



MEUBSN

Food and Drug Administration  
Washington DC 20204

JAN 10 2001

WARNING LETTER  
ONPLDS-04-01

BY CERTIFIED MAIL  
•RETURN RECEIPT REQUESTED

Mr. David Blechman  
President  
Twin Laboratories, Inc.  
2120 Smithtown Avenue  
Ronkonkoma, New York 11779

Dear Mr. Blechman:

The Food and Drug Administration (FDA) has reviewed the label for your Twinlab Protein Fuel Peanut Butter Sports Bar. We have concluded that this label causes the above product to be in violation of section 403 of the Federal Food, Drug, and Cosmetic Act (the act), and Title 21, Code of Federal Regulations (21 CFR), Part 101- Food Labeling.

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

The product is also misbranded because the label bears the statement "Glycerine is not a Carbohydrate but has a caloric value of 4.32 per gram" (403(a)). Glycerine is a carbohydrate. In addition, it is not clear whether glycerine is included in your declaration of "total carbohydrates" for this food. We advise that glycerine must be included in the value declared for "total carbohydrates."

The above violations are not meant to be an all-inclusive list of deficiencies on your label. It is your responsibility to assure 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 future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

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.

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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,

A handwritten signature in black ink, appearing to read 'JBF', is written over the typed name.

John B. Foret

Director

Division of Compliance and Enforcement

Office of Nutritional Products, Labeling  
and Dietary Supplements

Center for Food Safety  
and Applied Nutrition