DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

REGULATORY LETTER

Los Angeles District
1521 West Pico Boulevard
Los Angeles, California 90015-2486
Telephone (213) 252-7583

February 29, 1988

Ms. Jean Ross
Owner and Manager
Vibrant Life
1210 West Chestnut Street
Burbank, CA 91506

LA-13-8

Dear Ms. Ross:

This letter is written in reference to the marketing of "Organic Germanium" by your firm. Promotional material (labeling) associated with or accompanying your product states or suggests "Organic Germanium" is useful in the prevention or treatment of cancer and Acquired Immunodeficiency Syndrome (AIDS).

Because such labeling includes statements which represent and suggest that this article is intended to be used in the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or any function of the body of man, this product is a drug within the meaning of Section 201(g) of the Federal Food, Drug, and Cosmetic Act. Further, we are unaware of any substantial scientific evidence which demonstrates that "Organic Germanium" is generally recognized as safe and effective for its intended uses. Accordingly, marketing of this drug is a serious violation of the Federal Food, Drug, and Cosmetic Act as follows:

SECTION	BRIEF DESCRIPTION
502(a)	The aforesaid article of drug is misbranded in that its labeling is false and misleading by representations and suggestions that there is substantial scientific evidence to establish that the article is safe and effective for use in the prevention or treatment of cancer or AIDS.
502(f)(1)	The article of drug is misbranded in that its labeling fails to bear adequate directions for use in the prevention or treatment of cancer or AIDS and it is not exempt from this requirement under Regulation 21 CFR 201.115 since the article is a new drug within the meaning of Section 201(p) and no approval of an application filed pursuant to Section 505(b) is effective for this drug.

The article of drug "Organic Germanium" is further misbranded in that its labeling does not contain adequate directions for use as this term is defined in 21 CFR 201.5 since the conditions for which it is offered are not amenable to self diagnosis and treatment by the laity; therefore adequate directions for use cannot be written under which the layman can use this drug safely and for the purposes for which it is intended.

505(a) The article, "Organic Germanium" is a drug within the meaning of Section 201(g) of the Act which may not be introduced or delivered for introduction into interstate commerce under Section 505(a) of the Federal Food, Drug, and Cosmetic Act, since it is a new drug within the meaning of Section 201(p) of the Act and no approval of an application filed pursuant to Section 505(b) is effective for such drug.

This letter is not meant to represent a comprehensive listing of all violations which may be associated with "Organic Germanium," nor is it meant to represent that other violations may not exist with regard to other products distributed by your firm.

We request that you reply within ten (10) days of your receipt of this letter stating the action you will take to discontinue the marketing of this drug product. If such corrective action is not promptly undertaken, the Food and Drug Administration is prepared to initiate legal action to enforce the law. The Federal Food, Drug, and Cosmetic Act provides for seizure of illegal products and enjoining the manufacturer or distributor of illegal products (21 U.S.C. 332 and 334).

We request that your reply include:

1. An estimate of the quantity of the drug manufactured or received within the past twelve months.

2. An estimate of the size and frequency of shipments made by you in the past twelve months.

3. An estimate of the amount of the drug that is in inventory under your control and of the amounts that remain in channels of distribution outside your control.

4. The date of discontinuance in the event that you have already discontinued marketing this drug product.

5. Your intention with respect to the disposition of your inventories and outstanding stocks in trade channels.

Your reply should be directed to:

Mr. Thomas L. Sawyer
Director, Compliance Branch
U.S. Food and Drug Administration
1521 W. Pico Boulevard
Los Angeles, CA 90015

Sincerely,

George J. Gerstenberg
District Director