



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

g3175d

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

CERTIFIED MAIL – RETURN RECEIPT REQUESTED

April 1, 2002

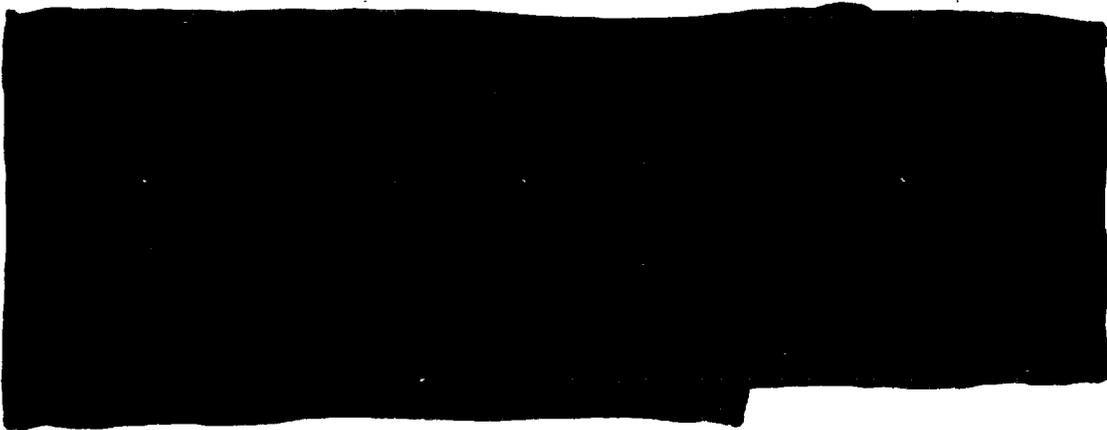
William D. Taylor, President
Production Laboratories, Inc.
2490 Ash Street
Vista, CA 92083-8424

W/L 36-02

Dear Mr. Taylor:

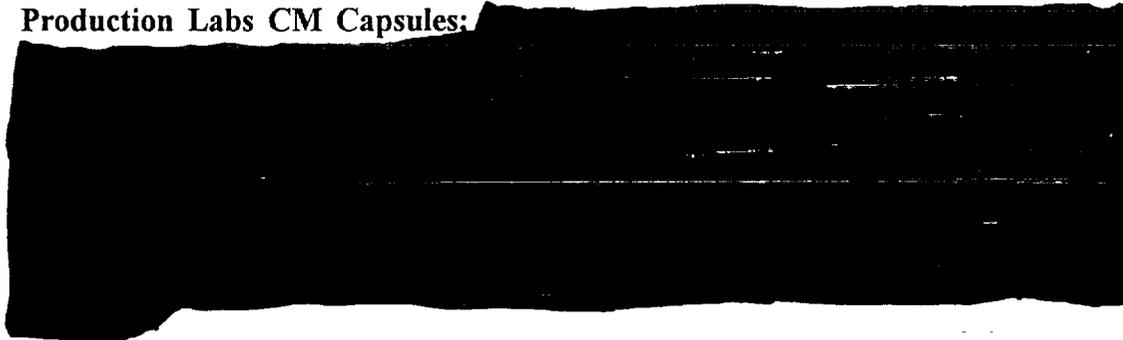
We inspected your firm, located at 2490 Ash Street, Vista, CA 92083-8424 between October 12 and 18, 2000 and between December 27 and 29, 2001. We found that your products, identified below, are misbranded under section 403 of the Federal Food, Drug, and Cosmetic Act (the Act) and applicable food labeling regulations in Title 21, Code of Federal Regulations, Part 101 (21 CFR 101) and adulterated under section 402(a)(2)(C) of the Act. We also determined that the product [REDACTED] is a drug under Section 201(g)(1)(B) of the Act.

The following products are misbranded under 21 CFR 101.3(g) and sections 403(i)(1) and 403(s)(2)(B) of the Act. The product labels do not include the mandatory statement of identity required for dietary supplements. Specifically, the term “dietary supplement” or a variation authorized by regulation must appear as part of the statement of identity. Use of the statement “as a dietary supplement” in the instructions for use, is not a suitable alternative to the statutory requirement that a dietary supplement be “labeled as a dietary supplement.”



