

## **Consumer Care Division**

8061 '01 JIN 11 P2:14

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

May 24, 2001

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 'C' Street, SW Washington, D. C. 20204



## **30-day Post Market Notification**

PRODUCT NAME:	One-A-Day® Prostate Health
NAME /ADDRESS OF	Bayer Corporation
DISTRIBUTOR	Consumer Care Division
	36 Columbia Road
	P. O. Box 1910
	Morristown, New Jersey 07962-1910
NAME OF DIETARY	TEXT OF STATEMENT BEING MADE:
INGREDIENT/SUPPLEMENT	
(SUBJECT OF THE STATEMENT):	
One-A-Day® Prostate Health	Supports Prostate Health*
Saw Palmetto Extract	• One-A- Day-Prostate Health goes beyond just Saw Palmetto to support a healthy prostate*.
(Serenoa repens) (fruit)	
Lycopene (Lycopersicon	Support a readily produce .
esculentum) (fruit	

\*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 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

Per the listed items in 21 CFR 101.93, the information contained in this notification is complete and accurate. Bayer Consumer Care Division has substantiation, on file, that the statement is truthful and not misleading. (This notification is comprised of an original and two (2) copies.)

Anita Fenty

Regulatory Affairs Manager