



6111 Broken Sound Parkway NW  
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rec'd 3/30/00

August 23, 1999

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

Lutein (Sundown): [It] is a carotenoid that promotes healthy eye function, particularly in the macular region. Carotenoids play an important protective role in the body's defense against cellular damage caused by free radicals.

Lutein 6mg (Thompson): [It] helps maintain healthy eye function. Lutein and Zeaxanthin are two important retinal carotenoids that may be associated with protection against eye degeneration.

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  
Vice President of Regulatory Affairs  
and Assistant General Counsel

Enclosure

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