

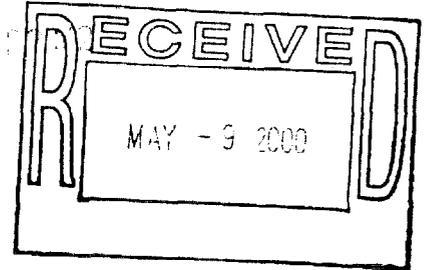


6111 Broken Sound Parkway NW
Boca Raton, FL 33487-3693
(561) 241-9400
Fax (561) 995-5188

May 4, 2000

Food and Drug Administration
Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
200 C Street, SW
Washington, DC 20204

MAY 25 10 31 AM '00



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, Rexall and Thompson brand names bearing the following statement(s) on the label and/or in the labeling:

Saw Palmetto (Rexall): For prostate and urinary health. More and more men are recognizing the importance of prostate 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. Saw palmetto is a palm tree with large leaves and dark red berries, native to the North American Atlantic coast. The berries contain a variety of fatty acids and sterols which have anti-androgenic properties helpful for prostate and urinary health.

Advanced Formula Saw Palmetto (Thompson): For prostate and urinary health. Many men recognize the importance of prostate health. Standardized Saw Palmetto extract has been shown to be helpful in promoting urinary tract and prostate health.

Saw Palmetto XTRA (Sundown): [For] prostate and urinary health. Saw palmetto supports the health of the prostate. In Sundown's Saw Palmetto XTRA, saw palmetto is combined with an XTRA premium blend of complementary ingredients to support prostate health. Saw palmetto helps to maintain normal prostate function and urinary health.

Saw Palmetto Complex (Sundown): [For] prostate and urinary health. Saw palmetto helps to maintain normal prostate function and urinary health. In Sundown's Saw Palmetto Complex, saw palmetto is combined with an XTRA premium blend of complementary ingredients to support prostate health.

Saw Palmetto (Sundown): [For] prostate and urinary health. Saw palmetto supports the health of the prostate. Sundown's Saw Palmetto helps to maintain normal prostate function and urinary health. Standardized extracts of saw palmetto berries have been shown to be helpful in promoting prostate health and supporting urinary flow.

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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,

A handwritten signature in black ink, appearing to read "Deborah Shur Trinker". The signature is written in a cursive, somewhat stylized script.

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

Enclosure