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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

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3/17/99

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:

Grape Seed XTRA™: For superior antioxidant protection. Free radicals are by-products of energy metabolism that damage cells and DNA. Antioxidants protect our cells from the damaging effects of free radicals. The biologically active flavonoids in Sundown Grape Seed XTRA have been shown in university studies to provide superior antioxidant protection. The combination of ingredients in Sundown Grape Seed XTRA helps provide natural antioxidant protection. This advanced formula features ActiVin™ Grape Seed Extract blended with the XTRA Premium Blend of Green Tea, Bilberry and Selenium that work in harmony to provide natural antioxidant protection.

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*

Deborah Shur Trinker  
Vice President of Regulatory Affairs  
and Assistant General Counsel

Enclosure

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