



JUN 29 2001 21 '01 AUG -8 P2:21

Ms. Heidi Horn
Perrigo Company of South Carolina
515 Eastern Avenue
Allegan, Michigan 49010

Dear Ms. Horn:

This is in response to your letter of June 15, 2001 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that the following claim, among others, appears on the label of TARGET™ BRAND Glucosamine Chondroitin:

“While pain relievers can only offer temporary pain relief, Glucosamine & Chondroitin has been formulated to actually promote long-term comfort...”

21 U.S.C. 343(r)(6) 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, prevent, cure or mitigate diseases such as joint disorders, and that it is represented as an alternative to approved drug products for such conditions. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims 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.

975-0163

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Please contact us if we may be of further assistance.

Sincerely,



John B. Foret

Director

Division of Compliance and Enforcement

Office of Nutritional Products, Labeling
and Dietary Supplements

Center for Food Safety
and Applied Nutrition

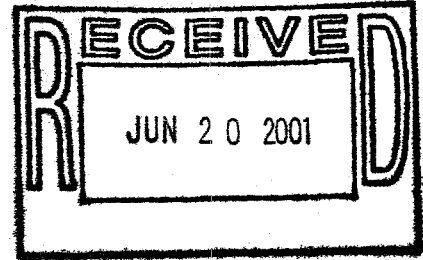
Copies:

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

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

FDA, Chicago District Office, Office of Compliance, HFR-MW140

Food and Drug Administration
 Office of Special Nutritionals (HFS-450)
 Center for Food Safety and Applied Nutrition
 200 C Street, SW
 Washington, DC 20204



NOTIFICATION OF DIETARY SUPPLEMENT CLAIMS

Manufacturer Name and Address:		
Perrigo Company of South Carolina 515 Eastern Avenue Allegan, MI 49010		
Statement Text:		
What Can Glucosamine & Chondroitin Do For You?		
While pain relievers can only offer temporary pain relief, Glucosamine & Chondroitin has been formulated to actually promote long-term comfort, joint flexibility and range of motion by helping to maintain healthy, mobile joints and cartilage.		
Our bodies produce enzymes, which can be a factor in cartilage breakdown. TARGET™ BRAND Glucosamine Chondroitin inhibits enzyme activity, thereby enhancing production and maintenance of healthy, new cartilage and connective tissue.		
TARGET™ BRAND Glucosamine Chondroitin, when taken daily as part of your nutritional regimen, may help to reduce joint stiffness and may play an important role in the maintenance and repair of cartilage, including cartilage adversely affected by age and physical activity.		
Dietary Ingredient:	Dietary Supplement Name:	
Glucosamine HCl Chondroitin Sulfate Sodium	Glucosamine Chondroitin	
Appears on the following labels:		
TARGET™ BRAND		

I hereby certify that the information presented and contained in this notice is complete and accurate.

I also certify that Perrigo Company has substantiation to verify that the statement is truthful and not misleading.

Heidi John 6/15/01
 Signature/Date

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