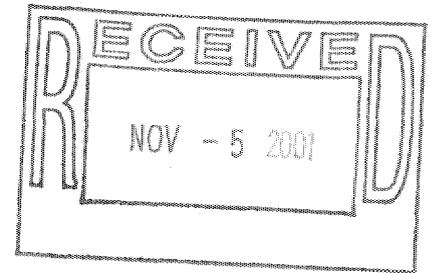




Innovative Nutrition Solutions

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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:

Kava Kava XTRA: [For] calm well-being. Stress and anxiety drain your energy. Kava kava is nature's "stress buster." Used for centuries in traditional ceremonies of the South Pacific, kava relaxes your muscles and calms your emotions while actually sharpening the senses. Research suggests that compounds found in kava root help to soothe everyday anxiety and promote a general feeling of well-being. Sundown's Kava Kava Xtra is combined with beneficial ingredients to keep you calm and mentally sharp while promoting a sense of peace and contentment.

Ginseng XTRA, Vitamin B-Complex [and] Vitamin C: Stress can rob your body of key nutrients needed to create energy. Restore physical vitality and mental clarity with these Sundown energy boosters.

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 8803

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