DEPARTMENT OF THE TREASURY
ALCOHOL AND TOBACCO TAX AND TRADE BUREAU
WASHINGTON, D.C. 20220

November 18, 2010

Mr. Michael Michail
United Brands Company, Inc.
5360 Jackson Drive, Suite 208
La Mesa, CA 91942

Dear Mr. Michail:

By letter dated November 17, 2010, the Food and Drug Administration (FDA) advised you that it had reviewed the regulatory status of your products, "Joose" and "Max,"[1] each of which contains caffeine that has been directly added to an alcohol beverage and packaged in combined caffeine and alcohol form. The FDA letter warned you that as it is used in your products,[2] caffeine is an unsafe food additive, and therefore your products are adulterated under section 402(a)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. § 342(a)(2)(C). Among other things, the FDA letter stated that "FDA is not aware of any publicly available data to establish affirmatively safe conditions of use for caffeine added directly to alcoholic beverages and packaged in a combined form."

The Alcohol and Tobacco Tax and Trade Bureau (TTB) enforces the labeling provisions of the Federal Alcohol Administration Act (FAA Act), 27 U.S.C. § 205(e). While TTB regulates the labeling of alcohol beverages, it is FDA's responsibility to evaluate the safety of ingredients added to alcohol beverages, pursuant to FDA's authority under the FFDCA. TTB is hereby putting you on notice that FDA's determination that a product is adulterated under the FFDCA would have consequences under the FAA Act. It is TTB's position that adulterated malt beverages are mislabeled within the meaning of the FAA Act.

Subject to the jurisdictional requirements of the FAA Act, mislabeled malt beverages, including adulterated products, may not be sold or shipped, delivered for sale or shipment, or otherwise introduced or received in interstate or foreign commerce, or removed from customs custody for consumption, by a producer, importer, or wholesaler, or other industry member subject to 27 U.S.C. § 205(e). TTB may pursue action to suspend or to revoke the FAA Act basic permit of industry members who willfully violate the conditions of their permit with respect to mislabeled, adulterated products. *See* 27 U.S.C. § 204(e). Violations of the labeling provisions of the FAA Act are punishable as misdemeanors and the Government

[1] The FDA letter addressed the following flavors of "Joose": green apple, raspberry lemonade, red, blue, orange, dragon, jungle, mamba, panther, watermelon, and lemon tea. The FDA letter also addressed the following flavors of "Max": green apple, watermelon, and vibe.
[2] We are sending copies of this letter to the brewers who have obtained certificates of label approval for these products from TTB.

may seek injunctive relief to prevent and restrain such violations. TTB also may seek an offer in compromise covering the liability arising with respect to such violations in the sum of not more than $500 for each offense. *See* 27 U.S.C. § 207. Under the Internal Revenue Code of 1986, TTB officers may, in appropriate circumstances, temporarily detain any alcohol beverage container that is being removed in violation of law, or seek a voluntary detention agreement with the industry member. *See* 26 U.S.C. § 5311.

TTB reminds you that each producer is responsible for ensuring that its alcohol beverage products comply with the laws and regulations that FDA administers. An approved certificate of label approval (COLA) or formula from TTB does not imply or otherwise constitute a determination that the product complies with the FFDCA, including a determination as to whether the product is adulterated because it contains an unapproved food additive. Therefore, if FDA determines that your alcohol beverage product is adulterated under the FFDCA, its sale or shipment in interstate or foreign commerce by an industry member subject to the provisions of 27 U.S.C. § 205(e) constitutes a violation of the FAA Act even if the product is covered by a COLA or an approved formula. It is each producer's responsibility to ensure that its alcohol beverages are in compliance with the requirements of the FFDCA.

FDA provided you with fifteen (15) days to advise them of the specific steps you have taken to correct the violation identified above and to assure that similar violations do not occur. The FDA letter provided that your response should include any documentation necessary to show that correction has been achieved. Finally, the FDA letter provided that if you cannot complete all corrections within the 15 days, you should explain the reason for your delay and the date by which each such item will be corrected and documented. We ask that you similarly advise TTB within that same time period of the steps that you have taken to correct any violations of the FAA Act and the date by which each violation will be corrected. You should send your response to Susan Berndt, Assistant Director, Advertising, Labeling and Formulation Division, Alcohol and Tobacco Tax and Trade Bureau, Suite 400 West, 1310 G Street, NW, Washington, DC 20220.

Sincerely,

Signed by Gracie Joy

Gracie Joy
Assistant Director
Advertising, Labeling and Formulation Division

cc: United Brands Company, Cold Spring, MN
United Brands Company, La Crosse, WI

City Brewery, City Brewing Co., LLC
CBC Latrobe Acquisition, LLC