



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
 Denver District Office  
 Building 20 – Denver Federal Center  
 P.O. Box 25087  
 Denver, Colorado 80225-0087  
 TELEPHONE: 303-236-3000

WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

October 1, 1999

Mr. Robert E. Yates, President  
 Vancol Industries, Inc.  
 1700 E. 68<sup>th</sup> Avenue  
 Denver, Colorado 80229

DEN-99-23

**REVIEWED  
 NOTHING PURGED**

Dear Mr. Yates:

This letter is in reference to the products "Immunity Green Tea", "Vitality Orange Pineapple", "High Energy Citrus Punch", "Potency Fruit Punch", and "Focus Watermelon Kiwi" promoted, marketed, and distributed by your firm. Product labels for these products make the following disease claims:

- **"Immunity Green Tea"** claims include: "Green Tea: anticancer properties; Ginseng: anticancer...; Angelica: Anticancer, antibacterial...; St. Johns Wort: Antidepressant, antiviral, antibacterial properties; Dandelion: ...anticancer properties";
- **"Vitality Orange Pineapple"** claims include: "Aloe Vera: antibacterial, antiviral, antifungal antiallergy, anti-inflammatory properties ... wound healing; Dandelion: ... anticancer properties; Ginseng: ... anticancer...; Ginkgo Biloba: ...antidepressant, and antiallergy properties";
- **"High Energy Citrus Punch"** claims include: "Ginkgo Biloba: ...antidepressant, and anti-allergy properties; Ginseng: ... anticancer ...";
- **"Potency Fruit Punch"** claims include: "... Ginkgo Biloba: ...antidepressant and antiallergenic properties; Ylang Ylang: ...antidepressant ...; Jasmine: antidepressant, anti-inflammatory, antiseptic ... "; and

- "Focus Watermelon Kiwi" claims include: "Ginkgo Biloba: ...antidepressant, and antiallergy properties; Ginseng: ... anticancer ...; Angelica: anticancer, antibacterial..."

Based on the claims made for these products and their intended uses, these products are drugs under Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). They are also new drugs under Section 201(p) of the Act and may not be legally marketed in the United States without approved New Drug Applications (Section 505 of the Act). These drugs are also misbranded within the meaning of Section 502(f)(1) of the Act because the labeling fails to bear adequate directions for use. They are further misbranded within the meaning of Section 502(a) of the Act because 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.

This letter is not intended to be an all-inclusive review of all labeling and products your firm markets. It is your responsibility to assure 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 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 seizure of illegal products (Section 304) and for injunction (Section 302) against the manufacturer and/or distributor of illegal products.

Your response should include (1) each step that has been or will be taken to completely correct the current violations and to prevent the recurrence of similar violations; (2) the time within which correction will be completed; and (3) any documentation necessary to show that correction has been achieved.

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 directed to the attention of Ms. Shelly L. Maifarth, Compliance Officer, at the above letterhead address.

**REVIEWED  
NOTHING PURGED**

Sincerely,

  
for Gary C. Dean,  
Director, Denver District