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NOV 14 2001

Ms. Deborah Shur Trinker, Esq.
Senior Vice President
Regulatory Affairs
Rexall-Sundown, Inc.
6111 Broken Sound Parkway, NW
Boca Raton, Florida 33487

Dear Ms. Trinker:

This is in response to your letter of October 24, 2001 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Rexall-Sundown, Inc. is making the following claims for its product **Calcium Citrate Malate**: "It helps build and maintain strong, healthy bones. Up to 40% more effective for maintaining bone density. It also offers up to 40% greater bone density in postmenopausal women over the age of 55 compared to the calcium carbonate form used in most other calcium supplements."

These statements are statements about the relationship solely between calcium and osteoporosis and are not claims subject to 21 U.S.C. 343(r)(6), but claims subject to 21 U.S.C. 343(r)(1)(B). FDA has authorized a health claim on the relationship between calcium and osteoporosis (see 21 CFR 101.72). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between calcium and osteoporosis. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.72 would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, failure to make a claim in accordance with the requirements in 21 CFR 101.72 subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, osteoporosis.

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Please contact us if you require further assistance.

Sincerely,

for Robert J. More

John B. Foret
Director

Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

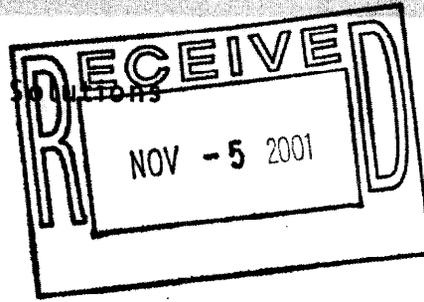
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Florida District Compliance, HFR-SE240



Innovative Nutrition Solutions



October 24, 2001

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 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 and Rexall brand names bearing the following statement(s) on the label and/or in the labeling:

Calcium (Rexall): [It] helps maintain strong bones.

Chewable Calcium (Sundown): [It] helps the heart and cardiovascular system by maintaining a regular heartbeat and assisting with the transmission of nerve impulses. It is vital to many body functions, helping to promote healthy blood, bone, teeth and muscles.

Calcium + Soy (Sundown): [For] bone health and hormonal balance. [It] is an advanced formula developed to help women maintain their health during the natural changes associated with menopause. It combines optimal levels of Calcium, Vitamin D, Magnesium, Soy Isoflavones and trans-Resveratrol that work together to maintain strong bones and teeth, support hormonal balance and promote cardiovascular health.

Calcium Citrate Malate (Sundown): [It] helps build and maintain strong, healthy bones. Up to 40% more effective for maintaining bone density. It also offers up to 40% greater bone density in postmenopausal women over the age of 55 compared to the calcium carbonate form used in most other calcium supplements.

Calcium Citrate + D (Sundown): [For] bone health. [It] helps the heart and cardiovascular system by maintaining a regular heartbeat and assists with the transmission of nerve impulses. It helps build and maintain good bone health and is essential for healthy teeth, blood and muscles. Vitamin D helps the body absorb Calcium.

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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.

Sincerely,



Deborah Shur Trinker, Esquire
Senior Vice President
Regulatory Affairs

Enclosure