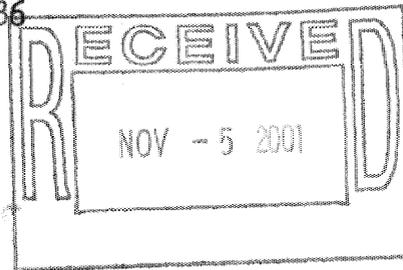




Innovative Nutrition Solutions

4405 '01 NOV 27 P1:36



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:

Milk Thistle and Milk Thistle XTRA: [For] liver health. Milk Thistle helps to protect the liver and maintain healthy liver function. It contains silymarin, a flavonoid with antioxidant activity that may also has a cell membrane-stabilizing effect. Research shows that Milk Thistle helps protect liver cells. Anyone who drinks alcohol, smokes or comes into contact with any pollutants will benefit from daily use of Sundown's Milk Thistle XTRA.

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*

Deborah Shur Trinker, Esquire  
Senior Vice President  
Regulatory Affairs

Enclosure

978-0162 LET 8792

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