

Bayer HealthCare
Consumer Care Division



JUN 25 2003

June 20, 2003

Office of Special Nutritionals
 Center for Food Safety and Applied Nutrition
 U.S. Food and Drug Administration
 5100 Paint Branch Parkway
 College Park, MD 20740-3835

**Subject: 30-Day Post Market Notification for
 Structure/Function Claims; One-A-Day® Active® Dietary
 Supplement**

Dear Sir or Madam:

Bayer HealthCare LLC, Consumer Care Division submits the information in this notification pursuant to Section 403(r)(6) of the Food, Drug and Cosmetic Act as notice of marketing structure/function claims on the product label of One-A-Day® Active® Dietary Supplement.

Bayer HealthCare LLC
 Consumer Care Division
 36 Columbia Road
 P.O. Box 1910
 Morristown, NJ 07962-1910

Phone: 973 254-5000

PRODUCT NAME	One-A-Day® Active®
NAME /ADDRESS OF DISTRIBUTOR	Bayer HealthCare LLC Consumer Care Division 36 Columbia Road P. O. Box 1910 Morristown, New Jersey 07962-1910
NAME OF DIETARY INGREDIENT/ SUPPLEMENT (SUBJECT OF THE STATEMENT)	One-A-Day® Active™ Dietary Supplement Multivitamin/Multimineral Product
TEXT OF STATEMENT BEING MADE	
Top Panel of Carton	<ul style="list-style-type: none"> • Supports Mental Energy with Ginseng, Thiamin, Riboflavin and Niacin* • Provides Physical Energy by converting food to fuel with Pantothenic Acid, Chromium and Vitamin B6* • Helps maintain a Healthy Immune System with Vitamins C, E, & A, Selenium and Zinc* • Promotes Cardiovascular Health with Folic Acid, Vitamins B6, B12, Potassium and Calcium*
5 th Panel of Carton	<ul style="list-style-type: none"> • Promote Mental Energy* • Convert Food to Fuel for Physical Energy*

975 0162 LET 12326

**30-Day Post Market Notification for Structure/Function Claims;
One-A-Day® Active® Dietary Supplement
Page 2**

Right Panel of Carton	Key Ingredients For Active Lifestyles* <ul style="list-style-type: none">• MENTAL ENERGY: Ginseng, Thiamin, Riboflavin, Niacin• PHYSICAL ENERGY: Ginseng, Vitamin B6, Pantothenic Acid, Iron, Chromium• CELL DEFENSE: Vitamin A, Vitamin C, Vitamin E, Selenium• IMMUNITY: Vitamins C, A, Selenium, Zinc• CARDIOVASCULAR: Vitamins B6, B12, E, Folic Acid, Magnesium, Calcium, Potassium
*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.	

In accordance with 21 CFR 101.93, the information contained in this notification is complete and accurate. Bayer HealthCare LLC, Consumer Care Division has substantiation on file that the statements are truthful and not misleading. This notification is comprised of an original and two (2) copies.

Should you have any questions or need any additional information, please contact the undersigned at 973-254-4793 or MaryRose Salvacion at 973-254-4675.

Sincerely,



Catherine W. Fish
Associate Director, Regulatory Affairs
BAYER HEALTHCARE LLC, CONSUMER CARE DIVISION