

Wyeth Consumer Healthcare

Marie C. Vicinanza

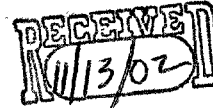
Associate Director, Regulatory Affairs

973-660-5848

Wyeth

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November 12, 2002



Centrum® with Lycopene

**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 Centrum with Lycopene, marketed by Wyeth Consumer Healthcare, a division of Wyeth.

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:** Centrum with Lycopene

**Ingredients:** Vitamin A, vitamin C, vitamin D, vitamin E, vitamin K, thiamin, riboflavin, niacin, vitamin B6, folic acid, vitamin B12, biotin, pantothenic acid, calcium, iron, phosphorus, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, potassium, boron, nickel, silicon, tin, vanadium, lutein, lycopene

**Company Name/** Wyeth Consumer Healthcare  
**Address:** Five Giralda Farms  
Madison, NJ 07940-0871

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## Statements on the Carton Label:

1. Front Panel/Top Flap
  - Lycopene is a potent antioxidant found in certain fruits and vegetables that may help promote a healthy heart.\*
2. Front Panel
  - Helps promote a healthy heart.\*
3. Back Panel/Top Flap
  - Beta-Carotene, selenium and vitamins C and E are antioxidants important for maintaining healthy immune function.\*
  - Vitamin C- Essential for healthy teeth, gums, and bones.\*
  - Calcium plus vitamin D help maintain strong bones and regulate heartbeat.\*
  - Vitamin E may help maintain a healthy circulatory system by helping to reduce low density lipoprotein (LDL) oxidation.\*
  - Lutein helps maintain healthy eyes.\*
  - Magnesium- Necessary for proper muscle and nerve function.\*
  - Zinc- An antioxidant mineral essential for normal tissue renewal and skeletal development.\*

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