### **Wyeth Consumer Healthcare**

Associate Director, Regulatory Affairs 973-660-5848



November 12, 2002

# Centrum® Silver 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 Silver 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 Silver 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, phosphorus, iodine, magnesium, zinc, selenium, manganese, chromium, molybdenum, chloride, potassium, boron, nickel, silicon, vanadium,

lutein, lycopene

Company Name/ Address:

Wyeth Consumer Heathcare

Five Giralda Farms

Madison, NJ 07940-0871

LET 11233 978 0162

# Wyeth

### Statements on the Carton Label:

- 1. Front Panel/Top Flap
  - Centrum Silver has now added lycopene. Lycopene is an antioxidant found in certain fruits and vegetables that may help promote a healthy heart and maintain a healthy prostate.\*
- 2. Front Panel
  - Helps promote a healthy heart.\*
- 3. Back Panel/Top Flap
  - Lycopene- An antioxidant to help promote a healthy heart and maintain a healthy prostate.\*
  - Lutein- An antioxidant to help maintain healthy eyesight.\*
  - Vitamin B6- A higher level to help your body convert food to energy.\*
  - Vitamin B12- Increased to help maintain heart health.\*
  - Calcium- A higher level to help strengthen and maintain healthy bones.\*
  - Chromium- A higher level to help your body metabolize sugars.\*
  - Vitamin E- A higher level to help protect against cell damage.\*
  - Vitamin K- An age-adjusted level to support normal blood clotting.\*
  - Phosphorus- An age-adjusted level to help increase calcium absorption.\*

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. Vicinanzo Associate Director Regulatory Affairs