



Whitehall-Robins  
Five Giralda Farms  
Madison, NJ 07940-0871  
Telephone (973) 660-5500  
Website address: <http://healthfront.com>

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June 25, 1999



**Caltrate<sup>®</sup> 600 + Soy**

**Notification of Statements on Dietary Supplement Labels**

Elizabeth A. Yetley, Ph.D., R.D., Director  
Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street, SW  
Washington, D.C. 20204

Dear Dr. Yetley:

Reference is made to Caltrate<sup>®</sup> 600 + Soy, 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 statements made on the following dietary supplement product.

**Product Name:** Caltrate 600 + Soy  
**Ingredients:** Calcium Carbonate, Vitamin D, Soy Isoflavones  
**Company Name/ Address:** Whitehall-Robins Healthcare  
Five Giralda Farms  
Madison, New Jersey 07940

**Statements on the Label:**

- 1.) Front Panel of Label
  - Helps support your body through natural changes \*
- 2.) Back Panel of Label
  - Soy contains natural substances called **isoflavones** which may provide many benefits for your body during menopause. **Caltrate 600 + Soy** is made with an extract of soy called **Novasoy<sup>™</sup>** that has these valuable isoflavones.\*

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- **A soy-rich diet may help:**
  - Support your body through the natural changes due to menopause\*
  - Promote good cardiovascular health\*
- Asian women have traditionally eaten a soy-rich diet and this may explain why they enjoy good menopausal health. Two **Caltrate 600 + Soy** tablets provide the amount of soy isoflavones in an Asian woman's average daily diet. While not a substitute for a soy-rich diet, combining this product with a healthy lifestyle may have many benefits.\*

3.) Side Panel of Label

- In addition to calcium, **Caltrate 600 + Soy** contains vitamin D to help maximize calcium absorption, and it has soy isoflavones which may help promote good menopausal health.\*

In accord with 21 CFR §101.93, the disclaimer statement is **bolded and boxed** on all panels of the carton 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) 660-575 1.

Sincerely,

WHITEHALL-ROBINS HEALTHCARE



Eleanor F. Barbo  
Senior Director  
Regulatory Affairs