

1804 '03 APR -4 P4:31

March 18, 2003

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

Valerian Calming Aid: [It is a] sleep aid. [It] is nature's natural sleep aid. Rosemary extract is included to naturally preserve herbal quality.

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

Cordially,

Deborah Shur Trinker, Esq. Senior Vice President

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Regulatory Affairs

Enclosures

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