

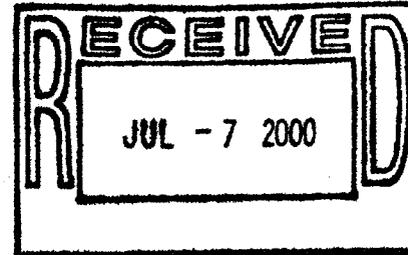


9725 '00 AUG -8 P2:28

**Eleanor F. Barbo**  
Senior Director, Regulatory Affairs

Whitehall-Robins Healthcare  
Five Giralda Farms  
Madison, NJ 07940  
Telephone (973) 660-5751  
Fax (973) 660-6048  
E-mail address: barboe@ahp.com

July 5, 2000



**Flexagen®**

**Notification of Statements on Dietary Supplement Labels**

Dr. Robert Moore, Branch Chief  
Dietary Supplements Branch (HFS-811)  
Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling, and Dietary Supplements  
Food and Drug Administration  
200 C Street, SW  
Washington, D.C. 20204

Dear Dr. Moore:

Reference is made to Flexagen®, marketed by Whitehall-Robins Healthcare, ("Whitehall-Robins"), a division of American Home Products Corporation.

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, as codified in 21 U.S.C. §343(r)(6), notification is submitted for structure/function (S/F) statements made on the following dietary supplement product.

**Product Name:** Flexagen®  
**Ingredients:** Glucosamine hydrochloride, Chondroitin sulfate, Vitamin C  
**Company Name/  
Address:** Whitehall-Robins Healthcare  
Five Giralda Farms  
Madison, NJ 07940-0871

975-0162

LET 5679

**S/F Statements on the Carton Label:**

**1. Front Panel/Top Flap**

- Helps regenerate and maintain cartilage\*
- Promotes healthy joints in a natural way\*
- A dietary supplement to promote healthy joints in a natural way\*

**2. Back Panel**

- Flexagen is a dietary supplement for joint care. Flexagen contains Glucosamine and Chondroitin, substances that are naturally produced in your body and serve as building blocks for healthy joints. When taken daily, studies show that over time these ingredients help promote healthy joints in a natural way.\* It also contains Vitamin C, an essential nutrient that helps support a healthy cartilage structure.
- Provide natural building blocks to help restore and rebuild cartilage.\*
- Help maintain healthy cartilage.\*
- Help promote and maintain normal joint flexibility and mobility.\*
- Helps promote comfortable joint movement.\*

In accord with 21 CFR §101.93, the disclaimer statement is bolded and boxed on all panels of the carton label where structure/function claims appear.

The undersigned certifies that the information contained in this notice is complete and accurate, and that Whitehall-Robins has substantiation that the statements made are truthful and not misleading.

As required, the original and two copies of this notification are enclosed. If you have any questions regarding this information, please contact the undersigned at (973) 660-5751.

Sincerely,

WHITEHALL-ROBINS HEALTHCARE



Eleanor F. Barbo  
Senior Director  
Regulatory Affairs