5 g) 150 Capsules in Glass Bottle Presentation:

Aboca S.p.a., Loc. Aboca 20, I-52037 Sansepolcro - ITALY Name and address of the manufacturer:

Aboca USA Inc., 126 South Spokane Street/Suite C, Seattle Name and address of the distributor:

Washington 98134

Helps to maintain cholesterol levels that are already **TEXT OF THE STATEMENT:** 

within the normal range\*

\*This statement has not been evaluated by the Food and Text of the disclaimer:

Drug Administration. This product is not intended to diagnose,

treat, cure or prevent disease.

**DIETARY INGREDIENTS** (Amount per Serving – 3 Capsules):

Total Fat - 1,190 mg

Saturated Fat - 70 mg;

Monounsaturated Fat - 110 mg;

Polyunsaturated Fat - 1,010 mg

Cholesterol - 0 mg;

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Aboca USA, Inc.

Fish Oil - 725.4 mg

Eicosapentaenoic acid - 151.1 mg;

Docosahexaenoic acid - 372.8 mg

Guggul oleo-gum-resin extract, (1:10) in flaxseed oil - 327.6 mg;

Garlic Bulb extract, (1:10) in flaxseed oil - 114.7 mg

Other ingredients:

gelatin (capsule), essential oil of rosemary.

**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.

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

Executive Vice-President

Aboca USA