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March 15, 1999

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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:

Hawthorn Berries: [It] promotes healthy heart function. European research studies indicate that Hawthorn Berries are rich in beneficial compounds called flavonoids. For years, many people have taken whole herb Hawthorn Berries for their positive effects in maintaining healthy heart and circulatory function. To further promote cardiovascular function and a healthy circulatory system, take this product with Sundown Vitamin E and Sundown Garlic. Vitamin E is a powerful antioxidant that contributes to normal blood flow and healthy heart function. Garlic helps promote healthy circulatory function and also helps maintain healthy serum cholesterol levels. Hawthorn Berries are native to Europe, Asia and North America and have been used for centuries to promote healthy heart function.

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