



JAN 10 1997

Ms. Deborah Shur Trinker
Director of Regulatory Affairs and Corporate Counsel
Rexall Sundown
901 Broken Sound Parkway NW
Boca Raton, Florida 33487-3693

Dear Ms. Trinker:

This is in response to your letter to the Food and Drug Administration (FDA) dated January 13, 1997. Your letter concerns claims being made for a number of products. Several claims do not appear to be made in accordance with section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act).

Saw Palmetto Complex- Sundown Vitamins

Contains a select combination of ingredients which help maintain and promote healthy prostate and urinary function. Saw palmetto berries contain a variety of fatty acids and sterols which have anti-inflammatory and anti-androgenic properties, helpful for prostate and urinary health. Pygeum contains naturally occurring phytosterols which inhibit the inflammation of the prostate gland. Nettles help promote proper urinary function.

Section 403(r)(6) of the act 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 or mitigate disease, in that Saw Palmetto Complex claims to contain ingredients "which inhibit the inflammation of the prostate gland" (symptoms of Benign Prostatic Hypertrophy or Prostatitis). This claim does not meet the requirements of section 403(r)(6) of the act. This claim suggest that this product is intended for use as a drug within the meaning of section 201(g)(1)(B) of the act, and that it is subject to regulation under the drug provisions of the act. If you intend to make a claim 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.

Folic Acid - Sundown Vitamins

Helps nutritionally in maintaining cardiovascular function and a healthy circulatory system by reducing the amount of homocysteine levels in the blood. Elevated homocysteine levels are associated with plaque buildup in the arteries and reduced circulatory function.

This statement appears to be an unauthorized health claim and thus may subject your product to regulation as a drug. A "health claim" is defined in 21 CFR 101.14(a)(1) as

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any claim made on the label or in labeling of a food that "characterizes the relationship of any substance to a disease or health-related condition." The statement that you are making characterizes the relationship between folic acid and atherosclerosis (plaque buildup in the arteries and reduced circulatory function) and thus, would be subject to the health claim provisions of section 403(r)(1)(B) of the act. Moreover, this statement further suggest that this product is intended to prevent circulatory disease. Thus, it appears that this product is intended for use as a drug within the meaning of section 201(g)(1)(B) of the act.

You should either submit an appropriate health claim petition or contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855, before marketing a product that bears this claim.

Please contact us if we may be of further assistance.

Sincerely yours,

James Tanner, Ph.D.
Acting Director,
Division of Programs and
Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:

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

FDA, Florida District Office, Office of Compliance, HFR-SE200

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



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January 13, 1997

BY FACSIMILE: 202-205-5295
AND CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Elizabeth A. Yetley, Ph.D., R.D., Director
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW, HFS-450
Washington, DC. 20204

Dear Dr. Yetley:

Rexall Sundown, Inc. ("Sundown") wishes to notify the Food and Drug Administration that it has marketed or will within the near future commence marketing dietary supplements which bear statements of nutritional support, pursuant to Section 6 of the Dietary Supplement Health and Education Act ("DSHEA"), Section 403(r) of the Federal Food and Drug Cosmetic Act ("the Act"). Please see the attachment for a listing of the dietary supplements and corresponding statements of nutritional support.

These statements are being accompanied by the required disclaimer pursuant to Section 403(r)(6)(C) of the Act. Two copies of this cover letter and its attachment are enclosed.

