



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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PURGED *PK*

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

August 31, 1999

cc: HFI-35
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 99 - 45

Larry C. Ormson
President
TRY-Lean, Inc.
113 Railroad Street
Elroy, Wisconsin 53929

Dear Mr. Ormson:

This letter is in reference to your firm's marketing and distribution of TRY-Lean Formula 1 & 2. Labeling for this product contains therapeutic claims which cause the product to be a drug [Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act)]. Labeling is not limited to the immediate product container but includes all promotional literature which you distribute in connection with your product.

The booklet entitled "Winning the War on Fat with Chitosan" (labeling) includes therapeutic claims for the ingredient Chitosan which is found in the TRY-Lean Formula 1 & 2.

Objectionable claims include:

reduce the risk of heart attack, reduce the risk of cancer, obesity, high blood pressure, ability to kill Candida, anti-tumor, anti-bacterial action, wound healing, acne, and anti-plaque build up for dental health

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TRY-Lean Formula 1 & 2 is a "new drug" [Section 201(p) of the Act]. Therefore, it may not be legally marketed in this country without an approved New Drug Application [Section 505(a) of the Act].

This drug is also misbranded because its labeling fails to bear adequate directions for the conditions for which it is offered [Section 502(f)(1) of the Act]. The labeling is false and misleading because it suggests that this product is safe and effective for its intended use when, in fact, this has not been established [Section 502(a) of the Act].

This letter is not intended to be an all-inclusive review of all labeling and products your firm may market. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

Labeling for Calor-Slim includes a brochure entitled "Calor-Slim" and your firm's Internet Web site. This labeling includes claims that this product can treat arthritis, atherosclerotic plaque, cataracts, glaucoma, diabetic retinopathy, decrease scars and provide UV protection. Based on these claims Calor-Slim may also be an unapproved new drug and a misbranded drug.

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. The Federal Food, Drug and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within 15 working days of receipt of this letter as to 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, state the reason for the delay and the time within which the corrections will be implemented.

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Larry C. Ormson
August 31, 1999

Your reply should be sent to the attention of Compliance Officer Lawrence R. Murphy at the address indicated on the letterhead.

Sincerely,


Cheryl A. Bigham
Acting Director
Minneapolis District

LRM/ccl