



DEPARTMENT OF HEALTH AND HUMAN SERVICES

94447d

Food and Drug Administration  
Los Angeles District  
Pacific Region  
19701 Fairchild  
Irvine, CA 92612-2445

Telephone: 949-608-2900  
FAX: 949-608-4415

WARNING LETTER

**CERTIFIED MAIL -**  
**RETURN RECEIPT REQUESTED**

December 16, 2003

Mr. David Levin, President  
NutraLife Laboratories  
2363 W. LaPalma Ave.  
Anaheim, CA 92801

W/L 15-04

Dear Mr. Levin:

The Food and Drug Administration conducted an inspection of [REDACTED] (REDACTED), located at [REDACTED], on [REDACTED] through [REDACTED]. According to information provided by [REDACTED] during the inspection, [REDACTED] is a contract manufacturer for your firm, NutraLife Laboratories. Labeling for your products Cholesterol Fighter, NiControl, and Testergin Booster was collected during the inspection at [REDACTED] and a review of that labeling indicates serious violations of the Federal Food, Drug and Cosmetic Act (the Act). You can find the Act along with the food, drug and dietary supplement labeling regulations on the Internet through links on FDA's web page [www.fda.gov](http://www.fda.gov).

Cholesterol Fighter: We have determined that this product is a drug under Section 201(g)(1)(B) of the Act because it is intended to treat, mitigate, cure, or prevent disease. The name of the product, "Cholesterol Fighter," implies that it is effective in the treatment, mitigation, cure or prevention of high cholesterol. Because the product is not generally recognized as safe and effective when used as labeled, it is also a new drug as defined under Section 201(p) of the Act. Under Section 505 of the Act, a new drug may not be legally marketed in the United States without an approved New Drug Application.

In addition, the product is misbranded under Section 502(f)(1) of the Act in that it fails to bear adequate directions for use.

Even if the product Cholesterol Fighter did not contain the implied disease claim in its labeling that causes it to be a drug, it would still be a misbranded product. The labeling of your product indicates that it is a dietary supplement. As a dietary supplement, the product is misbranded because it does not bear "supplement facts" nutrition labeling (section 403(q)(5)(F) of the Act; see 21 CFR 101.36) and because it is not labeled as a dietary supplement in the principal display panel (sections 403(i)(1) and 403(s)(2)(B) of the Act; see 21 CFR 101.3(g)).

We also reviewed the labels for NiControl and Testergin Booster. The following are the results of our review:

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NiControl: The labeling of your product indicates that it is a dietary supplement. As a dietary supplement, the product is misbranded because it does not bear "supplement facts" nutrition labeling (section 403(q)(5)(F) of the Act; see 21 CFR 101.36) and because it is not labeled as a dietary supplement in the principal display panel (sections 403(i)(1) and 403(s)(2)(B) of the Act; see 21 CFR 101.3(g)). The product is also misbranded under section 403(i)(2) of the Act because it contains botanical ingredients not named in accordance with the requirements of the Act and its regulations (sections 403(i)(2) and 403(s)(2)(C) of the Act; see 21 CFR 101.4(h)) and because its label fails to declare all ingredients (for example, the ingredient that makes up the capsule).

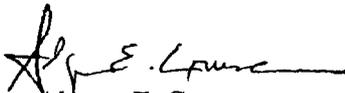
Testergin Booster: The labeling of your product indicates that it is a dietary supplement. As a dietary supplement, the product is misbranded because it does not bear "supplement facts" nutrition labeling (section 403(q)(5)(F) of the Act; see 21 CFR 101.36) and because it is not labeled as a dietary supplement in the principal display panel (sections 403(i)(1) and 403(s)(2)(B) of the Act; see 21 CFR 101.3(g)).

This letter is not intended to be an all-inclusive list of the deficiencies in your products and their labeling. It is your responsibility to ensure that all of your firm's products and their labeling are in compliance with the Act and its implementing regulations. We may take further action if you do not promptly correct these violations. For instance, we may seize your products and/or enjoin your firm from operating.

You should notify this office, within fifteen (15) working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations. Copies of any revised labeling for the products should also be submitted. If corrective action cannot be completed within 15 working days, state the reason(s) for delay and the time at which the corrections will be completed.

Please send your reply to the Food and Drug Administration, Attention: Acting Director, Compliance Branch, 19701 Fairchild, Irvine, CA 92612-2445. This case has been assigned to Compliance Officer MaryLynn Datoc. If you have any questions regarding any issue in this letter, you may contact Ms. Datoc at telephone number (949) 608-4428 if you have any questions.

Sincerely,



Alonza E. Cruse  
Director, Los Angeles District