



DEPARTMENT OF HEALTH & HUMAN SERVICES

90327

New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433
Tel. 718-340-7000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Michael Peng
President
Greenvalley, LLC
165A Marine Street
Farmingdale, NY 11735

September 26, 2003

Ref: NYK-2003-35

Dear Mr. Peng:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address: <http://www.gyconline.com> and has determined that the products "Revitalize," "Revitalize II™," and "Prostete Pads™," being offered for sale are promoted for conditions that cause the products to be drugs under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 USC 321(g)(1)]. The therapeutic claims on your web site establish that the products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease or are intended to affect the structure or any function of the body.

Examples of some of the claims observed on your web site include:

Revitalize:

"Ingredients: Puerariae Radis, Bupleuri Radix, Cimicifugae Rhizoma, Notoginseng Radix."

"Revitalize is a unique product than can relieve many diabetes-related symptoms..."

"Revitalize may help....relieve blood and qi stagnation, and speed the metabolism process, thus strengthening the immune system and the pancreas. By converting sugar into useful energy, Revitalize helps people, who suffer from diabetes, lead a more energetic life while numbness of extremities, itchy skin, edema, constipation, and other diabetes-related symptoms are quickly relieved after using Revitalize."

"Diabetes patients my gradually decrease the dosage of oral medication..."

“...diabetes-related syndromes should basically disappear;...”

Revitalize II™:

“...herbal ingredients: Chinese cimicifuga, Bupleurum root, Safflower, and Peach seed”

“To achieve the best effects, please use the patches for about 15 to 16 hours during daytime because the human’s body will have a more intense blood circulation than during nighttime and be more capable to absorb and utilize the natural herbal ingredients of Revitalize II Natural Body-Patches.”

“Revitalize II Natural Body-Patches is a great help for people who suffer from Type II Diabetes!”

”The dosage of oral medication can be gradually decreased after 30-day usage of the product....”

“Based on your own situation, you can stop taking oral medication and release your diet restrictions appropriately.”

Prostete™ Pads:

“The active ingredient of Prostete Pads is rape pollen...”

“Pollen has very abundant nutrition substances, and contains high-quality proteins, amino acid, vitamins, microelements and varied enzymes.”

“It works directly on that part of the body, improve the microcirculation in that part, and enhance the skin’s absorbency of pollen, so that pollen can directly play its role to help regulate the disorderly prostate functions.”

“Prostete?Pads are developed to help relieve many prostate-disease-related symptoms.”

Furthermore, FDA has no information that your products are generally recognized as safe and effective for the above referenced conditions and therefore, the products may also be "new drugs" under section 201(p) of the Act [21 USC 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 USC 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

The above products do not qualify as dietary supplements since they are not intended for ingestion as set forth in section 201(ff)(2)(A)(i) of the Act. Only products that are intended for ingestion may be lawfully marketed as dietary supplements. Topical products and products intended to enter into the body directly through the skin or mucosal tissues, such as transdermal products, are not dietary supplements.

Furthermore, false and misleading statements on your Internet website suggesting that these products are safe and effective for their intended uses cause these drugs to be misbranded under section 502(a) of the Act.

These products are also misbranded under section 502(f)(1) because your labels and labeling fail to bear adequate directions for use for the conditions these products are intended to treat. The continued marketing of these products with these claims violates the Act and may subject you or the products to regulatory actions without further notice.

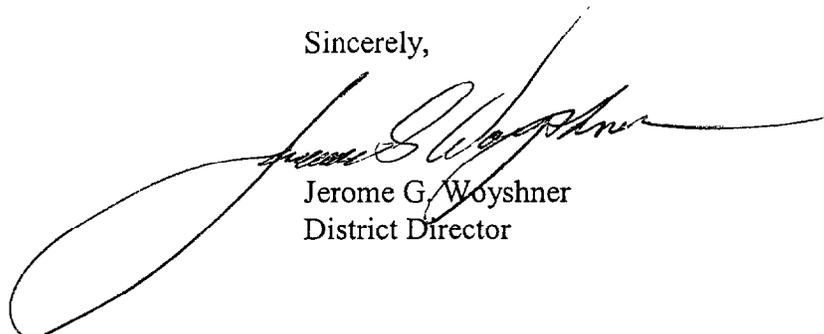
This letter is not intended to be an all-inclusive review of all labeling and products your firm may market. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

You are instructed to immediately cease marketing and distributing these products and to 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/or 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. 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 attention of Bruce A. Goldwitz, Compliance Officer at the above letterhead address.

Sincerely,

A handwritten signature in black ink, appearing to read "Jerome G. Woyshner", is written over a large, stylized loop that extends to the left and then curves back under the signature.

Jerome G. Woyshner
District Director