



JUL 21 2003

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

Dear Mr. Zaino:

This is in response to your letter of June 28, 2003 to the Food and Drug Administration (FDA) responding to our June 9, 2003 letter concerning claims you intend to make in the labeling of a dietary supplement named **Prostate Rx**[®] pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)).

In your letter you submitted a revised claim that states:

“The Prostate is one of the largest glands in the male human body. Most men experience a gradual increase in prostate size at some time after middle age. Clinical studies show using standardized liquid extract may promote prostate relief from these symptoms.”

The label you submitted also bears a vignette that, among other things, includes the term “enlarged prostate.”

We have carefully considered the revised claims you proposed in your letter and believe that, in the context of the explicit statement in the vignette about an “enlarged prostate,” in their totality, they continue to suggest that the product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B); that is, the product appears to be intended to treat a disease, namely, benign prostatic hypertrophy, which is a disease that is defined, in part, as an enlargement of the prostate in older men.

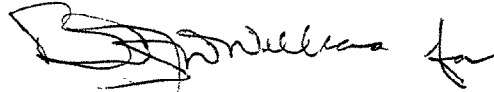
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Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Susan J. Walker" followed by a flourish.

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

54898

We will revise our label as of October 30, 2003

The Prostate is one of the largest glands in the male human body. Most men experience a gradual increase in prostate size at some time after middle age. Clinical studies show using standardized liquid extract may promote prostate relief.

Please mail any responses to 1206 Kingsway Naples, FL 34104

The prostate, is one of the largest glands in the male human body.

most men experience a gradual increase in prostate size at some time after middle age.

Clinical studies show using standardized liquid extract may promote prostate relief from these symptoms.*

WARNING KEEP OUT OF REACH OF CHILDREN

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Naples, FL
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1994

Prostate Rx

60 SoftGels
2 Month Supply

SAW PALMETTO 100%

320-mg
Maximum Strength

1-A-Day Dosage.
100% Pure Liquid Filled SoftGels 320mg.
You Are Buying Direct From The Grower!

Supplement Facts: Serving Size: 1 SoftGel

Active Ingredients: All Natural	Dosage	Purpose
100% Pure Saw Palmetto Standardized Premium Liquid Extract 93% to 98% Fatty Acids	1 A Day	Promotes Prostate Health

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

Directions: Take one 320 mg SoftGel per day with water, after dinner. Curb intake of liquids after 6 p.m. and exercise.

Visit Your Doctor yearly for a P.S.A test. Consult pharmacist before use if you are taking prescription drugs.

Toll Free Re-Ordering
1-888-772-2741
Web Site Ordering: www.ProstateRX.net
email: prostaterxx@aol.com

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.

[Handwritten Signature]
COO
6/25/03

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

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