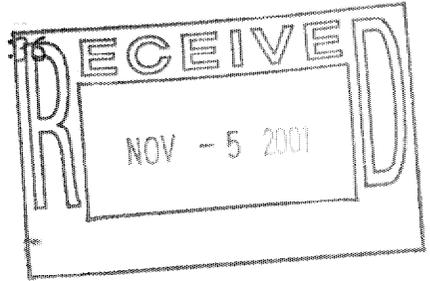




Innovative Nutrition Solutions

4391 '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:

Evening Primrose Oil: [For] women's nutrition and PMS support. Evening primrose oil contains two important fatty acids – linolenic acid and gamma-linolenic acid (GLA). GLA is necessary for cellular metabolism, membrane stability, and provides support for PMS. Sundown's Evening Primrose Oil is a superior source of gamma-linolenic acid (GLA). GLA has traditionally been used to provide support for PMS. [GLA is an] important fatty acid that is essential for optimal health.

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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6111 BROKEN SOUND PKWY. NW • BOCA RATON, FLORIDA 33487  
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