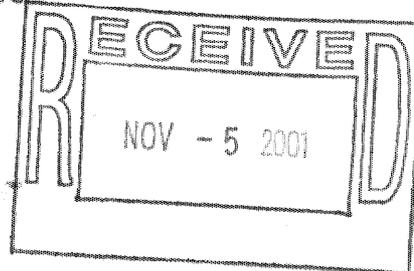




Innovative Nutrition Solutions

4399 '01 NOV 27 P1:36



October 24, 2001

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

Dear Sirs:

Notice is hereby given that Rexall Sundown, Inc. ("Sundown") located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement under the Sundown brand name bearing the following statement(s) on the label and/or in the labeling:

Calming Aid: Kava Kava and Valerian have been used for centuries to calm upset nerves and promote relaxation. Valerian's calming properties provide a safe and natural choice to soothe nervousness, tension and restlessness that promotes serene, restful sleep. Kava Kava has a unique ability to evoke a feeling of calm contentment. Relax with Sundown's Calming Aid, nature's natural relaxant that is a special herbal blend of valerian, kava kava and passionflower. This special blend helps promote a calming and soothing sense of well-being.

Ginseng XTRA [and] Vitamin B-Complex: Stress and anxiety due to the wear and tear of everyday life affect many Americans. Stress can drain your energy. Get relief with these Sundown products.

The undersigned certifies that the information contained in this notice is complete and accurate and that Sundown has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

Sincerely,

Deborah Shur Trinker, Esquire
Senior Vice President
Regulatory Affairs

Enclosure

975-0162 LET 8786

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