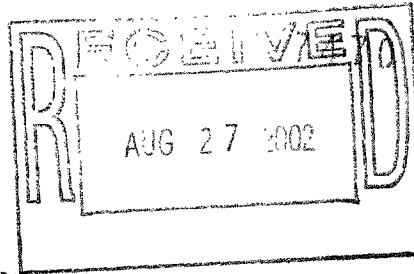


Wyeth Consumer Healthcare  
Five Giralda Farm  
Madison, NJ 07940

Marie C. Vicinanza  
Associate Director  
Regulatory Affairs

**Wyeth**



August 22, 2002

**Caltrate® Colon Health**

**Notification of Statements on Dietary Supplement Labels**

Dr. Robert Moore  
Branch Chief  
Dietary Supplement Branch (HFS-811)  
Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling, Dietary Supplements  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

Dear Dr. Moore:

Reference is made to Caltrate Colon Health, marketed by Wyeth Consumer Healthcare, a division of Wyeth 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.

<b>Product Name:</b>	Caltrate Colon Health
<b>Ingredients:</b>	Vitamin D and Calcium
<b>Company Name/ Address:</b>	Wyeth Consumer Healthcare Five Giralda Farms Madison, NJ 07940-0871

**Statements on the Carton Label:**

1. Back Panel
  - Help Promote Colon Health And Bone Health with Caltrate Colon Health\*
  - To Help Maintain Colon Health\*

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10964

# Wyeth

- Gastroenterology experts now recommend 1200 mg of calcium daily from calcium carbonate (as in 2 Caltrate® tablets daily) to help promote a healthy colon. \*

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 Wyeth Consumer Healthcare 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) 660-5848.

Sincerely,  
WYETH CONSUMER HEALTHCARE



Marie C. Vicinanza  
Associate Director  
Regulatory Affairs