



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

44-35 M31887

19900 MacArthur Blvd., Ste 300  
Irvine, California 92612-2445  
Telephone (714) 798-7600

**WARNING LETTER**

NOV 10 1999

CERTIFIED MAIL – RETURN RECEIPT REQUESTED

David P. Fan  
Corporate Executive Officer  
Viva America Corporation  
1239 Victoria Street  
Costa Mesa, CA 92627

W/L 09-00

Dear Mr. Fan:

This letter is in reference to your firm's marketing of the products [REDACTED] Viva Green Barley, [REDACTED], and Viva Royal Jelly.

Current product labeling, namely the accompanying product catalog that describes the products and the brochures that describe [REDACTED] and Viva Green Barley, makes the following disease claims:

[REDACTED] in the brochure titled "Millions of Americans are diagnosed with cancer every year. It has been proven Selenium can aid in reducing the risk of some cancers," claims that it "Maintains and improves immune function to help ward off cancer. \*\*\* suppresses cancer cells. \*\*\* lower cancer death rates. \*\*\* significant reductions in the incidence of lung cancer, colorectal and prostate cancers."

Viva Green Barley, in the brochure titled "Viva Green Barley," claims that it "May alleviate allergy symptoms and inflammatory reactions," and "Helps prevent fungal infections."

Your product catalog further includes claims for:

Viva Royal Jelly Capsules, such as: "antibacterial, antibiotic \*\*\* can have an inhibitory effect on the growth of bacteria \*\*\* reducing resident arterial plaque \*\*\*."

[REDACTED] such as: "Assists in lowering blood pressure \*\*\* Known to inhibit the formation of blood clots."

These claims cause your products [REDACTED] Viva Green Barley, [REDACTED], and Viva Royal Jelly to be drugs as defined in Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act).

Letter to Mr. Fan

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Further, these products are "new drugs" [Section 201(p) of the Act] because they are not generally recognized as safe and effective for treating the various diseases suggested in the previously mentioned labeling.

The drugs are also misbranded because their labeling is false and misleading because it represents and suggests that the products are safe and effective for their intended uses when in fact this has not been established [Section 502(a) of the Act]. The drugs are also misbranded because the labeling fails to bear adequate directions for those uses stated or suggested in product labeling [Section 502(f)(1) of the Act].

This letter is not intended to be an all inclusive review of your firm's products and product labeling and promotional materials. It is your responsibility to assure that all products marketed by your firm are in compliance with the Act and regulations.

We request that you take prompt action to correct these violations. Failure to make prompt corrections may result in enforcement action being initiated by the Food and Drug Administration. This could include seizure of illegal products and injunctions against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within 15 working days of receipt of this letter describing the specific steps that you have taken to correct the violations and to prevent their recurrence. If corrective action cannot be completed within the 15 working days, state the reasons for the delay and the time within which corrections will be completed.

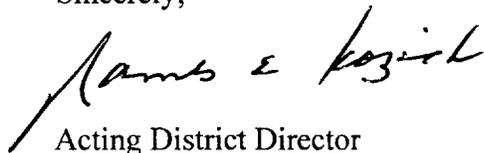
Your written response should be directed to the attention of:

Thomas L. Sawyer  
Director, Compliance Branch  
Food and Drug Administration  
19900 MacArthur Blvd., Suite 300  
Irvine, CA 92612

with a complete copy to:

Center for Drug Evaluation and Research  
Non-Traditional Drug Compliance Team  
7520 Standish Place  
Rockville, MD 20855-2737.

Sincerely,

  
Acting District Director