Very truly yours,

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

Deborah Shur Trinker
Director of Regulatory Affairs
and Corporate Counsel

DST/mw

Attachment

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Rexall Sundown, Inc.
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DIETARY SUPPLEMENT/ PRODUCT LINE	BRAND NAME	STATEMENT OF NUTRITIONAL SUPPORT
B Complex - Sundown Vitamins		Essential for a normal functioning nervous system and for promoting sustained energy levels throughout the day; important for the digestive system; helps with stress management.
Bilberry - Sundown Vitamins		Contains flavonoid compounds, the anthocyanosides, that can cause biochemical reactions that help promote healthy eye function.
Calcium - Sundown Vitamins		A factor in healthy pregnancies and childbirth because it helps promote blood pressure and kidney function; assists with the transmission of nerve impulses; maintains good cardiovascular health.
Calcium 900 - Sundown Vitamins		Helps maintain healthy heart and nerve function by assisting with the transmission of nerve impulses; an important nutritional regimen during childbearing years.
Chromium Picolinate - Sundown Vitamins		Essential for protein, carbohydrate and fat metabolism; necessary to support normal insulin function; supplementation can positively increase lean muscle tissue and decrease body fat in moderately obese individuals.
Co Q 10 - Sundown Vitamins		An antioxidant that helps protect from "free radical" effects that can lead to premature aging; as an antioxidant promotes healthy cells by protecting against oxidation, it has the important added benefit of promoting cellular regeneration to sustain energy levels.
Dong Quai - Sundown Vitamins		Used to provide energy.
Echinacea Complex - Sundown Vitamins (Claims for Echinacea, Goldenseal and Vitamin C)		Echinacea Complex contains a select combination of ingredients which help promote healthy immune and respiratory function. Echinacea provides superior herbal support for healthy immune function and promotes general well-being especially during the cold and flu season. Goldenseal helps maintain healthy respiratory function.
EPA and Fish Oils - Sundown Vitamins		Helps maintain healthy serum cholesterol levels and healthy heart function.
Folic Acid - Sundown Vitamins		Helps nutritionally in maintaining cardiovascular function and a healthy circulatory system by reducing the amount of homocysteine levels in the

Rexall Sundown, Inc.
Attachment - Page 2

DIETARY SUPPLEMENT/ PRODUCT LINE	BRAND NAME	STATEMENT OF NUTRITIONAL SUPPORT
		blood. Elevated homocysteine levels are associated with plaque buildup in the arteries and reduced circulatory function.
Garlic - Sundown Vitamins		Helps maintain healthy serum cholesterol levels; helps promote healthy circulatory function.
Ginkgo Biloba - Sundown Vitamins		Helps maintain brain function, memory and alertness by stimulating blood circulation to the brain; as an antioxidant promotes cell repair function.
Ginkgo Biloba Complex - Sundown Vitamins (Claims for Ginkgo Biloba, Siberian Ginseng and Bilberry)		Ginkgo Biloba Complex contains a select combination of ingredients which help promote healthy brain function and mental alertness. Ginkgo Biloba's leaves are useful in promoting oxygenation and blood flow in the brain, thereby enhancing brain function and alertness. Siberian Ginseng helps enhance memory, concentration and cognitive processes. Bilberry helps to promote circulation.
Ginseng - Sundown Vitamins		One of the most prized herbs for well-being; used as a tonic for extra energy; helps support normal body functions under environmental and physical stress.
Ginseng Complex - Sundown Vitamins (Claims for Siberian Ginseng, Korean Ginseng and Vitamin B12)		Promotes energy and endurance. Siberian Ginseng is reported to positively affect fatigue and lessen daily environmental stress. Korean Ginseng contains ginsenosides which help the body respond to stress and is also noted for its endurance-enhancing effects.
Glucosamine Complex - Sundown Vitamins/Thompson Nutritional Products (Claims for Glucosamine, Vitamin C, Copper, Manganese and Zinc)		Glucosamine Complex contains a select combination of ingredients which help in maintaining healthy, mobile joint function and connective tissue health. Helps repair cartilage and promotes healthy joint function. Glucosamine plays an important role in the repair and maintenance of cartilage, including cartilage adversely affected by aging and physical stress. Vitamin C is essential for the production and maintenance of collagen - the main component of cartilage and key to healthy bone and cartilage formation. Essential trace minerals such as copper, manganese and zinc are also required for maintaining bone metabolism and bone density, and work to promote strong, healthy bone joints.

