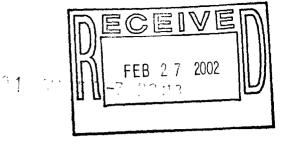


Office of Special Nutritionals, Center for Food Safety and Applied Nutrition, Food and Drug Administration 200 C St. SW. Washington DC - 20204



December 14, 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

Presentation: 30 Capsules 12g

Name and address of the manufacturer: Aboca S.p.a., 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: For relief of occasional sleeplessness or nervous

imitability

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 – 2 Capsules):

Passionflower - freeze-dried extract (leaf) 256mg;

Valerian Whole Plant Concentrate (WPC) – (root) 192mg; Lemon balm Whole Plant Concentrate (WPC)(leaf) 96 mg;

California Poppy Whole Plant Concentrate (WPC)

(leaf and flower) 89.6 mg.

WPC: Whole Plant Concentrate is a combination of freeze-dried extract with the powder of the specific herb.

Other ingredients: Gelatin (Capsule), essential oil of lavendar 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

978 0162

LET 9349

Aboca USA, Inc.



SUGGESTED USE

Take 2 capsules during the day and 2 at night before going to bed, or as directed by a qualified expert.

## Sedivitax

## Supplement Facts Serving size: 2

Servings per container: 15

Calones; 2.1	Amount Per Serving	
	mg	% Daily Value
Passionflower - Freeze-dried extract (Passiflora incarnata L.) (leaf) Standardized to 8% total flavonoids	256	•
Valerian - WPO**	192	

(Valeriana officinalis L.) (root) Standardized to 0.25% total valerenic acids

Lemon balm - WPO\*\* (Melissa officinalis L.) (leaf) Standardized to 6.5% rosmarinic acid

California Poppy- WPO\*\*

89.6 (Eschscholtzia californica Cham.) (leaf and flower) Standardized to 0.045% protopine

Other Ingredients: gelatin (capsule), essential oil of lavender and

This product contains no artificial excipients, colorings, flavorings, preservatives. GMO free.

\*% Daily Value not established

\*\*"Whole plant concentrate" WPO is a combination of freeze-dried extract with the powder of the specified herb.

WARNING:

Do not take if you are pregnant or nursing. For other contraindications and cautions, please consult your

health care practitioner. Do not drive or operate machinery after consuming this product.

> Keep out of reach of children

**MADE IN ITALY** 

Herbal Supplement

For relief of occasional sleeplessness or nervous irritability\*

Passionflower

Net Wt 0.42 oz (12 g) 30 Capsules

Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent

This

statement has

not been evaluated by the

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

Best before

Batch no

Keep in a dry cool place