

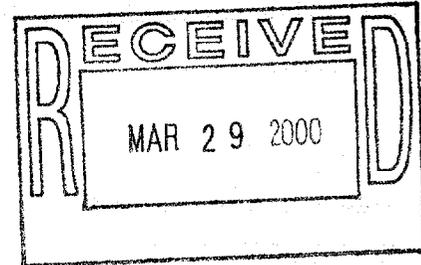


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March 15, 2000

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

B Complex (Rexall) (Sundown): [It is] essential for healthy nervous system function. A balanced complex of B vitamins promotes healthy nerve function and energy production. B vitamins also help promote healthy heart, circulatory and mental function.

B Complex XTRA (Sundown): [It] promotes energy and healthy immune function. B-Vitamins are essential for energy production from carbohydrates, fats and proteins. B-Vitamins also are necessary for blood-cell formation, cell division and maintaining a healthy nervous system. Sundown B Complex XTRA goes one step further to include a select combination of ingredients which provide antioxidant protection and support a healthy immune system. This Sundown high potency XTRA formula begins with the essential B-Vitamins which the body needs for proper health and growth. The ingredients in Sundown B Complex XTRA help to promote energy throughout our stressful days. This high potency Advanced Formula features Vitamin B Complex blended with Vitamin E, Vitamin C and the essential trace minerals Copper and Zinc. These ingredients work in harmony to promote energy, healthy immune function and protect cells from the damaging effects of free radicals.

B Maxi Complex; B "Fifty" Complex (Sundown) (Thompson): B-Vitamins are essential for energy production from carbohydrates, fats and proteins. B-Vitamins are required for blood cell formation, cell division and maintaining a healthy nervous system. [It] promotes healthy nerve function and energy. Sundown's B vitamins also help promote healthy heart, circulatory and mental function. A balanced complex of B vitamins promotes healthy nerve function and energy production. B vitamins also help promote healthy heart, circulatory and mental function.

B 100% Complex "Plus" (Sundown): A balanced complex of B vitamins promotes healthy nerve function and energy production. B vitamins also help promote healthy heart, circulatory and mental function.

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B Complex 100 (Rexall) (Sundown) (Thompson): [It is] essential for energy production and healthy nervous system function. B-Vitamins are essential for energy production from carbohydrates, fats and proteins. B-Vitamins are required for blood cell formation, cell division and maintaining a healthy nervous system. B Complex vitamins and nutrients help maintain healthy nervous system, muscle and heart function. B Complex helps promote sustained energy levels throughout the day. [It] promotes healthy nerve function and energy. Sundown's B vitamins also help promote healthy heart, circulatory and mental function.

B 150 Complex (Sundown): B Vitamins are required for blood cell formation, cell division and maintaining a healthy nervous system.

B1 (100 mg) (Sundown): [It] promotes energy. It is essential for proper carbohydrate metabolism and nerve cell function. [It] helps promote healthy mental function.

B2 (100 mg) (Sundown) (Rexall): Vitamin B-2 or Riboflavin is essential for normal growth, development, physical performance and general well-being. [It] promotes energy. Riboflavin (B-2) is essential for energy production and maintaining the defense function of the cell membranes. B-2 is also necessary for normal growth, development and normal physical performance.

B6 (50 mg, 100 mg, 500 mg) (Sundown) (Rexall) (Thompson): Vitamin B-6 functions as a coenzyme for more than 100 enzymes. Vitamin B-6 is necessary for the production of serotonin and other neurotransmitters. Vitamin B-6 promotes healthy cardiovascular function by maintaining healthy blood homocysteine levels. Vitamin B-6 is essential for healthy blood and immune function. [It] is required to convert protein and fat into energy. [It] plays a vital role in cell health, the proper functioning of enzymes in the body and helps the nervous system function properly.

B12 (100mg, 250mg, 500 mg, 1000mg, 1500 mg) (Sundown) (Rexall) (Thompson): B-12 is necessary for the formation and maintenance of red blood cells. B-12 is essential for the formation of nerve tissue and is important for healthy cardiovascular function. B-12 supplementation may help prevent B-12 deficiency in strict vegetarians and persons with impaired absorption, especially persons over 50 years of age. According to the National Academy of Sciences, 10 to 30% of Americans older than 50 years may have decreased bioavailability of Vitamin B-12 from food. [It is] essential for healthy cardiovascular, blood and nerve function. [It] helps protect the integrity of nerve cells. [It] is essential for normal blood formation and the protection of nerve cells.

B-C Complex (Sundown): [It] promotes energy production, healthy nerve and immune function. The Vitamin C in this Complex acts as an antioxidant, protecting cells from damage that can lead to premature aging. It is also essential for the production of collagen, which helps maintain healthy cartilage. B vitamins are essential for release of energy from food.

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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