

June 4, 1987

REGULATORY LETTER
CHI-423-87

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Kenneth R. Daub, D.C., President
Total Concept in Health Corporation
129 Phelps Avenue, Building #2
Rockford, Illinois 61108

Product: VMP Formula #1
 VMP Formula #2
 VMP Formula #3
 VMP Formula #4

Dear Mr. Daub:

Our information indicates that your firm is marketing the Vascular Maintenance and Prevention Program (VMP) which consists of VMP Formula #1, VMP Formula #2, VMP Formula #3, and VMP Formula #4. Promotional material (labeling) distributed with your product states or suggests that the VMP Formulas are useful in treating or preventing occlusive vascular disease (arteriosclerosis/atherosclerosis), strokes, heart attacks and heart disease; reducing elevated cholesterol levels, high blood pressure and inhibiting thrombosis; and controlling arthritis and other forms of inflammation, treating eczema, decreasing hyperactivity in children, and can be beneficial to those suffering problems from alcoholism to obesity to cancer.

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 documents that this drug is generally recognized as safe and effective for the above referenced disease conditions or any other disease conditions. Accordingly, marketing of this drug is a 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 treatment of occlusive vascular disease, strokes, heart attacks, heart disease, elevated cholesterol levels, high blood pressure, thrombosis, arthritis and other inflammations, eczema, hyperactivity in children and problems ranging from alcoholism to obesity to cancer.

502(f)(1)

The article of drug is misbranded in that its labeling fails to bear adequate directions for use in the treatment of occlusive vascular disease, strokes, heart attacks, heart disease, elevated cholesterol levels, high blood pressure, thrombosis, arthritis and other inflammations, eczema, hyperactivity in children and problems ranging from alcoholism to obesity to cancer in its promotional material and 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, Vascular Maintenance and Prevention Program, 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, Vascular Maintenance and Prevention Program, 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

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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.

The violations listed above are not intended to be all inclusive. It is your responsibility as a drug distributor to market drug products which are in compliance with the Federal Food, Drug, and Cosmetic Act.

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/or injunction against 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 12 months.
2. An estimate of the size and frequency of shipments made by you in the past 12 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 of 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 Larry E. Ormsbee, Director, Compliance Branch.

Sincerely,

George A. Masters
Acting District Director

GAM/LEO/JED/dag

DILLING, GRONEK AND ARMSTRONG

ATTORNEYS AT LAW

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ALBERT W. DILLING

(1917-1969)

get
8/19/

August 14, 1987

Mr. Joseph E. Dixius
Compliance Officer
U.S. Food and Drug Administration
Chicago District
1222-Post Office Building
433 W. Van Buren Street
Chicago, IL 60607

Dear Mr. Dixius:

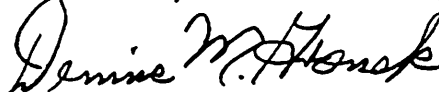
We represent Total Concept in Health Corporation, Rockford, Illinois. Our client has requested that we respond to Regulatory Letters received by it regarding its VMP products.

Total Concept has discontinued the distribution of the product brochures which your Agency considers to be in violation of the Federal Food, Drug and Cosmetic Act. It has also agreed that any future brochures will be reviewed by us to ascertain whether claims may be deemed unacceptable.

Also, Total Concept is revising its labels to delete the "VMP" nomenclature. This should satisfy the concerns expressed in your July 27, 1987 communication.

If, after reviewing this letter, you have any questions or comments contact the undersigned at your convenience.

Sincerely yours,
DILLING, GRONEK & ARMSTRONG



Dennis M. Gronek

DMG:

pr

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