

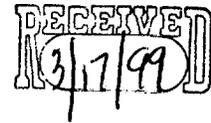


6111 Broken Sound Parkway NW  
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Fax (561) 995-5188

1300 '99 MAR 23 P2:16

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:

St. John's Wort XTRA™: [It] assists in mood enhancement. St. John's Wort has been used for thousands of years to promote well-being. Today, many people find it helps them to naturally cope with the emotional stress of modern life. In Sundown St. John's Wort XTRA, the gentle, mood-enhancing effects of St. John's Wort are complemented with an XTRA Premium Blend™ of Ginkgo Biloba, Siberian Ginseng and Ginger. The combination of ingredients in St. John's Wort XTRA helps support a positive mood.

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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