



PHARMAVITE

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March 14, 2005

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C St. SW  
Washington, DC 20204

APR - 4 2005

Pharmavite Reference: 14202P20AB

Dear Sir or Madam:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section 101.93 of FDA's regulations, we hereby notify you that we are using the following statement(s):

- (1) Name and address of manufacturer:  
Pharmavite LLC, PO Box 9606, Mission Hills, CA 91346
- (2) Text of the statement(s):  
For Everyday Stress & Anxiety

Stress Relief Formula

StressEez is a potent combination of Nature's Resource herbs including Bacopa, Gotu Kola and Valerian with Vitamins B1 and B6 from Nature Made. These herbal ingredients have long been shown to help improve stress-related symptoms.

Bacopa, (*Bacopa monnieri*), an herb from India, has the unique ability to invigorate mental processes while at the same time reducing the effects of stress and nervous anxiety.

Gotu Kola, another herb prized by Indian Ayurvedic herbalists, also helps promote mental acuity.

Valerian has long been used to help with occasional sleeplessness and restlessness. Valerian's popularity has increased along with the stresses of modern life.

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Vitamins B1 and B6 are each included as these vitamins are especially needed by our bodies during times of stress.

This multi-nutrient formula makes StressEez helpful in stressful work, home or study environments where clarity of thought is as important as being able to work under pressure and to deal with the stresses related to the demands of our fast-paced society.

Stress is one of America's leading health problems. Today, many people are caught up in a very hectic pace of life. We eat unhealthy fast foods and daily we are exposed to financial and social pressures. Stress can challenge your immune system and affect your mood, health, and well-being. Taking StressEez is one positive thing that you can do to help deal with the stress and anxiety of everyday life.

Bacopa, categorized as "Brahmi" in Ayurveda – India's 5,000 year-old holistic medical system, has been used for centuries to manage stress and to relieve nervous tension and anxiety. Bacopa's traditional use in Ayurvedic medicine for anxiety is supported by both animal and clinical research. Another herb prized for its revitalizing properties is Gotu Kola. One of the most important rejuvenating herbs in Ayurvedic medicine and Western herbal medicine, Gotu Kola promotes mental calm, clarity and reduces anxiety. Valerian has long been used for relief from occasional sleeplessness and restlessness. Together, the ingredients in StressEez can help you be more productive and focused, even at today's hectic pace.

StressEez has been specifically formulated to help balance mind and body during stressful and or anxious times to help you achieve and maintain an active and healthy lifestyle.

- (3) Name of the dietary ingredient(s) if not provided in the text of the statement:  
See above



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- (4) Name of the dietary supplement:  
StressEez or products containing the above ingredients as a single ingredient or in combination with other ingredients.

The above statement(s) may be used in one or more of the following brands of products: B.J.'s Wholesale, Kirkland Signature, Nature Made, Nature's Resource, Nutri Plus, Olay, Spring Valley, Target, Tru Nature, Walgreens.

We certify the information in this notice is complete and accurate, and we have substantiation that the above statement(s) is truthful and not misleading.

Sincerely,

David Kropp  
Director, Regulatory Affairs