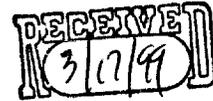




6111 Broken Sound Parkway NW
Boca Raton, FL 33487-3693
(561) 241-9400
Fax (561) 995-5188

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March 15, 1999



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 the requirements of Section 403(r)(6) (21 U.S.C. § 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR § 101.93, that Rexall Sundown, Inc. located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement within the last thirty days under the Sundown Herbals brand name bearing the following statement(s) on the label and/or in the labeling:

Kava Kava XTRA™: [It] promotes a calming and soothing sense of well-being. With the increasing stress of modern life, more and more people are relying on Kava Kava as a natural, effective way to promote relaxation. The ingredients in Sundown Kava Kava XTRA help you to relax naturally. For centuries, Pacific islanders have used Kava Kava for its unique ability to evoke a feeling of calm contentment. Sundown's Kava Kava XTRA combines Kava Kava extract with an XTRA Premium Blend of the whole herbs Passionflower, Hops and Chamomile to help promote a calming and soothing sense of well-being.

The undersigned certifies that the information contained in this notice is complete and accurate and that Rexall Sundown, Inc. 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
Vice President of Regulatory Affairs
and Assistant General Counsel

Enclosure

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