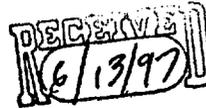




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June 5, 1997



BY CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

0178 '97 SEP 19 P1:48

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,

Deborah Shur Trinker  
Director of Regulatory Affairs  
and Corporate Counsel

DST/mw

Attachment

975-0162

LET 684

53080

DIETARY SUPPLEMENT/ PRODUCT LINE	BRAND NAME	STATEMENT OF NUTRITIONAL SUPPORT
<p><b>Combination Product -</b> (Claims for Glucosamine HCl (250mg) and Chondroitin Sulfate (200mg)) - Sundown Vitamins</p>	<p>Osteo-Bi-Flex 450™</p>	<p>Helps promote cartilage regeneration and healthy joints.</p> <p>Sundown's Osteo-Bi-Flex 450™ combination of Glucosamine and Chondroitin provides an important nutritional approach for healthy joints and cartilage in one convenient dietary supplement.</p> <p>Osteo-Bi-Flex 450 works to lubricate joints, which is a critical factor in promoting joint health and mobility. Glucosamine and chondroitin help provide and maintain lubricating fluid in joints and cartilage. This is necessary for our joint comfort because the lubricating fluid acts as a "shock absorber," cushioning joining bones.</p> <p>Our bodies produce enzymes which can be a factor in cartilage breakdown. Osteo-Bi-Flex 450 inhibits this enzyme activity, thereby enhancing the production and maintenance of healthy new cartilage and connective tissue.</p> <p>Osteo-Bi-Flex 450, as part of your nutritional regimen, will help you maintain healthy, mobile joints and cartilage.</p> <p>This nutritional combination of ingredients helps in maintaining healthy, mobile joint function and connective tissue. Cartilage rebuilding and regeneration is a normal function of the body. But as our bodies age, the ability to produce some of the nutrients necessary for cartilage building declines. Because of this, proper nourishment is essential for the health and mobility of all our joints -- such as our hands, fingers, wrists, elbows, shoulders, neck, back, hips, knees, ankles and feet.</p> <p>Glucosamine is a naturally occurring amino-sugar found in the body, which plays an important role in the maintenance and repair of cartilage, including cartilage adversely affected by aging and physical stress.</p> <p>Glucosamine and chondroitin help to form the structural components such as the tissues and fluids which are necessary for healthy new cartilage.</p> <p>The two ingredients in Osteo-Bi-Flex 450, Glucosamine (Glu-COS-a-mein) and Chondroitin (Con-DROY-tin), help to regenerate and maintain</p>

DIETARY SUPPLEMENT/ PRODUCT LINE	BRAND NAME	STATEMENT OF NUTRITIONAL SUPPORT
		<p>the natural lubricating fluid in joints and cartilage. This product works, over time, to nourish and replenish cartilage to promote healthy, mobile joints.</p> <p>Sundown's <i>Osteo-Bi-Flex 450™</i> is an exclusive patented formula combining Glucosamine and Chondroitin. This nutritional combination of ingredients helps in maintaining healthy, mobile joint function and connective tissue to further support and promote healthy, mobile joint function.</p>
<p><b>Combination Product -</b> (Claims for Glucosamine HCl (250mg) and Chondroitin Sulfate (200mg)) [SDV Vitamins]</p>		<p>Helps promote cartilage regeneration and healthy joints.</p>
<p><b>Combination Product -</b> (Claims for Glucosamine HCl (500mg) and Chondroitin Sulfate (400mg)) [Thompson]</p>	<p><i>Gluco-Pro 900™</i></p>	<p>Helps promote cartilage regeneration and healthy joints.</p> <p>This nutritional combination of ingredients helps in maintaining healthy, mobile joint function and connective tissue.</p> <p>This product works over time to nourish and replenish cartilage and to help regenerate and maintain the natural lubricating fluid in joints and cartilage.</p> <p>Thompson's <i>Gluco-Pro 900™</i> combination of Glucosamine and Chondroitin provides an important nutritional approach for healthy joints and cartilage in one convenient dietary supplement; to support and promote healthy, mobile joint function.</p> <p>Both components play a useful role in the repair and maintenance of cartilage.</p>
<p><b>Combination Product -</b> (Claims for Glucosamine HCl (250mg) and Chondroitin Sulfate (200mg)) [Hydron Healthcare]</p>	<p>Cartilage Formula</p>	<p>Helps promote cartilage regeneration.</p> <p>Helps rebuild and regenerate cartilage. Glucosamine and chondroitin also work to protect existing cartilage by inhibiting potentially harmful enzymes produced in the body which can play a role in cartilage breakdown.</p>

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		<p>Healthy cartilage is resilient and strong. However, age and physical exertion can adversely impact joint health if the essential nutrients for the building blocks of cartilage, such as glucosamine and chondroitin, are not available for the body to synthesize and replenish cartilage.</p> <p>Glucosamine is an aminosugar found in the body that plays an important role in the repair and maintenance of cartilage. It is used in the formation of structural components, such as tissues and fluids necessary in cartilage function, and is an essential component of many tissue molecules.</p> <p>Chondroitin sulfates are long chains of sugar molecules that help attract and hold water in cartilage. Water is the lubricating fluid which acts as a "shock absorber," cushioning joining bones and attracting nutrients into the cartilage. This is important because cartilage does not have its own blood supply and receives the nutrients from the lubricating fluid to keep cartilage strong and healthy.</p> <p>Glucosamine and chondroitin, as found in Cartilage Formula, are natural compounds that when taken on a regular basis and over a period of time, offers a nutritional approach to help restore and maintain healthy connective tissue.</p>
<b>Vitamin C</b> - Sundown Vitamins, Thompson Nutritional Products		To support and promote healthy, mobile joint function.
<b>Calcium</b> - Sundown Vitamins, Thompson Nutritional Products		To support and promote healthy, mobile joint function.
<b>Manganese</b> - Sundown Vitamins		To support and promote healthy, mobile joint function.