DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

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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."

We have carefully considered the revised claim you proposed in your letter and believe that it is still an implied disease claim that may not be made in the labeling of a dietary supplement. The claim for your product describes a characteristic sign associated with an abnormal prostate condition in aging men, that is a disease, namely, benign prostatic hypertrophy (BPH). You describe an "increase in prostate size at some time after middle age." This is a disease claim under 21 CFR 101.93(g)(2)(ii) and 21 CFR 101.93(g)(2)(iii), which provides that a claim about an effect on an abnormal condition associated with a natural state or process is a disease claim if the abnormal condition is uncommon or can cause significant or permanent harm. In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR at 1020-21), FDA discussed BPH and claims about the effect of a product on the prostate. The agency explained that BPH is not a normal consequence of the natural process of aging but rather is an abnormal condition associated with that process. Although BPH is common, claims to treat or prevent it are disease claims because failure to obtain effective treatment can cause significant or permanent harm. Specifically, your claim about an increase in prostate size

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in middle age men describes a hallmark characteristic of the development of BPH and is, therefore, an implied disease claim. This claim suggests 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.

You also proposed in your letter to develop new labels, but you also requested that you be allowed to continue marketing product bearing labels with the disease claims cited in our earlier letter until December 30, 2003. FDA recognizes that a certain amount of time is needed to institute new product labeling to correct a violation. The agency recognizes that to require violative labels to be remedied immediately may not be reasonable in every instance. However, we believe that in the instant case, the proposed six month period of time to implement revised labeling is not reasonable. The agency believes that a reasonable date to expect your product to be in compliance with applicable requirements of the Act is October 31, 2003.

Please contact us if we may be of further assistance.

Sincerely yours,

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

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"We Care About Your Health"™

MAY18,2003

DEAR, SUSAN J. WAILKER, M.D. AND STAFF

IN REPELY TO YOUR LETTER DATED APRIL, 10,2003 WE UNDERSTAND YOUR CONCERNS AND WE WOULD LIKE TO PROPOSE A SOLUTION WE WOULD DUMP ANY LABELS WE HAVE LEFT AFTER DEC 30,03 AND ON NEW LABELS AFTER THIS DATE WOULD BE CHANGED TO READ AS FOLLOWS:

MOST MEN EXPERIENCE A GRADUAL INCREASE IN PROSTATE SIZE AT SOME TIME AFTER MIDDLE AGE. CLINICAL STUDIES USING SAW PALMETTO STANDARDIZED LIQUID EXTRACT MAY SHOW RELIEF.

THANK YOU
GREGORY ZAINO
PROSTATE RX

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