



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

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→ HFI-35

4/9/98

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

19900 MacArthur Blvd., Ste 300  
Irvine, California 92612-2445  
Telephone (714) 798-7600

February 10, 1998  
W/L 17-8

WARNING LETTER

Thomas Gillette, Ph.D., President  
Real Health Laboratories  
2121 El Cajon Boulevard  
San Diego, CA 92104-1101

Dear Dr. Gillette:

This letter is in reference to your firm's marketing, and distribution of your product "The Prostate Supplement".

Labeling for the product (promotional materials) contains drug claims for the treatment and prevention of Benign Prostatic Hypertrophy (BPH). These claims include "prostate dysfunction", "the prevention of BPH and relief of its symptoms", "antiproliferative effect on prostate cancer cells", "reductions in prostate size and symptoms of BPH", and "certain natural ingredients can produce results similar to the leading prostate drugs". Claims associated with symptoms of BPH such as "the constant need to urinate, day or night; difficulty in starting or restricting urination; inability to fully empty bladder; inability to urinate; weak urine stream; incontinence; pain while urinating; painful ejaculation" are also made.

A Federal Register notice dated February 27, 1990, titled "Benign Prostatic Hypertrophy Drug Products for Over-the-Counter Human Use" established that no drug product offered for over-the-counter (OTC) human use for Benign Prostatic Hypertrophy is generally recognized as safe and effective and therefore, the product would be misbranded.

"The Prostate Supplement" is a drug [section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act)] and a "new drug" [section 201(p) of the Act]. This product may not be marketed in the United States without an approved new drug application [section 505(a) of the Act].

This drug is also misbranded [section 502(f)(1) of the Act] because the labeling fails to bear adequate directions for use and because the labeling is false and misleading as it suggests that the product is safe and effective for its intended use when, in fact, this has not been established [section 502(a) of the Act].

This letter is not intended to be an all inclusive review of all labeling and products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

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We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by the Food and Drug Administration

without further notice. The Federal Food, Drug and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Your promotional material claims that the product "is manufactured in the United States in a licensed pharmaceutical facility to the exacting standards of the U.S. Food and Drug Administration (FDA)." Invoking the name "FDA" implies approval of the product or its manufacture when, in fact, this is not the case.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. You should also include an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to:

John A. Nicholson, Investigator  
U.S. Food and Drug Administration  
Phoenix Resident Post  
4615 East Elwood Street, #200  
Phoenix, AZ 85040.

Sincerely,



Elaine C. Messa, District Director  
Los Angeles District Office