

0866 '03 MAR -3 P1:51

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

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 an herbal dietary supplement imported from Italy. Aboca will sell the product to medical practitioners, primarily in the Pacific Northwest.

**NOTIFIES** 

The marketing of the following Herbal Supplement:

**Brand Name:** 

**SEDIVITAX** 

Presentation:

1.27 Oz (36 g) 90 Capsules in Glass Bottle

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.

HERBAL INGREDIENTS (Amount per Serving - 2 Capsules):

^Passiflo' 2-LMF (Passionflower) - multifraction freeze-dried extract (leaf) - 256 mg;

Valerian - W.P.C.\*\* (root) - 192 mg;

^Lemon balm - W.P.C.\*\* (leaf) - 96 mg;

^California poppy - W.P.C.\*\* (leaf and flower) - 89.6 mg

Other ingredients: gelatin (capsule), essential oils of lavender and marjoram.

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## ^ = Certified Organic

\*\* W.P.C.:

Whole Phytocomplex Concentrate (W.P.C.) is a combination of the freeze-dried extract and micronized powder from a specialized portion of the same plant, which assures a full-spectrum of constituents and a uniform content of active principles.

**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.

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