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July 30, 1987

REGULATORY LETTER
CHI-425-87

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Henry K. Rosenberger, President
Nutrition Headquarters, Inc.
104 W. Jackson St.
Carbondale, IL 62901

Product: ATHEREX

Dear Mr. Rosenberger:

Our information indicates that your firm is marketing the product Atherex capsules. Promotional material (labeling) distributed with your product states or suggests that Atherex is useful for treating or preventing occlusive vascular disease (arteriosclerosis/ atherosclerosis) and related conditions including coronary artery disease angina, dizziness, poor circulation and removing or lowering cholesterol deposits.

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, 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 treatment or prevention of occlusive vascular disease and related conditions including coronary disease angina, dizziness, poor circulation and removing or lowering cholesterol deposits.

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 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, Atherex capsules, 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.

We request that you reply within ten 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,

Raymond V. Mlecko
District Director
Food and Drug Administration

RVM/LEO/JB/dag

cc: HFN-304
cc: HFW-35
cc: HFR-5150
cc: JB
cc: HFR-53
cc: HFR-5100
cc: HFR-5512