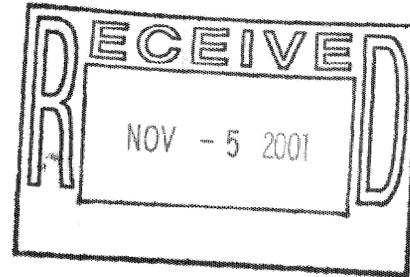




Innovative Nutrition Solutions

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October 24, 2001

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 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 brand name bearing the following statement(s) on the label and/or in the labeling:

Saw Palmetto: The prostate gland is located under the bladder and surrounding the urinary tract in men. Saw Palmetto supports the health of the prostate. Sundown's Saw Palmetto helps to maintain normal prostate function and urinary health. The prostate is critical to optimal urinary health and sexual vitality. Standardized extracts of Saw Palmetto Berries have been shown to be helpful in promoting prostate health and supporting urinary flow.

Lycopene. Soy Isoflavones [and] Flax Seed Oil: Two of the biggest health concerns of maturing men are prostate and cardiovascular health. Protect yourself with these Sundown products that can provide dual health benefits.

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,

Deborah Shur Trinker, Esquire
Senior Vice President
Regulatory Affairs

Enclosure

975-0162

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