



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-99-46

March 11, 1999

Paul Romano, President
Premier Direct, Inc.
d/b/a Healthier You
150 E. Palmetto Park Road
Suite 705
Boca Raton, Florida 33432

Dear Mr. Romano:

This letter is in reference to your firm's marketing and distribution of the products "XP-100," "SORE NO-MORE," "AHF Anti homocysteine Formula," "CoQ10-Forte," "EUROPEAN HEALTH CAPSULE," "Clear Lungs," "EYE-BRIGHT," "OXY-LIFE," "PROS-TAMINA PLUS," and "G.I./COLON CLEANSING KIT." Promotional material (labeling) makes therapeutic claims which cause the products to be drugs as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

Examples of the claims include the following:

- "XP-100": "...containing DL-Phenylalanine." "...helps relieve the symptoms of PMS, reduce the swelling and inflammation of arthritis, and helps relieve migraines... More Effective Than Morphine. Safer Than Aspirin". (catalog) and "...miraculous relief (from) neuralgia.rheumatism.carpal tunnel syndrome..." (brochure).
- "SORE NO-MORE": "arthritis treatment" and "...regenerate deteriorating cartilage... repairing damage that has already occurred." (catalog).

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- **"AHF Anti homocysteine Formula":** "TOTAL FREEDOM FROM HEART ATTACK, STROKE OR VASCULAR DISEASE"; and "homocysteine... elevated levels (are) a strong independent risk factor for arteriosclerosis...is involved in all the disease processes associated with cardiovascular disease" (catalog).
- **"CoQ10-Forte":** "...used regularly to treat most major heart conditions, including congestive heart failure, angina, high blood pressure, arrhythmia and mitral valve prolapse" and "...hyperactive thyroid gland, heart disease, diabetes or even poor sperm motility, COQ10...may help treat a wide range of health conditions." (catalog).
- **"EUROPEAN HEALTH CAPSULE":** "...may lower your risk of heart attack and reduce total body cholesterol...reduce plaque (fat deposits) in the arteries...possibly protects against cancer." (catalog).
- **"Clear Lungs":** A Chinese herbal remedy for "...the temporary relief of bronchial congestion due to emphysema, bronchitis, pneumonia, flu...restore free breathing," "...A natural alternative to Bronkaid and all lung congestion prescription drugs." (catalog).
- **"EYE-BRIGHT":** "cataracts, diabetic retinopathy and other health problems..."
- **"OXY-LIFE":** "Gently eliminates infectious bacteria, viruses, fungus and parasites!" and "OXY-Life is for you, if you... ...Have asthma or emphysema" (catalog).
- **"PROS-TAMINA PLUS":** "...much of the pain and discomfort of prostate disorders can be completely avoided" and in, "A Guide for Men over 40" it states "Even if you have been diagnosed with Stage D cancer, my program can help you control your condition--without surgery."
- **"G.I./COLON CLEANSING KIT"** which contains **"SUPER COLO₂ZONE with EDTA," "DYNAMO₂," "LACTOBACILLUS PLUS," "CELL-REGEN," AND "FIBER-FLUSH":** "...fungi and parasites...cannot get past Super Colo₂Zone with EDTA...kills parasites and worms...reduce problems such as Candida, Giardia, and other parasites...reduces the tendency toward hemorrhoids, irritable 'bowel' syndrome..."

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The products are "new drugs because there is not evidence that they are generally recognized as safe and effective for their intended use [section 201(p) of the Act]. Therefore, they may not be legally marketed in this country without approved New Drug Applications [section 505(a) of the Act].

The drugs are also misbranded because their labeling fails to bear adequate directions for use [section 502(f)(1) of the Act]. The labeling is false and misleading as it suggests that the products are safe and effective for their intended uses when 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.

We request that you take prompt action to correct these violations. Failure to promptly correct these 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 an injunction against the manufacturer and/or distributor of illegal 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, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not occur. 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 directed to Martin E. Katz, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Ste. 200, Maitland, Florida 32751, telephone no. (407) 475-4729.

Sincerely,



Douglas D. Tolen
Director, Florida District