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MAR 22 2001

WARNING LETTER  
ONPLDS-08-01

BY CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Mr. Clyde Rockoff  
President  
Universal Nutrition, Inc.  
3 Terminal Road  
New Brunswick, New Jersey 08901

Dear Mr. Rockoff:

The Food and Drug Administration (FDA) has reviewed the label for your Doctor's Diet LowCarb Bar, S'mores variety. We have concluded that the above product is in violation of sections 402 and 403 of the Federal Food, Drug, and Cosmetic Act (the act), and Title 21, Code of Federal Regulations (21 CFR).

Your Doctor's Diet LowCarb Bar is adulterated under section 402(a)(2)(C) of the act because it contains Stevia, which is an unapproved food additive. Unapproved food additives are considered unsafe under section 409 of the act.

The product is misbranded under section 403(r)(1)(A) of the act because the label bears the claim "low carb." "Low carb" is a nutrient content claim that is not authorized by regulation or the act.

The product is also misbranded under sections 403(a) and 403(q) of the act because the label is false and misleading in that glycerine is not included in the value declared for "total carbohydrates." The label bears the statement "Glycerine, while included in the 'Calories' count, has been omitted from the 'Total Carb.' count...." Glycerine is a carbohydrate and must be included in the value declared for "total carbohydrates."

The product is further misbranded under section 403(q) of the act because the label bears the claim "high protein," but fails to declare in the nutrition information the amount of protein per serving expressed as a percentage of the Daily Value (DV) [21 CFR 101.9(c)(7)(i)].

The above violations are not meant to be an all-inclusive list of deficiencies on your label. It is your responsibility to ensure that all of your products are labeled in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct these deviations and prevent their recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

Page 2 – Mr. Clyde Rock

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. Copies of the revised label should also be submitted. If corrective actions cannot be completed within 15 working days, state the reason for delay and the time within which corrections will be completed.

You should direct your written reply to me at the Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810), 200 C Street, S.W., Washington, D.C. 20204.

Sincerely yours,

  
John B. Foret  
Director  
Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition