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MAY 17 2001

WARNING LETTER  
ONPLDS-16-01

Food and Drug Administration  
Washington DC 20204

BY CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Mr. Ronald McAfee  
ISS Research  
9800-D Twin Parkway  
Charlotte, North Carolina 28269

Dear Mr. McAfee:

The Food and Drug Administration (FDA) has reviewed the label for your "COMPLETE Pro 42 Bar," 3.7 ounces, Almond Rocky Trail variety. We have concluded that the above product is in violation of the Federal Food, Drug, and Cosmetic Act (the Act), and Title 21, Code of Federal Regulations (21 CFR).

Your product is misbranded within the meaning of section 403(q)(5)(F) of the Act because the label bears a "Nutrition Facts" panel. The product's statement of identity is "dietary supplement;" therefore, the label should bear a "Supplement Facts" panel.

The product is misbranded under section 403(a)(1) of the Act because the label bears the statement "Glycerine is not a Carbohydrate but has a caloric value of 4.32 grams." Glycerine is a carbohydrate. In addition, it is not clear whether glycerine is included in your declaration of "total carbohydrates" for this food. Glycerine must be included in the value declared for "total carbohydrates."

The product is misbranded under section 403(r)(1)(A) of the Act because the label bears the claims "Minimum Fat" and "minimum amount of carbohydrates and fat." The term "minimum" has not been defined by regulation; therefore, it is an unauthorized nutrient content claim and may not be used.

The product is also misbranded under section 403(r)(1)(A) of the Act because the label bears the claim "high-protein," but fails to declare the amount of protein per serving expressed as a percentage of the Daily Value (DV) in the nutrition information [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.

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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,

A handwritten signature in black ink, appearing to read "J. Foret", is written over a horizontal line.

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