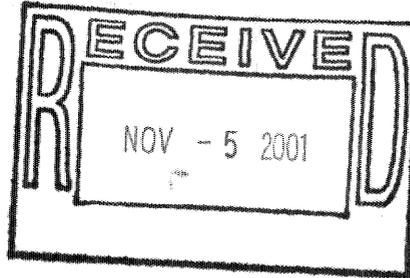




Innovative Nutrition Solutions

4425 '01 NOV 27 P1:37



October 24, 2001

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 brand name bearing the following statement(s) on the label and/or in the labeling:

Osteo-Bi-Flex®: Helps rebuild cartilage and lubricate joints...Osteo-Bi-Flex actually promotes long-term joint flexibility, comfort and range of motion without side effects by helping to improve the health of joints and cartilage over time. As our bodies age, the ability to produce some of the nutrients necessary for cartilage building declines. Osteo-Bi-Flex contains the clinically studied daily dosage of glucosamine (1500 mg) and chondroitin (1200 mg), nutrients that naturally help to maintain and rebuild cartilage for all your joints.

Osteo-Bi-Flex Performance™: ...active nutrition for joints and muscles to help keep you active and fit. [It] is an advanced formula that combines Vitamin C, Arginine, Niacinamide, Vitamin B-12 and Boron with clinically studied levels of glucosamine to support flexible joints and healthy tendons, muscle strength [and] energy and circulation.

When taken daily, [it] helps reduce the pain and stiffness from overexertion and physical activity as it provides critical nutrients that lubricate and replenish joints and cartilage. In addition to supporting overall joint health during physical activity, this special formula also promotes muscle strength, helps maintain healthy tendons, and contributes to overall energy and circulation.

Osteo-Bi-Flex® Plus MSM: [It is] a timed-release formula that combines glucosamine, chondroitin and MSM to promote healthy, flexible joints. MSM (Methylsulfonylmethane) is a source of dietary sulfur, a mineral that is necessary for the structure of living cells. The dietary sulfur in MSM complements the action of glucosamine and chondroitin in maintaining the flexibility of connective tissue. With Osteo-Bi-Flex Plus MSM, our timed-release formula works throughout the day to nourish and repair cartilage so you can continue doing the things you love.

975-0162 LET 8812

6111 BROKEN SOUND PKWY. NW • BOCA RATON, FLORIDA 33487  
561-241-9400 • FAX 561-995-5188

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Osteo-Bi-Flex Fast-Acting: ...a unique blend of glucosamine and chondroitin plus willow bark – for faster joint comfort...the glucosamine and chondroitin work long term to help repair and rebuild cartilage to promote healthy, flexible joints essential to full range of motion, performance and mobility.

Osteo-Bi-Flex® Soft Fruit Chews: [It] contains nutrients that naturally help to maintain and repair cartilage for all your joints. Glucosamine and chondroitin are nutrients that work over time to repair cartilage and lubricate joints, keeping them healthy and flexible.

The undersigned certifies that the information contained in this notice is complete and accurate and that Rexall Sundown, Inc. 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, Esquire  
Senior Vice President  
Regulatory Affairs

Enclosure