

March 24, 2003

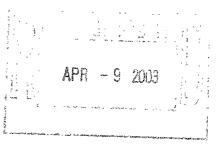
200 C Street, SW

Washington, DC 20204

Food and Drug Administration

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

## 2012 03 APR 15 P1:57



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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>Coral Calcium</u>: [For] bone strength. [It] helps to support women's health. Calcium helps build and maintain good bone health and is essential for healthy teeth, blood and muscles.

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,

Deborah Shundrule

Deborah Shur Trinker, Esq. Senior Vice President Regulatory Affairs

Enclosures

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