DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

CERTIFIED RETURN RECEIPT REQUESTED

Los Angeles District
1521 West Pico Boulevard
Los Angeles, California 90015—2486
Telephone: 213-688-3771

Regulatory Letter

November 4, 1985 LA-3-6

Mr. Ollie Jenkins, Chairman of the Board
Westlake Dynamics International, Inc.
650 Hampshire Road, #112
Westlake Village, CA 91361

PRODUCT: Dyna-CHE tablets

Dear Mr. Jenkins:

Our information indicates that your firm is marketing the product Dyna-CHE tablets, labeled to contain vitamins, minerals, amino acids, glandular and herbal material. Promotional material (labeling) distributed with your product states or suggests that Dyna-CHE tablets is useful for preventing or treating occlusive vascular disease conditions (arteriosclerosis/atherosclerosis) and related conditions including hypertension, which produce stroke and heart attacks through blocking free radical damage, eliminating and preventing plaque, fiber, calcium, and cholesterol build-up.

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 of 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, continued 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 the prevention or treatment of strokes, heart attacks, and occlusive vascular disease, including atherosclerosis, arterio-sclerosis, and hypertension.

502(f)(1) The article of drug is misbranded in that its labeling fails to bear adequate directions for use in the total management of occlusive vascular disease for which it is offered 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, Dyna-CHE tablets, 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 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, Dyna-CHE tablets, 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.

The charges and the product contained in this letter are not meant to be all-inclusive. It is your responsibility to ensure that all products manufactured (distributed, held, labeled) by your firm are in compliance with the provisions of 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 or injunction against the manufacturer or distributor of illegal products (21 USC 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 (12) months.

2) An estimate of the size and frequency of shipments made by you in the past twelve (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:

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

Sincerely yours,

Abraham I. Kleks
District Director

cc: Dr. Robert L. Preston,
Executive Vice President
Westlake Dynamics Int'l., Inc.
650 Hampshire Rd. #112
Westlake Village, CA 91361

bcc: HFR-9200
HFR-9250
HFA-224
HFR-93/C. Bigley
E.I. File
HFN-316 (M. Karpers)
HFI-20 (Bruce Brown)
GQAP
Reg. File
Chron/RCN

State Department of Public Health
Environmental Services
Attn: Chief, Food & Drug
714 "P" Street, Room 400
Sacramento, CA 95814

RCN:mlbe