The following products are misbranded under 21 CFR 101.36 and section 403(q)(5)(F) of the Act because the labels fail to bear nutrition labeling ("Supplement Facts" panel) and are not exempt from this requirement

Production Labs CM Capsules;



The following products are misbranded under 21 CFR 101.36 and section 403(q)(5)(F) of the Act because the nutrition labeling contain significant deviations in format or content from the requirements in the regulations:

- [REDACTED] (does not declare amounts of dietary ingredients);**
- [REDACTED] (does not separate 21 CFR 101.36(b)(2) and (b)(3) ingredients);**
- [REDACTED] (not all dietary ingredients are declared in the supplement facts box); and**
- [REDACTED] (contains a proprietary blend [REDACTED] that does not declare all of its constituent dietary ingredients).**

The following products are misbranded under 21 CFR 101.36(b)(2) and section 403(q)(5)(F) of the Act because the nutrition labeling contains (b)(2) dietary ingredients that are not present or are present in amounts that can be declared as zero under 21 CFR 101.9(c):

- [REDACTED] (cholesterol),**
- [REDACTED] (cholesterol), and**
- [REDACTED] (calories, total fat, sodium, and protein).**

The following products are misbranded under 21 CFR 101.4 and section 403(i)(2) of the Act because they contain ingredients that are not declared on the label. Each of the products is contained in a capsule, but the capsule ingredients are not declared on the label:

- [REDACTED]; Production Labs, Inc. CM Capsules;**
- [REDACTED]**
- [REDACTED] and**
- [REDACTED]**

[REDACTED] and [REDACTED]

The following products are misbranded under 21 CFR 101.4(h) and section 403(s)(2)(C) of the Act because they contain one or more botanical or herbal dietary ingredients or extracts of an herb or botanical and the labels do not identify the part of each of the plants from which the dietary ingredients are derived:

[REDACTED]; and [REDACTED]

The product [REDACTED] is misbranded because it bears an NDC number but the product is not registered with FDA as a drug and, therefore, the presence of this label statement is false and misleading under section 403(a)(1) of the Act.

The products [REDACTED] and [REDACTED] are adulterated under section 402(a)(2)(C) of the Act because they contain a food additive (stevia) that is unsafe within the meaning of section 409 of the Act. Under the ACT, any substance intentionally added to a food must be used in accordance with a food additive regulation unless the ingredient is generally recognized as safe (GRAS) among qualified experts for its intended use in food, or unless some other exception to the food additive definition applies. The presence of an unapproved food additive causes the food containing the additive to be adulterated under section (402(a)(2)(C) of the Act. We are not aware of a basis for concluding that stevia is GRAS for use in food or that any other exception to the food additive definition applies. Although dietary ingredients are exempted from the food additive definition, stevia is not listed in the "Supplement Facts" panel is a dietary ingredient and therefore is not a dietary ingredient. Further, FDA has not issued a food additive regulation authorizing the use of stevia in food. Therefore, stevia is an unapproved food additive that is unsafe within the meaning of section 409 of the Act, and the presence of stevia in your products renders them adulterated."

The product [REDACTED] bears the claims "inhibits fatty buildup in the heart" and "will reduce chronic fatigue and sleeping disorders." These claims are disease claims under 21 CFR 101.93(g) and cause [REDACTED] to be a drug as defined in section 201(g)(1)(B) of the Act. Further, because we are unaware of any evidence that the product is generally recognized as safe and effective when used as labeled, it is a new drug 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.

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This letter is not intended to be an all-inclusive list of deficiencies in your labeling. It is your responsibility to ensure adherence to each requirement of the Act and regulations. You should review all of labeling for your products to assure that they comply with the Act and regulations. You can find the Act and 21 CFR through links in FDA's home page at www.fda.gov.

You should know these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizure and/or obtaining a court injunction against further marketing of your violative products.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you receive this letter what steps you are taking to correct the problems. We also ask that you explain how you plan to prevent these violations from happening again. If you need more time, let us know why and when you expect to complete your corrections.

Your written response should be directed to the attention of:

Thomas L. Sawyer
Director, Compliance Branch
Food and Drug Administration
19900 MacArthur Blvd., Suite 300
Irvine, CA 92612

Sincerely,



Alonza E. Cruse
District Director