

# MARY KAY®

June 18, 1998

pg. 1 of 2

Food and Drug Administration  
Office of Special Nutritionals (HFS-450) 758 '98 JUN 30 P2:25  
Center for Food Safety and Applied Nutrition  
200 C Street, SW  
Washington, DC 20204

Dear Sirs,

Notice is hereby given pursuant to the requirements of section 403(r)(6) (21U.S.C. 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, that Mary Kay Inc., 16251 Dallas Parkway Dallas, Texas 75248 within the past 30 days commenced marketing a dietary supplement bearing the following statements on the label and/or labeling.

*Daily Benefits™ for Men Dietary Supplements*

*.....support the body's natural defenses to protect our health.*

*Vitamins, minerals and herbs scientifically formulated to help:*

*Protect the cardiovascular system*

*Support a healthy immune system*

*Promote your ability to cope with stress*

*Maintain a healthy prostate function*

*This [Daily Benefits for Men] includes vitamin E to help protect the cardiovascular system, antioxidants to support a healthy immune system, a balanced B-complex to help improve the body's ability to manage stress, saw palmetto extract and lycopene to help maintain a healthy prostate function, and much more.*

*Vitamin E may also play a role by helping maintain healthy arteries.*

*That part [grape seed] of the grape contains the highest concentration of flavonoids, a nutrient compound shown to promote vascular health. Flavonoids also enhance the body's antioxidant defense system and may be a more powerful antioxidant than beta-carotene or vitamins C and E.*

*Antioxidants protect cells from the damaging effects of free radicals--unstable, toxic molecules.*

*Antioxidants support the body's immune system.*

97S - 0162

Mary Kay Inc.  
Research and Development Division  
1330 Regal Row  
Dallas TX 75247

LET 1799

# MARY KAY®

pg. 2 of 2

*L-Carnitine is essential for the body to metabolize fat, and it also plays a role in supporting healthy heart functions.*

*Moreover, studies show that nutrients found in the B-complex also help regulate homocysteine levels in the blood, which can help enhance cardiovascular health.*

*The B vitamins are best known for their role in forming red blood cells.*

*Some B vitamins are involved in forming neurotransmitters, the chemical messengers of the nerves. Others help maintain healthy nerves and proper brain function, while still others produce protective sheaths that cover nerves.*

*The berries [red berries/saw palmetto extract] contain fatty acids and plant sterols that can help to regulate the action of dihydrotestosterone, and thus may help to maintain prostate health.*

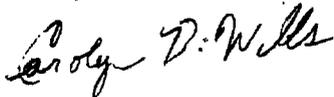
*Lycopene provides antioxidant benefits that have been shown to enhance prostate health in men who consume significant amounts of this nutrient.*

*.....selenium and zinc to help keep your body's defenses strong.*

*Beta Carotene,.....,along with Folate, sometimes known as Folic Acid, have both been closely linked to maintenance of a healthy heart.*

The undersigned certifies that the information contained in this notice is complete and accurate and that Mary Kay Inc. has substantiated that the statement is truthful and not misleading.

Sincerely,



**Carolyn B. Wills**  
Manager, Regulatory Affairs and Compliance