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APR 25 2003

WARNING LETTER
ONPLDS 01-03

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Kurtis D. Nielson
President
PureDe-lite Products, Inc.
1020 South 250 East
Provo, Utah 84606

Dear Mr. Nielson:

The Food and Drug Administration (FDA) has reviewed the label for Pure De-lite Chocolate Bar. Our review reveals that this label causes the above product to be in violation of the Federal Food, Drug, and Cosmetic Act (the act) and Title 21, Code of Federal Regulations (21 CFR).

This product is misbranded under section 403(r)(1)(A) of the act, because the label bears the unauthorized nutrient content claims "LOWCARB" and "ONLY 1.1 CARBS!" .

The label bears the statement, "Maltitol . . . is omitted from the total carbohydrate count. . . ." This product is misbranded under section 403(q)(1)(D) of the act, because maltitol is a carbohydrate and must be included in the value declared for "Total Carbohydrate" in accordance with 21 CFR 101.9(c)(6).

Furthermore, the label bears the claim "SUGAR FREE!" and maltitol is present in the food but the nutrition labeling does not declare the sugar alcohol content, as required by 21 CFR 101.9(c)(6)(iii).

In addition, the nutrition information on the label is not set off in a box as required by 21 CFR 101.9(d)(1)(i).

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

Page 2- Mr. Kurtis D. Nielson

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken or plan to take to correct the noted violations. Copies of revised labels for the product should 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-820), 5100 Paint Branch Parkway, College Park, Maryland 20740.

Sincerely yours,

A handwritten signature in cursive script that reads "Felicia B. Satchell".

Felicia B. Satchell
Director
Division of Food Labeling
and Standards
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition