



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

San Francisco District <sup>d2005b</sup>  
1431 Harbor Bay Parkway  
Alameda, California 94502-7070  
Telephone: (510) 337-6700

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

**WARNING LETTER**

Our Reference No.: 2953931

August 18, 1998

Robert N. Miura  
President  
The VisionPlus Network, Inc.  
1124 20th Ave.  
Honolulu, HI 96816

Dear Mr. Miura:

This letter is in reference to your firm's marketing and distribution of the products "VisionHealth Z-Power Gelcaps," "VisionHealth AquaHerb Capsules," "VisionHealth The Catalyst Capsules," "VisionHealth D-Tox Capsules," "VisionHealth ChitoGold Capsules," and "VisionHealth SteviLite." Labeling for these products makes therapeutic claims which cause the products to be drugs [section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act)]. Labeling is not limited to the immediate product containers but includes all promotional literature, including audio and video tapes, which you distribute with your products.

Objectionable claims include the following:

1. Z-Power: "Diabetes . . . Osteoporosis, Rheumatoid arthritis . . . Reduced sexual potency in males . . . Cirrhosis of the liver . . . High blood pressure . . . Slow healing of wounds, Thinning or loss of hair . . . Psoriasis, Night blindness, Thyroid problems, Dermatitis, Aches and pains, Heart problems, Prostate disease . . . Acne, Insomnia, Depression," "macular degeneration," "[prostate] infection, enlargement and tumors," "throat cancer . . . colon cancer . . . carcinoma . . . cancerous cell growth . . . prevention and treatment of cancer," "developed to overcome the defective conditions of zinc metabolism (absorption and secretion) prevalent in a large portion of the population," and "Zinc

Malabsorption Syndrome has been linked to diseases such as diabetes, hypertension . . . infectious diseases, the common cold, osteoporosis, dental disease, skin disorders, gastric and peptic ulcers, growth retardation in children, male impotency, neurological disorder, etc."

2. AquaHerb: "anti-arthritis" and "skin disorders and age associated diseases"
3. The Catalyst: "preventing chronic degenerative disease," "prevention of heartburn and indigestion," "headaches, blood clotting and depression," "edema," and "prostate inflammation"

In addition, the promotional literature (labeling) titled "Health News Update" shows abnormal laboratory tests, in the form of patient blood smears, which purportedly are returned to normal through use of The Catalyst.

4. D-Tox: "colon cell damage," "arthritis, cancer, and other degenerative conditions," and "Joint pain and stiffness, Skin problems, such as acne, psoriasis, Weakened and stressed heart, . . . lung irritation and breathing problems, Depression and anxiety"
5. ChitoGold: "cardiovascular disease," "obesity, clogged arteries, hypertension, heart attack, stroke, arthritis & gout, kidney disease, diabetes, liver disorders, various forms of cancer such as breast, endometrial, colon, rectal, prostate, ovarian and cervical," "promotes wound healing," "antibacterial/candida/viral," "Inhibits plaque/tooth decay," and "Helps dental restoration/recovery."
6. SteviLite: "reduces glucose absorption in diabetics, helps prevent tooth decay also reduces blood pressure in hypertensives."

These products are also "new drugs" [section 201(p) of the Act] and therefore, may not be legally marketed without approved New Drug Applications [section 505(a) of the Act].

These drugs are misbranded because their labeling fails to bear adequate directions for use for the conditions for which they are offered [section 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 [section 502(a) of the Act].

Also, Z-Power Gelcaps are misbranded since their labeling makes a false and misleading statement that this product has an approved IND, [REDACTED] when in fact, IND [REDACTED] does not pertain to Z-Power Gelcaps [section 502(a) of the Act].

Additionally, claims for the treatment of heartburn and indigestion and for use as an antacid, cited above for The Catalyst and ChitoGold, cause these products to be subject to the OTC drug

product final rule (monograph), Antacid Products for Over-the-Counter (OTC) Human Use. The monograph is found in Title 21 Code of Federal Regulations (21 CFR), part 331. Neither the formulation nor the labeling for the product conform to this final regulation.

Additionally, we have reviewed your proposed labeling changes dated July 1, 1998 and submitted to FDA on July 10, 1998. A few of the disease claims, such as, the antacid claims and a table of claims for ChitoGold that included: "promotes wound healing," "Acts as antacid," "Helps to speed bone repair," "Reduces levels of uric acid," "anti bacterial/candida/viral," "Inhibits plaque/tooth decay," "Helps dental restoration/recovery" have been removed. However, remaining serious disease claims still cause the products to be drugs and the submission did not include revisions to all of the violative labeling. Since your firm's submission had no cover letter, we do not know whether any of these changes have been implemented. Therefore, these statements were included in the objectionable claims.

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 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 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, please state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to Raymond T. Oji, Drug/Bioresearch Monitoring Team Leader, Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502 (phone 510-337-6829).

Sincerely,

A handwritten signature in cursive script that reads "Patricia C. Ziobro".

Patricia C. Ziobro  
District Director  
San Francisco District