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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 letters of March 20 and March 21, 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 submissions state that Rexall Sundown, Inc. is making the following claims, among others, for the following products:

Potassium Gluconate (Rexall)

“...helps maintain healthy blood pressure function.”

Niacin 250 mg, 400 mg, 500 mg (Sundown)

“...assist in maintaining healthy cholesterol levels.”

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 statements that you are making for these products suggest that they are intended to treat, prevent, cure or mitigate diseases, namely hypercholesterolemia and hypertension. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are 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

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Page 2 - Ms. Deborah Shur Trinker

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 (r/f, file)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-605
HFV-228 (Benz)
GCF-1 (Dorsey, Barnett, Nickerson)
f/t:HFS-811:rjm:3/30/00:docname:69981.adv:disc46



6111 Broken Sound Parkway NW
Boca Raton, FL 33487-3693
(561) 241-9400
Fax (561) 995-5188

March 20, 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 Thompson brand names bearing the following statement(s) on the label and/or in the labeling:

Timed-Release Niacin 500mg (Thompson): [It] helps promote healthy circulatory function.

Niacin 250mg, 400mg, 500mg (Sundown): Sundown's Niacin (B-3) promotes energy production and the proper functioning of the nervous and circulatory systems. It can also assist in maintaining healthy cholesterol levels.

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,

A handwritten signature in cursive script that reads "Deborah Shur Trinker".

Deborah Shur Trinker
Vice President of Regulatory Affairs
and Assistant General Counsel

Enclosure

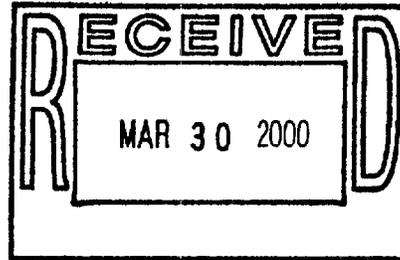
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6111 Broken Sound Parkway NW
Boca Raton, FL 33487-3693
(561) 241-9400
Fax (561) 995-5188

March 21, 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 Rexall and Sundown brand names bearing the following statement(s) on the label and/or in the labeling:

Potassium (Rexall): For healthy muscles, nerves and cardiovascular function. Potassium is a vital electrolyte which helps maintain proper pH and water balance in body tissues and cells. Potassium helps to preserve the normal function of kidneys, nerve, heart and skeletal-muscle cells. Potassium promotes normal muscle contraction, heartbeat and nerve conduction.

Potassium (Sundown): [It] promotes healthy nervous system and cardiovascular function. It helps maintain water balance in body tissues. Sundown's Potassium promotes normal muscle contraction and a regular heartbeat. It is also important in the normal function of the kidneys.

Potassium Gluconate (Rexall): [It] helps maintain healthy blood pressure function.

Potassium Gluconate (Sundown): Potassium is an essential mineral that helps maintain proper pH and water balance in body tissues and cells. Potassium helps to preserve the normal function of the kidneys, nerve, heart and skeletal-muscle cells.

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,

A handwritten signature in cursive script that reads "Deborah Shur Trinker".

Deborah Shur Trinker
Vice President of Regulatory Affairs
and Assistant General Counsel

Enclosure

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