



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

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Telephone (973) 526-6008

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

WARNING LETTER

**Certified Mail
Return Receipt Requested**

File # 00-NWJ-26

March 30, 2000

Patrick Garrad
President and Owner
KGB Media, Inc.
11 John Applegate Road
West Redding, CT 06896

Dear Mr. Garrad:

This letter is in reference to the marketing and distribution of various "Healing Herbs of China" products by your firm, KGB Media, 1903 Merrywood Drive, Edison, NJ 08817. Labeling for these products contain therapeutic claims that cause the products to be drugs under Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act). Labeling includes product labels, catalogs, Internet sites and any other promotional literature that you distribute in connection with your products.

Products and objectionable claims include the following:

- Bilberry Extract 40 mg. tablets and 60 mg. capsules -- night blindness, lowers blood pressure, reduces clotting, eye disease, pigmentosa, retinitis, glaucoma, myopia, vascular and blood disorders;
- Echinacea and Echinacea with Goldenseal -- remedy for winter sickness, alternative to antibiotics, fight bacterial and viral infections;
- Emperor's Teapills (Tian Wang Bu Zin Dan Wan) -- hyperthyroidism, insomnia, palpitations, burning urination, mouth and tongue ulcers;
- Essential Harmony Tea -- high blood sugar, diabetes;
- Gan Mao Ling Pills -- colds, flu, chills high fever, swollen lymph glands, sore throat;

- Healthy Heart (Guan Zin Er Hao Fang) -- dilate the coronary artery, increase the volume of blood flow of the coronary artery, raise the hypoxia toleration of the cardiac muscle, promote the fibrinolytic system, inhibit platelet buildup, suitable for both acute and chronic conditions, heart disease;
- Imperial Astragali Extract and Jade Screen Teapills (Astralagus) -- diabetes, heart disease, high blood pressure, Alzheimer's, helping the body to fight disease;
- Joint Inflammation Formula (Guan Jie Yan Wan) -- chronic or acute joint pain, low back pain, achy knees and ankles, swollen or puffy joints, flaring of the sciatic nerve, rheumatoid arthritis;
- Kai Kit Wan -- prostate enlargement/swelling, reduces pain, makes urination easier;
- Lingzhi Reishi Capsules -- lowering blood pressure, treat high cholesterol, normalizing blood pressure, cure allergies, effective tumor fighter;
- Royal Jelly -- senility, depression;
- Saw Palmetto Berries -- treat urinary, prostate and reproductive disorders, enlarged prostate, enuresis, nocturia, atrophy of the testes, impotence, inflammation of prostate;
- St. John's Wort -- antidepressant, anti-viral activity against herpes simplex, influenza, and Epstein-Barr virus;
- The Snake and the Dragon (Lung Tan Zie Gan Wan) -- urinary tract infection, headaches, migraine headaches, gallstones, inflamed gallbladder, jaundice and hepatitis, herpes, external genital and vaginal discharge, kidney infection, testicle swelling;
- Gastrodia Uncaria Pills (Tian Ma Gou Teng Yin Wan) -- high blood pressure, migraine headaches, a ringing in the ears, hypertension.

The above products are "new drugs" as defined by Section 201(p) of the Act. Therefore, they may not be legally marketed in this country without FDA-approved New Drug Applications, as called for in Section 502(a) of the Act.

The above products are also misbranded in that (a) their labeling fails to bear adequate directions for the conditions for which they are offered, as defined by Section 502(f) of the Act, and (b) their labeling is false and misleading because the labeling suggests the products are safe and effective for their intended use, when in fact, this has not been established, as is called for in Section 502(a) of the Act.

Also, the labeling for your products state that "These medicines are created from natural drugs." The labeling also states that "all herbal ingredients imported into the U.S. are tested by ... the FDA," and "all [your firm's] products are laboratory tested to meet or surpass FDA standards." The FDA does not perform laboratory testing on all herbal ingredients imported into the United

States. Further, we are unaware of the existence of any FDA testing standards for products such as yours or of any FDA programs to perform this testing.

Therapeutic claims for additional products are included in your firm's product labeling. Such claims may also cause these products to be misbranded. Products and claims include:

- Bojenmi Tea -- removes atherosclerotic plaque, high blood pressure, heart disease and stroke;
- Bright Eyes Formula (Ming Mu Di Huang Wan) -- photophobia, glaucoma, cataracts;
- Central Chi (Bu Zhong Yi Qi Wan) -- cure those in the aftermath of a very serious disease or illness, all forms of debilitation, neurasthenia, anemia, muscle atrophy and digestive disorders;
- ChemoAid -- chemotherapy, leukopenia;
- Curing Pills (Kan Ning Wan) -- Montezuma's Revenge (diarrhea), mild food poisoning, and stomach flu accompanied by sudden, violent cramping, vomiting and headaches;
- Damiana -- asthma, bronchitis, depression;
- Dang Gui (Angelica Sinesis or Donq Quai) -- abnormal menstruation, suppressed menstrual flow, painful or difficult menstruation, uterine bleeding;
- Defense Enhancer (Mian Yi Yin) -- improving T-cell counts, upper respiratory tract infections, fever, coughing, sore throat, colds, flu, alternative to antibiotics;
- Emperor's Secret Classic Tea -- high blood pressure;
- Feverfew -- fevers, arthritis, other aches and pains, inflammation;
- Fibrocare -- uterine fibroids, intramural tumors, submucosal tumors;
- Free and Easy Wanderer Pills (Xiao Yao Wan) -- depression;
- Garlic -- parasites, respiratory problems, anti-bacterial action;
- Goldenseal Root -- relieve pain, heal wounds, stop bleeding, gastric and genitourinary disorders, inflamed mucous membranes including stomach, intestinal, vaginal and rectal, anti-bacterial action helps reduce or prevent infection of open sores;
- Gotu Kola -- antibiotic, anti-inflammatory, reduce fevers, fight infections, high blood pressure, mental disorders;

- Hayfever and Allergies Formula (Pe Min Kan Wan) -- hayfever, allergies, drying phlegm, opens nasal passages, stuffy noses, sneezing, supplement to cold formulas;
- Ma Huang -- coughing, disuria, edema;
- Margarite Acne Pills -- acne, furuncles, skin itching, rashes, hives;
- Panta Tea -- high cholesterol;
- Pau D'Arco -- infectious diseases, wounds, toothache, sexually transmitted diseases, as potent as ketoconazole, a common anti-fungal drug;
- Peaceful Sleep Tablets -- insomnia, anxiety;
- Valerian -- insomnia, hysteria, natural tranquilizer ... Unlike many prescription drugs, it has almost no unpleasant side-effects;
- Yi Shen Ling Formula -- natural alternative to Viagra.

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

You should take prompt action to correct all labeling and promotional violations. If you do not promptly correct the violations, FDA may execute regulatory action against you and/or your firm without further notice. Such regulatory action can include seizure of products, injunction of marketing and distributing operations, or criminal prosecution.

You should notify this office in writing, within 15 working days upon receipt of this letter, of the steps you have taken to bring your firm into compliance with the law. Your response should 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 frame within the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to the Food and Drug Administration, Attention: Kirk D. Sooter, Compliance Officer, at the address and telephone number above.

Sincerely yours,



Douglas I. Ellsworth
District Director