Shaklee Corporation

Hacienda Campus 4747 Willow Road Pleasanton, CA 94588-2740 Telephone 925/924-2586 Fax 925/924-2155 Marjorie L. Fine Senior Vice President and General Counsel

MAY 1 7 2002

May 13, 2002

Office of Special Nutritionals (HFS-810) Center for Food Safety and Applied Nutritionals Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

Re: Section 403(r)(6) Notification

Dear Sir or Madam:

In accordance with the requirements of section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, Shaklee Corporation hereby notifies FDA that it has begun using the following statements:

- Stress Relief Complex (product name).
- Promotes a tranquil state of mind.
- Shaklee Stress Relief Complex helps relax the body & mind and promotes alertness while enhancing the body's ability to adapt to stress.
- This blend of natural ingredients also helps blunt cortisol a hormone produced during physical stress that affects long-term health.
- Promotes a calm, relaxed state without causing drowsiness.
- Allows you to be more alert and able to concentrate during times of everyday stress.
- Enhances the body's ability to adapt to continuing stress.
- Stress Relief Complex offers nutritional support to help you quickly relax and stay calm without drowsiness.
- Stress Relief Complex contains a unique blend of natural ingredients that provide quick relief from tension while promoting alertness.

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- Promotes relaxation without drowsiness. L-theanine, a naturally occurring amino acid found in green tea, facilitates the generation of alpha waves that are associated with a relaxed yet alert mental state.
- Enhances the body's ability to adapt to continuing stress. Ashwagandha, an Ayurvedic herb traditionally used to enhance the body's ability to adapt to stress.
- Helps you avoid the effects of stress on long-term health by blunting the cortisol response to stress. Beta-Sitosterol, a natural plant sterol, helps to blunt the response of cortisol, a hormone produced during physical stress.
- Helps make norepinephrine, which is involved in mood regulation. L-tyrosine is an amino acid used by the body to make the neurotransmitter norepinephrine.
- Unique approach to help you quickly relax; enhances your body's ability to adapt to stress while promoting long-term health.
- Unique blend of premium ingredients that support a calm, relaxed state without drowsiness during times of everyday stress, while promoting alertness.
- Relaxation, alertness, better concentration and relief from tension experienced by users.
- The natural way to manage life's everyday stresses.
- Providing quick relief from tension, it allows you to enjoy much-needed relaxation and focus.

which contain the statutory statement on the following product:

## **Stress Relief Complex**



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I certify that the foregoing is complete and accurate, and that Shaklee Corporation has substantiation that the statements are truthful and not misleading.

Very truly yours,

Mayone L. June Marjorie L. Fine

/MLF