

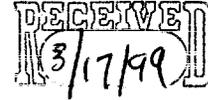


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March 15, 1999

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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:

Milk Thistle: For healthy liver function. Milk Thistle seed extract contains a group of flavonolignans collectively called silymarin which protect and strengthen the liver and promote healthy liver function. For additional antioxidant protection take this product with Sundown Vitamin C and Sundown Vitamin E. Vitamin C is an important antioxidant that helps provide protection for healthy cells and body functions. In addition, Vitamin C helps promote healthy immune function. Vitamin E enhances other antioxidants and contributes to normal blood flow and healthy cholesterol levels. Milk Thistle is the ripe seed from the prickly milk thistle. It has a rich history of use to enhance liver 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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