

2013 '03 APR 15 P1:57

March 24, 2003

APR - 9 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:

<u>Papaya Enzyme</u>: [It] contains a blend of enzymes that help support digestion. Papain (from Papaya) and Bromelain (from Pineapple) help break down protein.

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.

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Senior Vice President

Regulatory Affairs

**Enclosures** 

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