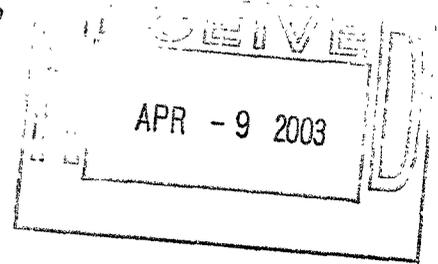




tomorrow's nutrition today

2015 '03 APR 15 P1 57



March 25, 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:

SAM-e 200: For mood enhancement and emotional well-being. [It] enhances mood by helping maintain healthy neurotransmitter balance and brain cell function. By promoting a vital uplifting affect on the mood regulating activities of the brain, you can experience an improvement in mood, mental outlook and emotional balance. Because SAM-e is not readily available in foods, supplementing your diet with Sundown's SAME-e 200 can help provide your body with levels of SAM-e needed for mood enhancement and emotional well-being. [Tosylate, the clinically studied form of SAM-e]...is the only form on SAM-e studied in two decades of research and documented in respected medical journals for its benefits. As a complement to SAM-e, take this product with any one of the following Sundown products:

Vitamin B-Complex – Helps maintain a healthy nervous system and promotes healthy circulatory and mental function.

St. John's Wort – Provides additional support to maintain a positive outlook.

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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 Trinkler, Esq.

Senior Vice President

Regulatory Affairs

Enclosures