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January 19, 1998



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 the requirements of section 403(r)(6) (21 U.S.C. 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, that Rexall Sundown, Inc. located at 851 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 within the past 30 days commenced marketing a dietary supplement bearing the following statement(s) on the label and/or in the labeling:

Sundown's Homocysteine Defense Formula promotes healthy heart and circulatory function. [It] contains a select combination of vitamins which help nutritionally to fortify the body, promoting healthy heart and circulatory function. Research confirms the importance of healthy homocysteine levels for optimum cardiovascular and circulatory function. The body requires vitamins B-6, B-12 and Folic Acid to break down homocysteine into non-harmful nutrients. These three essential B vitamins, plus Vitamin B-2 and Choline, when taken regularly, help maintain healthy levels of homocysteine in the blood. For additional cardiovascular protection, take this product with any one of Sundown's quality Vitamin E, CoQ-10 or Garlic products.

The undersigned certifies that the information contained in this notice is complete and accurate and that Rexall Sundown, Inc. 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
Director of Regulatory Affairs
and Corporate Counsel

Enclosure

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