



APR 10 2003

2106 '03 APR 18 P1:59

Mr. Gregory P. Zaino
President
Prostate Rx, Inc.
432 Pinelake Drive
Naples, Florida 34112

Dear Mr. Zaino:

This is in response to your letters of March 13, 2003 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 Prostate Rx, Inc. is making the following claims for the product **Prostate Rx**[®]:

“...Most men experience a gradual increase in prostate size at some time after middle age...an enlarged prostate can lead to an obstruction of urinary flow. For many men, this can mean discomfort in urination or increased night time urination.. Clinical studies show using standardized liquid extract may promote prostate relief from these symptoms.”

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 statements that you are making for this product suggests that it is intended to treat, prevent, or mitigate disease (i.e., benign prostatic hypertrophy). These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product 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.

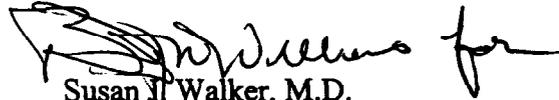
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Please contact us if we may be of further assistance.

Sincerely,



Susan J. Walker, M.D.

Acting Director

Division of Dietary Supplement Programs

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, Florida District Office, Office of Compliance, HFR-SE240

30 day

RECEIVED
MAR 31 2003
BY:

SUBMITTING SECTION :403(r)(6)

3/13/03

DISTRIBUTOR, MANUFACTURER:

Prostate Rx,inc.
1206 Kingsway
NAPLES , FL. 34104
1-239-272-3590

PACKER&SOFTGEL MAKER:

PACIFIC ENCAPSULATION,INC
JEFF PETERSON
784 CHANNEL ST.
SAN PEDRO,CA. 90731

TEXT OF STATEMENT MADE : NONE

NAME OF DIETARY SUPPLEMENT : SAW PALMETTO /PROSTATE RX

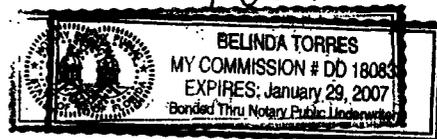
OWNER NAME: GREGORY P.ZAINO

I,GREGORY P. ZAINO CERTIFY THE ACCURACY OF THE INFORMATION
PRESENTED AND CONTAINED IN THIS NOTICE AND THAT IT IS COMPLETE
AND TRUTHFUL AND IS NOT MISLEADING.

Gregory P. Zaino Pres.
GREGORY P. ZAINO PRES. 3/ 13 /03

FLDL
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Belinda Torres
WITNESS NOTARY 3/ 13 /03



If your're not buying from Prostate Rx you're not buying direct ! !™



BLADDER
ENLARGED PROSTATE
URETHRA

The prostate, is one of the largest glands in the male human body. The prostate size normally remains constant between the ages of 30 and 45, most men experience a gradual increase in prostate size at some time after middle age. Because the prostate surrounds the urinary tract, an enlarged prostate can lead to an obstruction of urinary flow. For many men, this can mean discomfort in urination or increased night time urination. Clinical studies show using standardized liquid extract may promote prostate relief from these symptoms.*

WARNING: KEEP OUT OF REACH OF CHILDREN

Prostate RX

60 SoftGels
2 Month Supply

SAW PALMETTO
100%

600-MG
Maximum Strength

Supplement Facts:	Serving Size: 1 SoftGel
Active Ingredients: All Natural	Dosage: 1 A Day
100% Pure Saw Palmetto Standardized Premium Liquid Extract 80% to 85% Fatty Acids	Purpose: Promotes Prostate Health

Other Ingredients: None. No Fillers No Sweeteners.
SoftGel Ingredients: Water, Glycerin, Gelatin.

Directions: Take one 320 mg SoftGel per day with water, after dinner. Curb intake of liquids after 6 p.m. and onwards.
Visit Your Doctor yearly for a PSA test. Consult pharmacist before use if you are taking prescription drugs.

Toll Free Re-Ordering
1-888-772-274-1

Web Site Ordering: www.ProstateRX.net
email: prostateRX@soLoom

Always Free Shipping & Handling. \$2 OFF On Reorders.
Do not use if safety seal is broken or missing. Store in cool dry place.

*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.

Not Available in the following states: CA, HI, IL, IN, MD, MI, MN, NY, RI, VA, WI, WV, DC



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NOTE: COLOR PROOFS ARE PROVIDED ONLY AS A VISUAL REFERENCE TO THE FINAL PRINTED PIECE. THE COLORS SHOWN ARE ONLY REPRESENTATIONAL, AND ARE NOT INTENDED TO MATCH ACTUAL PRESS COLORS.

Size: 6.375 X 2.25

Job #: SAW 101 - revised 03/03

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