



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

11/27/97  
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**PURGED** RJK

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

cc: HFI-35/FOI Staff  
DWA

August 19, 1997

**WARNING LETTER**

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

Refer to MIN 97-57

Conrad LeBeau  
President  
Vital Health Products, Ltd.  
17000 West Janesville Road  
Muskego, Wisconsin 53150

Dear Mr. LeBeau:

This letter concerns your marketing of BIO-OXYGEN powder and capsules, Liquid Stabilized BIO-OXYGEN, and various vitamin and mineral products.

On March 10, 1992, the U.S. Court for the Eastern District of Wisconsin issued a final judgement on the Food and Drug Administration's (FDA's) Complaint for Injunction. The Court's order barred Vital Health Products, Ltd. from manufacturing, packaging, or distributing 35% Hydrogen Peroxide Solutions, Peroxy Gel (17.5% Hydrogen Peroxide and glycerine), Lymph System, White Birch Mineral Water, Licorice Root Tea, or any product containing hydrogen peroxide in any form. The injunction included any products having or purporting to have a similar composition, appearance, name, or intended use to any of those products.

Your catalog (labeling) offers for sale Bio-Genesis brand BIO-OXYGEN capsules, BIO-OXYGEN powder, and Liquid Stabilized BIO-OXYGEN. Your catalog denotes that the BIO-OXYGEN products contain magnesium peroxide(similar to

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hydrogen peroxide). The label for Liquid Stabilized BIO-OXYGEN states that it is "formulated to increase production of nascent oxygen and enhance additional oxidation potential." The label for the BIO-OXYGEN powder states that it is formulated with "oxygen enhancement." Your promotion of the enjoined hydrogen peroxide products was based on the therapeutic effect of the increased nascent oxygen which was purportedly produced by the absorption of hydrogen peroxide. Your leaflet entitled "Peroxy Gel: A Source of Nascent Oxygen" stated that the product would help the body fight internal infections and referred to T-cells, interferon, and weakened immune systems (references to this intended use). Hence, your marketing of the BIO-OXYGEN and Liquid Stabilized BIO-OXYGEN products violates the permanent injunction granted on March 10, 1992, in that these products have or purport to have similar composition and have a similar intended use as the hydrogen peroxide products.

Your catalog also includes numerous therapeutic claims for vitamins and minerals under the headings "VITAMINS WHAT THEY DO" AND "MINERALS WHAT THEY DO." Objectionable products and claims include:

- B Vitamins--"emotional instability, depression"
- Vitamin D--"nearsightedness"
- Vitamin E--"preventing clots...muscle wasting, shortness of breath"
- Vitamin K--"colitis"
- Calcium--"muscle cramps...joint pains...insomnia, cramps"
- Chromium--" low blood sugar...atherosclerosis"
- Copper--"skin sores"
- Magnesium--"irregular heart rhythm, depression"
- Manganese--"high blood sugar"
- Potassium--"irregular heart rate, nervous disorders...diarrhea"

These statements represent claims that your products can be used to treat diseases or disease symptoms. Because these statements are disease claims rather than structure/function claims, these products do not fall under the Dietary Supplement Health and Education Act (DSHEA). Further, these claims do not address diseases resulting from traditional dietary deficiencies and so do not meet the criteria of exemption for disease or health related conditions under 21 CFR Section 101.14(a)(6) or Section 403(r)(6)(a) of the Federal Food, Drug, and

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Cosmetic Act (the Act) . Therefore, these claims promote products that are intended for use in the prevention or treatment of disease and cause them to be drugs as described in Section 201(g) of the Act.

Since these drugs are "new drugs" as defined in Section 201(p) of the Act they may not be marketed in the U.S. without an Approved New Drug Application as required by Section 505 of the Act.

Also, these drugs are misbranded as described in Section 502(f)(1) of the Act because their labeling fails to bear adequate directions for use for the conditions for which they are offered and because their labeling is false and misleading since it suggests that these products are safe and effective for their labeled uses when, in fact, this has not been established under Section 502(a) of the Act.

The injunction bars Vital Health Products from promoting, labeling, advertising, or representing that any product constituting a drug under 21 U.S.C. §321 is safe and effective unless an Approved New Drug Application is in effect for such drug. Therefore your marketing of these unapproved new drugs also violates the permanent injunction.

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.

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 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.

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Your catalog also includes numerous disease treatment claims for colloidal silver. For your information we enclose a copy of the Federal Register, Vol. 61, No. 200, dated October 15, 1996, which describes FDA's proposed ruling on the status of colloidal silver products.

Your reply should be directed to Compliance Officer Howard E. Manresa at the address indicated on the letterhead. Mr. Manresa may be reached at (612)334-4100 ext. 156.

Sincerely,



James A. Rahto  
Director  
Minneapolis District

HEM/ccl

Enclosure: 61 FR 53685