

2024 '03 APR 15 21:58

March 25, 2003

200 C Street, SW

Washington, DC 20204

Food and Drug Administration

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition APR - 9 2003

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:

<u>Fenugreek</u>: ... Fenugreek has a long history as both a culinary and medicinal herb. Fenugreek seed powder contains many beneficial phytochemicals including galactomannan, a viscous soluble fiber, amino acids, saponins and flavonoids.

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.

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Cordially,

Reboran Drun Finken

Deborah Shur Trinker, Esq. Senior Vice President Regulatory Affairs

Enclosures

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