

**Bayer HealthCare
Consumer Care Division**



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September 9, 2003

Catherine W. Fish, MS, RD
Senior Associate Director
Regulatory Affairs

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® Men's Health
Formula Dietary Supplement**

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

Phone: (973) 254-4793
Fax: (973) 254-4875

Dear Sir or Madam:

The following information is an amendment to the 30-Day Post Market Notification for Structure/Function Claims dated July 16, 2002 for One-A-Day® Men's Health Formula Dietary Supplement. The purpose of this amendment is to notify the Agency of additional claims now being made on the product label and to modify claims originally submitted.

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® Men's Health Formula Dietary Supplement.

PRODUCT NAME	One-A-Day® Men's Health Formula
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® Men's Health Formula Dietary Supplement Multivitamin/Multimineral Product

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TEXT OF STATEMENT BEING MADE	
Top Panel of Carton	<ul style="list-style-type: none"> • Support Prostate Health with a unique combination of Lycopene, Selenium, Vitamin E and Zinc.* • Promote Healthy Homocysteine levels, an emerging measure of Heart Health, with Vitamins B6, B12 and Folic Acid.* • Help Maintain Normal Blood Pressure⁺⁺ with Calcium, Magnesium, Potassium and Vitamin C.* <p>⁺⁺For people with blood pressure already within the normal range</p>
5th Panel of Carton	<p>Complete Multivitamin for Men Plus More to support:*</p> <ul style="list-style-type: none"> • HEALTHY PROSTATE • HEALTHY HEART
Right Panel of Carton	<p>Key Ingredients for Men*</p> <ul style="list-style-type: none"> • HEALTHY PROSTATE: Lycopene, Selenium, Vitamin E, Zinc • HEALTHY EYES: Vitamin A, Vitamin C, Vitamin E, Zinc • BLOOD PRESSURE⁺⁺: Calcium, Magnesium, Potassium, Vitamin C • ENERGY: Vitamin B6, Biotin, Magnesium, Niacin, Pantothenic Acid, Riboflavin, Thiamin • HEALTHY HEART: Vitamin C, Vitamin B6, Vitamin B12, Folic Acid, Vitamin E <p>⁺⁺Helps maintain blood pressure already within the normal range</p>
Back of Carton	<p>It has a unique combination of nutrients for men's health concerns, and Lycopene, an antioxidant found in nature in fruits and vegetables, to support a healthy prostate.* In addition to Lycopene, Men's Health Formula also contains Zinc, Selenium and Vitamin E – key ingredients shown to support a healthy prostate.*</p>
<p>*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.</p>	

Page 3 of 3

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,

A handwritten signature in cursive script that reads "Catherine W. Fish".

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