



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Barbara  
Public Health Service 11/6/97

# PURGED

Food and Drug Administration  
Minneapolis District  
240 Hennepin Avenue  
Minneapolis MN 55401-1999  
Telephone: 612-334-4100

October 27, 1997

cc: HFI-35/FOI Staff  
DWA

## WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Refer to MIN 98 - 8

Kelvin K. Yip  
Manager  
Yat Chau U.S.A. Ginseng City, Inc.  
400 Main Street  
Marathon, Wisconsin 54448

Dear Mr. Yip:

The Food and Drug Administration (FDA) recently conducted an inspection of your nutritional supplement facilities at Marathon, WI. Investigator Girolamo collected samples of labeling and products manufactured and/or distributed by your firm including promotional brochures (labeling) for your ginseng products entitled "WHAT IS WISCONSIN GINSENG," "How Ginseng is Used," and "American Ginseng."

Your promotional brochures include therapeutic claims for ginseng which cause your ginseng capsules to be drugs [Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act)]. For example, objectionable claims include the following:

Under the heading "WHAT IS WISCONSIN GINSENG": "...protect against the harmful effects of drinking and smoking, reduce serum cholesterol.... ...reduces the side effects of chemotherapy.... ...and prevent illness or disease."

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Under the heading "How Ginseng is Used": "...preventing or coping with a hangover.... ...dysentery.... ...depression and insomnia.... ...abnormally high blood pressure.... Regulating blood pressure. ...reduction in the blood pressure. ...heart attack or heart disease. Anti-diabetic. ...restore sexual function.... ...prevent possible menopausal disorder."

Under the heading "American Ginseng": "...senile dementia and amnesia. ...improvement of healthy condition of Aids [sic] and cancer patients. ...prevent stress-induced ulcers. ...activity against blood platelet aggregation. ...prevention and treatment of thrombus, such as cerebral thrombus. Anti-arrhythmic [sic] activity. ...reduces serum cholesterol, triglyceride. ...treatment and prevention of arteriosclerosis and heart attack. Anti-cancer activity: ...used for treatment of cancer patients. Hypoglycemic activity: ...reduces glucose level in serum. ...treatment of phase II diabetes. ...relieves alcoholic intoxication.... ...reduces the toxicity of hydrocortison [sic], prednison [sic], prednisolone and some anticancer drugs, such as cyclophosphamide. Radioprotective Effect: ...used for radiation illness. ...increased sperm counts and enhanced sex ability.... ...used for sex degeneration."

In addition, under the heading "American Ginseng," your brochure specifically states that your ginseng capsules are not intended as an aphrodisiac, a substance which enhances normal sexual function: "The herb [ginseng], however, is not an aphrodisiac--a substance to be taken at the time of sexual activity to increase virility." Because your ginseng capsules are not intended for use as an aphrodisiac, your references to the treatment of sexual dysfunction represent disease claims.

Further, claims that ginseng can relieve alcohol intoxication cause your product to be subject to the Final Rule for "Orally Administered Drug Products for Relief of Symptoms Associated with Overindulgence in Alcohol and Food for Over-the-Counter (OTC) Human Use; Decision on Ingredients Intended to Minimize or Prevent Inebriation." In that Final Rule, FDA determined that no ingredient is regarded as safe and effective for use in an OTC drug either as a sobriety aid or to minimize or prevent inebriation. Such products may present a potential health hazard, particularly when motorists rely on unsubstantiated claims that the products will prevent or minimize the effect of alcohol or reduce an inebriated state. This rule banned all such products as unapproved new drugs.

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Since this is a new drug [Section 201(p) of the Act] it may not be marketed in the U.S. without an approved new drug application [Section 505(a) of the Act].

Also, this drug is misbranded [Section 502(f)(1) of the Act] because its labeling fails to bear adequate directions for use for the conditions for which it is offered and because its labeling is false and misleading since it suggests that ginseng capsules are safe and effective for their labeled uses 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.

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 injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within 15 working days of receipt of this letter of 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 ensure 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.

Additionally, the disease claims listed above are not associated specifically with any one of your ginseng products and so your brochures may cause all of your firm's ginseng products to be new drugs and to be misbranded.

Your reply should be sent to Compliance Officer Thomas P. Nelson at the address indicated on the letterhead.

Sincerely,



Albert H. Schwab  
Acting Director  
Minneapolis District