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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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Refer to CFN: 1125280

Food and Drug Administration
Baltimore District Office
Central Region
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3461 x122
FAX: (410) 962-2307

July 23, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ross Z. Pierpont, M.D., President
Gempro International, Inc.
1340 Charwood Road, Suite F
Hanover, Maryland 21076

Dear Dr. Pierpont:

A Food and Drug Administration (FDA) inspection, conducted February 25 to 27, 1998 at your Hanover, Maryland facility, determined that your firm promotes and distributes a product called "ProstaCare." Labeling and promotional material were collected during the inspection. This letter is in reference to the promotion, marketing, and distribution of ProstaCare.

ProstaCare is a drug as defined by Section 201(g) of the Food, Drug, and Cosmetic Act (the Act), and a new drug as defined by Section 201(p) of the Act. This product may not be legally marketed in the United States without an approved New Drug Application, as specified in Section 505 of the Act.

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

Examples of disease claims found in the promotional literature, "Introducing ProstaCare," include:

- "Waking up nights to go to the bathroom; Frequent, urgent need to urinate; Slowness starting urination, or weak stream, tendency to dribble; Inability to empty your bladder completely; Start-and-stop urination";
- "Improved peak flow; less urine held in the bladder; improved "International Prostate Symptom Score"; and

- "Making your bladder force urine through a partly closed prostate could . . . risking kidney damage."

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.

Your promotional literature also exceeds the statement made in your 30-Day Notification, dated August 14, 1997, for this product. The only statement made in that notification concerning this product was that it is "a pure, natural supplement formulated for men age 45 and older."

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.

We request that you take prompt action to correct these violations. Failure to do so may result in enforcement action being initiated by the FDA without further notice. The Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of such products.

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 the Food and Drug Administration, Baltimore District Office, 900 Madison Avenue, Baltimore, MD 21201, Attention: Thomas C. Knott, Compliance Officer.

Sincerely,



Elaine Knowles Cole
Director, Baltimore District

Mr. Michael E. DeDomenico

July 22, 1998

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cc: (CERTIFIED MAIL – RETURN RECEIPT REQUESTED)

Mr. William Vandergiessen,
General Manager, Eastern Division
Praxair Distribution, Inc.
145 Shimersville Road
Bethlehem, PA 18015

Charles Hayes
Plant Manager
Praxair Distribution, Inc.
8124 Norris Lane
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