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June 23, 1998

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6/30/98

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 has marketed or will market a dietary supplement under the Sundown and Thompson brand names bearing the following statement(s) on the label and/or in the labeling:

Soy Isoflavones: Research shows significant health benefits for those consuming a diet high in soy. Sundown's/Thompson's concentrated Soy Isoflavone extract is a natural combination of soy isoflavones, including Genistein, Daidzein and Glycitein. Isoflavones are considered to be the active compounds which research indicates are among the important healthy components found in soy. Helps provide nutritional support during menopause, for healthy bones and healthy prostate function.

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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