



AUG 15 2001

WARNING LETTER
ONPLDS-22-01BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

James J. Duffy
President
Clearly Canadian Beverage Corp.
1600 Port Drive
Burlington, Washington 98233

Dear Mr. Duffy:

The Food and Drug Administration (FDA) has reviewed the label of your "reebok FITNESS WATER ENHANCED WATER BEVERAGE." We have concluded that the label causes the product to be in violation of the Federal Food, Drug, and Cosmetic Act (the Act), and Title 21, Code of Federal Regulations (21 CFR), Part 101- Food Labeling.

"Reebok FITNESS WATER ENHANCED WATER BEVERAGE" is misbranded under section 403(q)(1)(A)(i) of the Act because the product serving size (710 ml (24 fl oz)) is nearly three times the Reference Amount Customarily Consumed (RACC) established for non-carbonated beverages (240 ml) [21 CFR 101.12(b)] and cannot reasonably be consumed at a single-eating occasion [21 CFR 101.9(b)(6)].

The product is also misbranded under section 403(r)(1)(A) of the Act because the label bears a nutrient content claim that is not authorized by regulation or the Act or is not consistent with an authorizing regulation. Use of the claim "ENHANCED WATER BEVERAGE," in conjunction with highlighting vitamins C, B6, B12, Folic Acid and the minerals selenium, zinc, calcium as well as the electrolytes magnesium and potassium on the principal display panel puts the term "enhanced" in the context of an unauthorized synonym for the nutrient content claim "added." The regulations define the nutrient content claim "added" in part, that the food contains at least 10 percent or more of the Reference Daily Intake (RDI) of vitamins or minerals or of the Daily Reference Value (DRV) of protein, dietary fiber, or potassium per RACC than an appropriate reference food [21 CFR 101.54(e)]. The RACC for beverages is 240 ml. Since this beverage does not contain 10% of the RDI for vitamins C, B6, B12, folic acid and minerals selenium, zinc, calcium, magnesium nor of the DRV for potassium per RACC (240 ml), the claim "ENHANCED WATER BEVERAGE" misbrands the product. Furthermore, Citrimax™ and Chromemate® are not one of the substances included in 21 CFR 101.54(e), therefore the claim "enhanced" in association with these two ingredients is not authorized.

Page 2 – James J. Duffy

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 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 revised labels 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