



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 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 – 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 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*  
 Anna Tucci  
 Executive Vice-President  
 Aboca USA

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**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.

**Supplement Facts**

Serving size: 2

Servings per container: 15

	Amount Per Serving	
	mg	% Daily Value
Calories: 2.1		
<b>Passionflower</b> - Freeze-dried extract ( <i>Passiflora incarnata</i> L.) (leaf) Standardized to 8% total flavonoids	256	*
<b>Valerian</b> - <b>WPC**</b> ( <i>Valeriana officinalis</i> L.) (root) Standardized to 0.25% total valerenic acids	192	*
<b>Lemon balm</b> - <b>WPC**</b> ( <i>Melissa officinalis</i> L.) (leaf) Standardized to 6.5% rosmarinic acid	96	*
<b>California Poppy</b> - <b>WPC**</b> ( <i>Eschscholtzia californica</i> Cham.) (leaf and flower) Standardized to 0.045% protopine	89.6	*

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

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

\*% Daily Value not established

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

Sedivitax

CAPSULES

**Sedivitax**

Herbal Supplement

For relief of occasional  
sleeplessness or  
nervous irritability\*

Passionflower

Net Wt 0.42 oz (12 g) 30 Capsules

*Aboca*<sup>®</sup>  
Herbs and Health  
100% Natural

**Manufactured by:**  
Aboca s.s., 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](http://www.abocausa.com)

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**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**

Best before

Batch n°

Keep in a dry cool place

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