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Ms. Deborah Shur Trinker
Vice President of Regulatory Affairs
and Assistant General Counsel
Rexall Sundown, Inc.
6111 Broken Sound Parkway NW
Boca Raton, Florida 33487-3693

Dear Ms. Trinker:

This is in response to your letter of September 11, 2000 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, among others, for the products Natural Oyster Shell Calcium Plus Vitamin D, Calcium 250 Plus Vitamin D, Calcium 500, Calcium 600, Calcium 600 Plus D, Calcium 900 Plus D, Calcium 1200 Plus D (Sundown):

“...may support healthy blood pressure function.”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, cure, or mitigate disease, namely, hypertension. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

LET-391

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Please contact us if we may be of further assistance.

Sincerely,

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 Office, Office of Compliance, HFR-SE240

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-811 (file)

HFD-40 (Behrman)

HFD-310

HFD-314 (Aronson)

HFS-605

HFV-228 (Benz)

GCF-1 (Dorsey, Nickerson)

f/t:HFS-811:rjm:9/14/00:docname:72395.adv:disc50

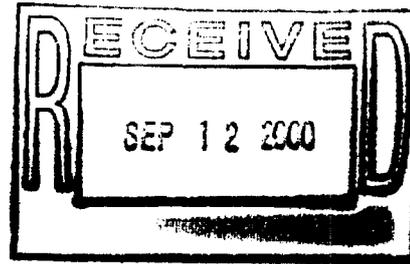


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6111 Broken Sound Parkway NW
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(561) 241-9400
Fax (561) 995-5188

September 11, 2000

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 XTRA™ with Soy Isoflavones, Vitamin D and Minerals (Sundown): [It] promotes bone strength. The ingredients in Sundown Calcium XTRA work in harmony to help promote the building and maintaining of bone mass and bone density.

X Natural Oyster Shell Calcium Plus Vitamin D, Calcium 250 Plus Vitamin D, Calcium 500, Calcium 600, Calcium 600 Plus D, Calcium 900 Plus D, Calcium 1200 Plus D (Sundown): [It] helps the heart and cardiovascular system by maintaining a regular heartbeat and assisting with the transmission of nerve impulses. It helps build and maintain good bone health and is essential for healthy teeth, blood and muscles. [It] may support healthy blood pressure function in some individuals. Vitamin D helps the body absorb calcium.

Calcium Magnesium with Zinc (Sundown): The combination of Calcium, Magnesium and Zinc helps maintain strong bones and healthy teeth. Calcium, a major component of bones and teeth, is also important for proper nerve function, muscle contraction and normal heart rhythm. Magnesium helps regulate calcium flow in cells. It also helps strengthen teeth and aids bone growth. Zinc is necessary for normal metabolism, immune health and cell function.

Calcium 500, Calcium 600 Plus D, Calcium 900, Calcium 1200, Oyster Shell Calcium 1000 (Rexall): [It] helps maintain strong bones and healthy teeth. [It] helps maintain healthy cardiovascular function. [It] supports and promotes healthy, mobile joint function. Regular exercise and a healthy diet that includes adequate amounts of calcium are helpful in building and maintaining bone density. Calcium is vital to many body functions, helping to promote healthy blood, bones, teeth and muscles.

Calcium Magnesium Zinc (Rexall): [It] helps maintain strong bones and healthy teeth. Calcium is a major constituent of bones and teeth and is important for nerve function, muscle contraction and cardiovascular health. Magnesium is one of the prime regulators of calcium flow within cells. Magnesium also helps strengthen teeth and aids bone growth. Zinc is necessary for normal metabolism, immune health and cell function.

Food and Drug Administration

September 11, 2000

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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
Vice President of Regulatory Affairs
and Assistant General Counsel

Enclosure