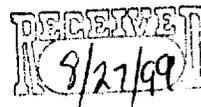




6111 Broken Sound Parkway NW
Boca Raton, FL 33487-3693
(561) 241-9400
Fax (561) 995-5188

August 18, 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 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 statement(s) on the label and/or in the labeling:

Folic Acid XTRA: [It] promotes healthy heart and circulatory function. Folic Acid, an essential B-Vitamin, helps break down homocysteine into non-harmful nutrients. Research shows that a healthy homocysteine level is important for optimum cardiovascular and circulatory function. This Sundown XTRA formula begins with an essential nutrient, Folic Acid, which the body needs for proper health and growth. The ingredients in Sundown Folic Acid XTRA promote healthy heart and circulatory function. Sundown Folic Acid XTRA ingredients work in harmony to help promote healthy heart and circulatory 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

Enclosure