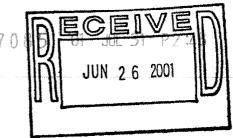


Office of Special Nutritionals, Center for Food Safety and Applied Nutrition, Food and Drug Administration 200 C St. SW. Washington DC - 20204



June 19, 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:** 

SEDIVITAX Drops

Presentation:

75 ml (2.54 fl oz)

Name and address of the manufacturer:

Aboca S.s., Loc. Aboca 20, I-52037 Sansepoicro - ITALY

Name and address of the distributor:

Aboca USA Inc., 126 South Spokane Street/Suite C, Seattle

Washington 98134

TEXT OF THE STATEMENT:

For relief of occasional sleeplessness or nervous

irritability

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 – 25 Drops):

Passionflower - freeze-dried extract (leaf) 36.2 mg;

Passionflower leaf extract (1:10) in organic grain alcohol 70% (by vol.) 147 mg;

Valerian root extract (1:10) in organic grain alcohol 70% (by vol.) 147 mg;

Kava root extract (1:10) in organic grain alcohol 70% (by vol.) 147 mg;

Lemon balm leaf extract (1:10) in organic grain alcohol 70% (by vol.) 147 mg;

California poppy aerial part extract (1:10) in organic grain alcohol 70% (by vol.) 147 mg;

Other ingredients:

Essential oil of lavender and marjoram.

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

975 0162 LET 8282

Aboca USA, Inc.

