



tomorrow's nutrition today

March 25, 2003

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APR -9 2003

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 Section 403(r)(6) (21 U.S.C. § 343(r)(6)) of the Federal Food, Drug and Cosmetic Act 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 statements(s) on the label and/or in the labeling:

Sundown Kids™ Gummies Multivitamin: The Calcium your children get during their growing years helps determine the strength of their bones and teeth for the rest of their lives. Vitamin A is essential for new cell growth and healthy tissue. Vitamin D helps maintain strong bones and teeth by enhancing absorption of Calcium and Phosphorus. Thiamin metabolizes sugar and starch to provide energy. Riboflavin is important for metabolism and energy production. Niacin helps maintain a healthy nervous system. Vitamin C is essential for healthy immune function. Vitamin B-6 is essential for metabolism of protein and proper hormone function. Folic Acid helps maintain a healthy circulatory system. Vitamin B-12 aids normal development and regeneration of red blood cells. Iron is essential for healthy red blood cells and for carrying oxygen to the tissues.

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.

Cordially,

Deborah Shur Trinker, Esq.  
Senior Vice President  
Regulatory Affairs

Enclosures

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