



DEPARTMENT OF HEALTH & HUMAN SERVICES

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4/15/98

Public Health Service
Food and Drug Administration

Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

April 2, 1998

Ref: 98-DAL-WL-32

WARNING LETTER

**VIA FACSIMILE
AND FEDERAL EXPRESS**

Mr. Tom Spinks, Owner/President
Quest IV Health Products, Inc.
2106 West Pioneer Parkway, Suite 131
Arlington, Texas 76013

Dear Mr. Spinks:

This letter is in reference to your firm's marketing and distribution of the products Restores+ and Caucasicum+. Your promotional brochures (labeling) titled, "Quest IV Health Products, Inc. Restores+ Feeding the Brain," "The Nutrition Works! Newsletter," "Caucasicum+," and "The Addictive Brain" make therapeutic claims for Restores+ and Caucasicum+ which cause the products to be drugs [§ 201(g) of the Federal Food Drug, and Cosmetic Act (the Act)].

Objectionable claims for Restores+ include the following:

- "Helps Relieve Depression."
- "Depression Reliever"
- "Eliminates the Need for Medication In Most ADD/ADHD Patients."
- "ADD/ADHD Controller"
- "And after 2 months of Restores+, 53% of ADD/ADHD people were off all medications!"
- "anxiety attacks" and "panic attacks"
- "Helps relieve the Compulsion to Drink alcohol"

In addition, promotional literature provided in "The Addictive Brain" promotes Restores+ for the treatment of alcohol and numerous drug addictions, PMS, and obesity. This literature also refers to: "imbalances of neurotransmitters thereby impairing brain function" and "restoring neurotransmitter balance." Reference to treatment of abnormal or insufficient levels of neurotransmitters is also made in The Nutrition Works! Newsletter and the Restores+ brochure.

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Objectionable claims for Caucasicum+ include:

"Used in elite foreign university hospitals for the treatment of:

Heart Disease
Arthritis & Gout
High Cholesterol
High and Low Blood Pressure
Depression
Neuroses and Psychoses"

In addition, the Caucasicum+ brochure states that the product can prevent colon cancer through the inhibition of hyaluronidase and that it's anti-oxidant activity prevents tumors, strokes, cancer, kidney failure, and emphysema through antioxidant activity.

In 1994, Congress passed and President Clinton signed the Dietary Supplement Health and Education Act (DSHEA). This Act which defines dietary supplements and dietary ingredients establishes a new framework for assuring safety; outlines guidelines for literature display; and provides guidance for literature displayed where supplements are sold. While DSHEA carefully describes the use of certain statements in the labeling of dietary supplements, these statements may not include claims for the diagnosis, prevention, mitigation, treatment, or cure of a specific disease. Products making such disease claims are considered drugs, not dietary supplements.

Restores+ and Caucasicum+ are "new drugs" [§ 201(p)]. Therefore, they may not be legally marketed in this country without approved New Drug Applications [§505(a) of the Act].

These drugs are also misbranded, because their labeling fails to bear adequate directions for the conditions for which they are offered [§ 502(f)(1) of the Act] and their labeling is false and misleading. The labeling suggests that these products are safe and effective for their intended uses, when in fact, this has not been established [§ 502(a) of the Act].

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.

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

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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 fifteen (15) working days of receipt of this letter as to 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 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 Reynaldo R. Rodriguez, Jr., Compliance Officer, at the above letterhead address.

Sincerely,



for Joseph R. Baca
Dallas District Director

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