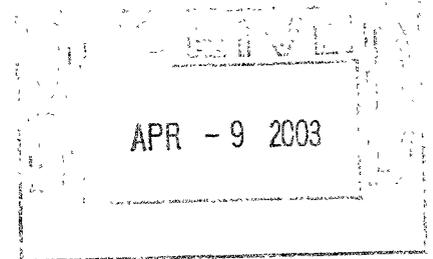




March 25, 2003

2022 '03 APR 15 P1:57



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 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:

Vitamins To Go® For Men: [It] is specially formulated to support men's needs: healthy prostate, healthy heart, immune system boost, muscle health, antioxidant protection, proper metabolism.

Vitamin E 400 IU: [It] is a high-potency antioxidant that helps promote a healthy heart. It protects cells from free-radical damage that may lead to premature aging and works with Vitamin C and Beta-Carotene to provide maximum antioxidant protection.

B Maxi Complex: The B Complex vitamins are essential in maintaining healthy nerves, skin and muscles. They are required for the proper metabolism of carbohydrates, fats and proteins.

C-500% All-Inclusive Complex: [It] is essential for the growth and repair of tissues and organs. Vitamin C and the "C Complex partners" Rose Hips, Citrus Bioflavonoids, Rutin and Acerola help promote capillary strength. Vitamin C acts as an antioxidant to help protect healthy cells and body systems. Vitamin C is vital to the production of collagen that provides the stability necessary for proper cardiovascular function.

Beta-Carotene: A safe source of Vitamin A, this important antioxidant helps prevent cellular damage. It contributes to healthy eyes, skin and lungs. Beta-Carotene also promotes healthy circulatory and immune function.

Zinc Essential: Essential for cell division, repair and growth, zinc also boosts the immune system and supports healthy prostate function.

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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.

Cordially,



Deborah Shur Trinker, Esq.
Senior Vice President
Regulatory Affairs

Enclosures