



tomorrow's nutrition today

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APR - 9 2003

March 24, 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:

B-12 1000 mcg: [It] is essential for normal blood formation and the protection of nerve cells.

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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