

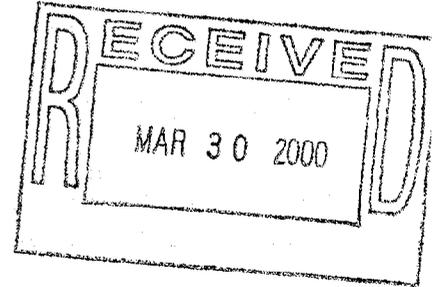


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0830 '00 APR -6 P3:25

March 18, 2000

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

The Guardians™ (SDV): Vitamin C and Vitamin E are antioxidants. Selenium is a necessary component of the antioxidant enzyme glutathione peroxidase. Antioxidants help prevent damage to cells caused by oxidation and free radicals. Vitamin E helps protect cell membranes while Vitamin C helps protect the water-soluble portion of cells and tissues. The Guardians™ includes antioxidants, trace elements, vitamins and other nutrients to help protect cells, provide essential nutrients and promote general well-being.

The Guardians™ (Sundown): [It] helps protect cells from free radical damage. The Guardians from Sundown includes powerful antioxidants that neutralize free radicals which can cause cellular damage and lead to premature aging. The Guardians also promotes general well-being. Selenium helps form the enzyme that protects red blood cells and cell membranes. Vitamin E helps protect the integrity of cell membranes. Beta-Carotene, a form of Vitamin A, works to promote healthy cardiovascular and immune function.

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

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