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JUL 25 2002

Ms. Catherine W. Fish  
Associate Director, Regulatory Affairs  
Bayer Consumer Care Division  
36 Columbia Road  
**P.O.Box** 1910  
Morristown, New Jersey 07962-1910

Dear Ms. Fish:

This is in response to your letter of July 16, 2002 to the Food and Drug Administration (FDA) pursuant to 21 **U.S.C.** 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Bayer Consumer Care Division is making the following claim for the product One-A-Day@Men's Health Formula.

The product One-A-Day@Men's Health Formula uses the claim "...to help maintain blood pressure." In the preamble to the **January** 6, 2000 final rule on structure/function claims for dietary supplements (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. FDA considers a cholesterol claim not qualified as described above to be an implied claim to prevent coronary heart disease by preventing the development of elevated cholesterol levels or reducing elevated cholesterol. The same principle applies to your claim about the maintenance of blood pressure level; that is, a claim that does not make clear that the product is only for people with blood pressure that is already within normal limits implies that the product is intended to treat hypertension, which is a disease.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate a disease. This claim does not meet the

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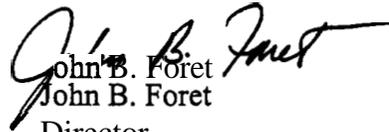
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requirements of 21 U.S.C. 343(r)(6). This claim suggests that this products is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,



John B. Foret  
John B. Foret

Director

Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200

FDA, New Jersey District Office, Office of Compliance, HFR-MA340

Consumer Care Division

Bayer Corporation  
 36 Columbia Road  
 P.O. Box 1910  
 Morristown, NJ 07962-1910  
 Phone: 973 254-5000

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July 16, 2002

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**

Dear Sir or Madam:

Bayer 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.

<b>PRODUCT NAME</b>	One-A-Day® Men's Health Formula
<b>NAME /ADDRESS OF DISTRIBUTOR</b>	Bayer Corporation Consumer Care Division 36 Columbia Road P. O.Box 1910 Morristown, New Jersey 07962-1910
<b>NAME OF DIETARY INGREDIENT/SUPPLEMENT (SUBJECT OF THE STATEMENT)</b>	One-A-Day® Men's Health Formula Dietary Supplement Multivitamin/Multimineral Product
<b>TEXT OF STATEMENT BEING MADE</b>	
<b>Top Panel of Carton</b>	<ul style="list-style-type: none"> <li>• A combination of <b>Lycopene, Selenium, Vitamin E and Zinc</b> for</li> <li>• <b>Calcium, Magnesium and Vitamin C</b> to help</li> <li>• <b>B-Vitamins</b> for the release of energy from food*</li> </ul>
<b>5<sup>th</sup> Panel of Carton</b>	<p>Enhanced Multivitamin for Men designed to</p> <ul style="list-style-type: none"> <li>• <b>PROTECT</b></li> <li>• <b>HEALTHY HEART</b></li> </ul> <p>NOW WITH LYCOPENE, a cell</p>

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<b>Right Panel of Carton</b>	Key Ingredients for Men* <ul style="list-style-type: none"><li>• HEALTHY PROSTATE: Lycopene, Selenium, Vitamin E, Zinc</li><li>• HEALTHY EYES: Vitamin A, Vitamin C, Vitamin E, Zinc</li><li>• BLOOD PRESSURE: Calcium, Magnesium, Potassium, Vitamin C</li><li>• ENERGY: Vitamin B6, Biotin, Magnesium, Niacin, Pantothenic Acid, Riboflavin, Thiamin</li><li>• HEALTHY HEART: Vitamin C, Vitamin B6, Vitamin B12, Folic Acid, Vitamin E</li></ul>
<b>Back of Carton</b>	It has a unique combination of nutrients for men's health concerns, plus Lycopene, a natural antioxidant found 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.*

In accordance with 21 CFR 101.93, the information contained in this notification is complete and accurate. Bayer 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 Joanne Robinett at 973-408-8093.

Sincerely,



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