



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

MB207 n

1990 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

W/L 25-01

February 21, 2001

Greg Rubin, CEO
Vitamin Classics, Inc.
24007 Ventura Blvd. #35
Calabasas, CA 91302

Dear Mr. Rubin:

The Food & Drug Administration (FDA) has reviewed labels for your Tropical Fruit Punch flavored "Burn That Fat" beverage, and your Wild Grape Splash flavored "Burn That Fat" beverage. Our review reveals that these labels cause the products to be in violation of section 403 of the Federal Food, Drug and Cosmetic Act (the Act), and Title 21, Code of Federal Regulations (21CFR), Part 101 – Food Labeling, as follows:

Burn That Fat - Tropical Fruit Punch
Burn That Fat – Wild Grape Splash

These products are misbranded under section 403(i)(2) of the Act in that they are foods which purport to be beverages containing fruit juice and fail to bear a statement, on the information panel, of the total percentage of such fruit juice contained in the food (21 CFR 101.30).

The products are further misbranded within the meaning of section 403(r)(1)(B) of the Act in that the labels bear statements that characterize a nutrient to a disease or health-related condition that are not authorized by regulation or the Act. The unauthorized health claims include "Burn That Fat is formulated from a select blend of herbs and chromium picolinate to...lower cholesterol."

The above violations concern certain labeling requirements and are not meant to be an all-inclusive list of deficiencies on your labels. Other label violations can subject the food to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by FDA. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice, such as seizure.

Under the Act, any ingredient intentionally added to a conventional food like these beverages must be used in accordance with a food additive regulation unless it is generally recognized as safe (GRAS) among qualified experts for its intended use in food. The use of a food ingredient that is neither GRAS nor an approved food additive causes a food to be adulterated under section 402(a)(2)(C) of the Act.

We note several ingredients, which appear to be in the aforementioned products, have neither been approved for use as food additives nor are we aware of a basis for considering their use to be GRAS. For example, FDA has not approved the use of chromium picolinate, *Ginkgo biloba*, or *Garcinia cambogia*, and we are not aware of a basis for concluding that their use in conventional foods is GRAS. Therefore, the use of these ingredients in conventional foods could cause these foods to be adulterated.

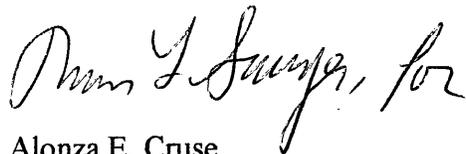
Please notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

In addition to the specific violations above, we offer the following comments:

All ingredients used in the aforementioned products must be included on the label and must be listed by the common or usual names for ingredients. "Oxidizer" and "rosemary herbal complex" are not common or usual names for ingredients. In addition, the ingredients that make up "rosemary herbal complex" are not declared on the label.

Your written reply should be directed to Mr. Thomas L. Sawyer, Director, Compliance Branch, U.S. Food & Drug Administration, 19900 MacArthur Blvd, Suite 300, Irvine, CA 92612-2445.

Sincerely,



Alonza E. Cruse
District Director
Los Angeles District

cc: California Department of Health Services, Food & Drug Branch
601 N. 7th Street
Sacramento, California 94234-7320
Attn: Stuart Richardson, Jr., Chief