



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

9894 01 JUL -2 P157

JUN 11 2001

Ms. Anna Tucci
Executive Vice-President
Aboca USA
126 South Spokane Street
Suite C
Seattle, Washington 98134

Dear Ms. Tucci:

This is in response to your letter to the Food and Drug Administration (FDA), dated May 29, 2001, pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Aboca USA is making the following claim for the product **Colest-Oil**:

“Helps maintain a healthy cholesterol level.”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate disease, namely hypercholesterolemia. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

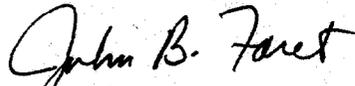
978-0163

LET 375

Page 2 - Ms. Anna Tucci

Please contact us if we may be of further assistance.

Sincerely,



John B. Foret

Director

Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Seattle District Office, Compliance Branch, HFR-PA340

Page 3 - Ms. Anna Tucci

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (file, r/f)

HFS-810

HFS-811 (file)

HFD-40 (Behrman)

HFD-310

HFD-314 (Aronson)

HFS-605

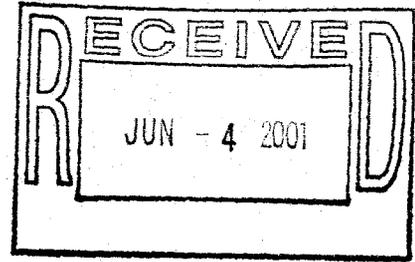
HFV-228 (Betz)

GCF-1 (Nickerson)

f/t:rjm:HFS-811:6/6/01:76202.adv:disc56



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



29 May 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 28.3g
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:

Text of the disclaimer: **Helps maintain a healthy cholesterol level**
 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):

- Saturated Fat 0.07 mg;
- Monounsaturated Fat 0.11mg;
- Polyunsaturated Fat 1.01mg;
- Cholesterol 0 mg;
- Fish Oil 0.72 mg;
- Guggul oleo-gum-resin extract 0.33 mg;
- Garlic bulb extract 0.11mg

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
 Executive Vice-President
 Aboca USA

Aboca USA, Inc.

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

76202