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DEPARTMENT OF HEALTH AND HUMAN SERVICE

Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

Telephone: 504-253-4519
FAX: 504-253-4520

March 10, 2005

WARNING LETTER NO. 2005-NOL-14

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. John Solomon, President and CEO
RealPure Beverage Group, LLC
2015 Highpoint Drive
Brandon, Mississippi 39042

Dear Mr. Solomon:

On October 19 and 21, 2004, an investigator with the U.S. Food and Drug Administration (FDA) inspected your firm, located at 130 Coby Drive, Magee, Mississippi. During the inspection, labels of your beverage concentrates were collected. The FDA reviewed your labels for 100% Juice Orange Concentrate, Premium Orange Juice and 100% Grape Juice Concentrate. Our review revealed the above products are misbranded under Section 403 of the Food, Drug, and Cosmetic Act (the Act), Title 21 of the *United States Code* § 343 (21 USC 343). You can find the Act and regulations through links in FDA's home page at http://www.fda.gov.

The label deviations are as follows:

1. 100% Juice Orange Concentrate:

   - Your product is misbranded under Sections 403(a) and 403(i)(1) of the Act [21 USC 343(a) and 343(i)(1)] in that the statement of identity for this concentrated juice blend represents it as consisting only of orange juice when, in fact, it is composed of both concentrated orange juice and concentrated apple juice. In addition, the product is misbranded under Section 403(g) of the Act in that it is falsely represented as concentrated orange juice, a food for which a standard of identity has been prescribed in Title 21 of the *Code of Federal Regulations*, Part 146.150 (21 CFR 146.150). Your product does not conform to such standard since (among other reasons) it consists of both apple juice and orange juice. The product must bear a statement of identity as required in 21 CFR 102.33, which is the regulation for the common or usual name of beverages containing fruit or vegetable juice.

   - Your product is also misbranded under Section 403(i)(2) of the Act [21 USC 343(i)(2)] as it contains an undeclared color additive, [redacted] (see 21 CFR 70.3(f) and 21 CFR 73.95). Under Section 403(i)(2) of the Act [21 USC 343(i)(2)] and 21 CFR 101.22(k)(2), [redacted] and other color additives exempt from certification are not

required to be declared in the ingredient statement individually by their common or usual names, but must be declared in the ingredient statement generically (e.g. "artificial color" or "color added").

2. Premium Orange Juice Concentrate:

- Your product is misbranded under Section 403(g) of the Act [21 USC 343(g)] in that it is represented as concentrated orange juice, a food for which a standard of identity has been prescribed in 21 CFR 146.150. Your product does not conform to such standard since (among other reasons) it is a concentrate for a diluted orange juice beverage rather than for orange juice. The product must bear a statement of identity consistent with the requirements in 21 CFR 102.33(a), common or usual name regulation of fruit and vegetable juice beverages containing less than 100% juice (e.g. "orange juice drink concentrate").

- Your product is also misbranded under Section 403(i)(2) of the Act [21 USC 343(i)(2)] as it contains an undeclared color additive, [redacted] (see 21 CFR 70.3(f) and 73.95). Under Section 403(i)(2) of the Act [21 USC 343(i)(2)] and 21 CFR 101.22(k)(2), [redacted] and other color additives exempt from certification are not required to be declared in the ingredient statement individually by their common or usual names, but must be declared in the ingredient statement generically (e.g. "artificial color" or "color added").

3. 100% Grape Juice Concentrate:

- Your product is misbranded under Section 403(i)(2) of the Act [21 USC 343(i)(2)] in that the label fails to declare certified color additives in the ingredient statement by their common or usual names. Specifically, the color designation has been omitted for the color additives FD&C Red No. 40 and FD&C Blue No. 1, which are listed on the product label as "FD&C #40" and "FD&C #1." The common or usual name of a certified color additive may be abbreviated by omitting the "FD&C" prefix and/or the term "No." (e.g. "Red 40" or "Blue 1").