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DIETARY SUPPLEMENT/ PRODUCT LINE	BRAND NAME	STATEMENT OF NUTRITIONAL SUPPORT
Goldenseal - Sundown Vitamins		For general well-being.
Hawthorn Berries - Sundown Vitamins		Helps maintain heart function; promotes circulatory function.
Lecithin - Sundown Vitamins		Contains Phosphatidylcholine which emulsifies, disperses and promotes healthy serum cholesterol; helps in absorption of the fat-soluble vitamins.
Multinutrient Formulation and Vitamin C Formulation (600 mcg) - Rexall Showcase International (Vitamins, Minerals and Other Nutrients)	Cellular Essentials [®]	A multinutrient formula designed in accordance with recognized principles about the importance of cellular nutrition for good cardiovascular health. Maintains maximum stability and function of the blood vessel walls; helps promote important cell repair function of the cardiovascular system; provides optimal nutrition at the cellular level. Vitamin C is vital to the production of collagen molecules that provide the stability necessary for proper cardiovascular function. Taken regularly, these nutritional supplements provide the building blocks for healthy, stable body systems.
Niacin - Sundown Vitamins		Necessary for a healthy nervous system and brain function; assists the body in the proper utilization of food, promoting energy.
Papaya Enzyme - Sundown Vitamins		Promotes efficient digestion function which helps to absorb vitamins and minerals.
Saw Palmetto Complex - Sundown Vitamins (Claim for Saw Palmetto, Pygeum, Zinc and Nettles)		Contains a select combination of ingredients which help maintain and promote healthy prostate and urinary function. Saw Palmetto berries contain a variety of fatty acids and sterols which have anti-inflammatory and anti-androgenic properties, helpful for prostate and urinary health. Pygeum contains naturally occurring phytosterols which inhibit the inflammation of the prostate gland. Nettles help promote proper urinary function. Adequate levels of zinc are associated with prostate health.
Selenium - Sundown Vitamins/Thompson Nutritional Products (Claims for Selenium and Vitamin C)		Helps promote cell repair in the lungs and other organs; helps promote healthy immune system function. Selenium works to neutralize free radicals. Free radical damage is thought to be a major contributor to cellular destruction which breaks down the immune system. The body needs Selenium to produce glutathione peroxidase, a critical antioxidant

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DIETARY SUPPLEMENT/ PRODUCT LINE	BRAND NAME	STATEMENT OF NUTRITIONAL SUPPORT
		enzyme which is essential for the protection of red blood cells and cell membranes; promotes healthy prostate function.
Soya Lecithin 400 mg Concentrate- Sundown Vitamins		Enhances mental alertness.
Valerian Root - Sundown Vitamins		Used for its calming effects; recognized as an aid for restlessness and for sleep.
Valerian Complex - Sundown Vitamins (Claims for Valerian Root, Kava Kava and Passion Flower)		Valerian Complex contains a select combination of ingredients which help promote restful well-being in today's stressful environment. Used for its ability to promote a sense of calm and relaxation. Kava Kava is used for its natural calming and soothing effects. Passion Flower has been used for the past 200 years to calm nerves and promote relaxation.
Vitamin B-6 - Sundown Vitamins		Helps maintain the proper balance of sodium and potassium which regulate body fluids; promotes the healthy functioning of the nervous and muscular system.
Vitamin C - Sundown Vitamins		Helps maintain healthy blood cholesterol levels. Vitamin C is vital to the production of the collagen molecules that provide the stability necessary for proper cardiovascular function.
Vitamin E - Sundown Vitamins		Helps nutritionally in maintaining cardiovascular function and a healthy circulatory system by contributing to normal blood flow and healthy serum cholesterol levels; an antioxidant that helps to protect from unhealthy oxidative "free radicals" that can lead to premature aging; contributes to healthy skin; helps to promote healthy circulatory function.
Zinc - Sundown Vitamins		Assists in maintaining the proper concentration of Vitamin E in the blood; contributes to good prostate health.
Zinc Lozenges - Sundown Vitamins/Thompson Nutritional Products (Claims for Zinc, Vitamin C and Echinacea)		Zinc Lozenges provide a combination of Zinc, Vitamin C and Echinacea which helps support and promote healthy immune function and general well-being especially during the cold and flu season. Zinc is an important mineral which is essential for protein synthesis and which helps to regulate the production of cells in the body's immune system; necessary

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DIETARY SUPPLEMENT/ PRODUCT LINE	BRAND NAME	STATEMENT OF NUTRITIONAL SUPPORT
		for normal metabolism; helps to maintain healthy cell function. Vitamin C assists with healthy immune system activities.
Zinc Picolinate - Sundown Vitamins		Essential for protein synthesis, healthy immune function and prostate health; necessary for normal metabolism and helps maintain healthy cell function; necessary to help maintain the proper concentrations of Vitamin E in the blood.