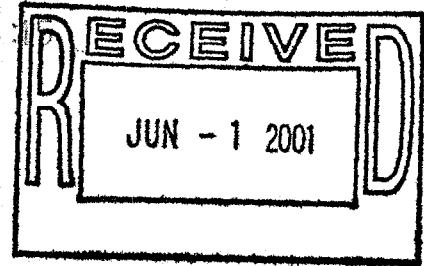




Innovative Nutrition Solutions

8085 '01 JUN 11 P2



May 31, 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 pursuant to Section 403(r)(6) (21 U.S.C. § 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act 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:

Sleep Zone™: [It] gently promotes restful sleep. Wake up refreshed without lingering effects. [It] is a natural herbal supplement that helps promote nighttime relaxation and natural, restful sleep. The special combination of concentrated valerian extract and calmativ hops found in Sleep Zone helps you relax and allows you to fall asleep naturally. Unlike many sleep medications that may cause "morning hangover" or grogginess, Sleep Zone helps to gently bring about natural sleep patterns over time, so you wake up refreshed.

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*

Deborah Shur Trinker, Esq.  
Senior Vice President  
Regulatory Affairs

Enclosure

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