Furthermore, Section 403(q) of the Act [21 USC 343(g)] requires packaged food to bear nutrition labeling unless they qualify for an exemption. Your products, which currently do not bear any nutrition labeling, may qualify for an exemption based on your firm size and/or amount produced. The small business nutrition labeling exemptions for food are outlined in 21 CFR 101.9(j)(1) and 21 CFR 101.9(j)(18). We have enclosed information on the small business food labeling exemption, a model form, and instructions.

In addition to the above food labeling violations, we also found significant deviations from the Juice Hazard Analysis Critical Control Point (HACCP) regulations (21 CFR 120). The Juice HACCP regulation requires you to implement a preventive system of food safety controls known as HACCP. HACCP essentially involves: (1) identifying each food safety hazard that, in the absence of controls, is reasonably likely to occur in your products; and, (2) having controls at each "critical control point" in the processing operation to eliminate or minimize the likelihood the identified hazard will occur. Prudent processors already take these kinds of measures. HACCP provides a systematic way of identifying, implementing, and documenting those

measures demonstrating to us, to your customers, and to consumers, you are routinely practicing food safety by design. In accordance with 21 CFR 120.9, failure of a processor to have and implement a HACCP plan complying with this section, or otherwise operate in accordance with the requirements of this part, renders the juice products adulterated within the meaning of Section 402(a)(4) of the Act [21 USC 342(a)(4)].

Our investigator provided your firm with a list of Inspectional Observations (Form FDA 483), which presents his evaluation of your firm's performance regarding various aspects of the HACCP and Current Good Manufacturing Practice (CGMP) requirements (21 CFR 110). Based on the inspection, the significant deficiencies identified are as follows:

1. You must have and implement a written HACCP plan to control any food safety hazards reasonably likely to occur to comply with 21 CFR 120.8(a). However, your firm does not have HACCP plans to control the food safety hazard of pathogens.

2. You must have sanitation standard operating procedure (SSOP) records documenting, at minimum, the monitoring and corrections to comply with 21 CFR 120.6(c). However, your firm does not maintain SSOP records for:

   a. Safety of the water contacting food or food contact surfaces or used in the manufacture of ice;

   b. Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments;

   c. Prevention of cross-contamination from insanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to processed product;

   d. Maintenance of hand washing, hand sanitizing, and toilet facilities;

   e. Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants;

   f. Proper labeling, storage, and use of toxic compounds;

   g. Control of employee health conditions which could result in the microbiological contamination of food, food packaging materials, and food contact surfaces; and,

   h. Exclusion of pests from the food plant.

We encourage you to make the necessary improvements as soon as possible. However, if you disagree with our preliminary assessment of deviations from the Juice HACCP regulation, you should explain how your system identifies hazards and implements controls in a manner the agency should regard as complying with the regulation. We understand HACCP systems may be uniquely tailored to meet the circumstances of the individual processor and there may be more than one right way to control hazards.

The above violations are not meant to be an all-inclusive list of deficiencies at your facility. Other violations can subject your products to legal action. It is your responsibility to assure your products and operations are in compliance with all applicable statutes and regulations enforced by FDA.

We may take further regulatory action if you do not promptly correct these violations. For instance, we may seize your products and/or enjoin your firm from operating.

Please respond in writing, within fifteen (15) working days from your receipt of this letter, to the noted violations. Your response should outline specific actions you have taken to correct the noted violations. You may wish to include copies of revised labels or other useful information to assist us in evaluating your corrections. If corrective action cannot be completed within the above timeframes, please state the reason for the delay and the time within which corrections will be completed.

Please send your response to the U.S. Food and Drug Administration, Attention: Rebecca A. Asente, Compliance Officer, at the address above. If you have questions regarding any issue in this letter, please contact Ms. Asente at (504) 253-4519.

Sincerely,

Patricia K. Schafer

Patricia K. Schafer
Acting District Director
New Orleans District

Enclosures: Form FDA 483, Small Business Food Labeling Exemption Information, Model Form, and Instructions); 21 CFR, Parts 70, 73.95, 101, 102, 110, 120, 146.150

cc: Mr. Bert Swensen, COO
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Magee, Mississippi 39111

[redacted] Plant Manager
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