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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:

Saw Palmetto: For prostate and urinary health. Studies indicate that Saw Palmetto berries contain a variety of fatty acids and sterols which have antiandrogenic properties that may be helpful for prostate and urinary health. To further promote healthy prostate function, take Sundown Whole Herb Saw Palmetto with Sundown Nettle and Sundown Zinc. The roots of the Nettle herb have been used traditionally to provide support for healthy prostate function. Zinc is an essential trace element associated with prostate health. Saw Palmetto has become popular with men for promoting healthy prostate 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

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