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October 19, 1999

FOOD & DRUG ADMINISTRATION
466 FERNANDEZ JUNCOS AVENUE
SAN JUAN, P.R. 00901-3223

WARNING LETTER
SJN-00-02

Certified Mail
Return Receipt Requested

Mr. Jesus Zambrana
President
Refresqueria Jerry
300 Francia St. Int. Julia St.
Hato Rey, PR 00917

Dear Mr. Zambrana

An Investigator from this office of the Food and Drug Administration conducted an inspection at your firm on May 6, 11, & 12/99. During that inspection, samples of juice beverage products were collected, copies of your product labeling were obtained, and a FDA-483, Inspectional Observations form was issued to you. Our analysis of samples and review of your labels, and the inspection evidence reported, found serious violations of the Food, Drug and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (CFR) Part 101 – Food Labeling, as follows:

1. Your "Refresqueria Jerry" Piña (pineapple) and Toronja (grapefruit) beverage drinks and your "Refresqueria Jerry" China (orange) and Parcha (passion fruit) juice beverages are adulterated within the meaning of Section 402(c) of the Act because they contain the color additive FD&C Yellow #5 and their labeling do not state that fact.
2. These beverages are also misbranded because they are made from two or more ingredients, but the labels fail to bear the common or usual name of each artificial coloring ingredient [403(i)(2) and 21 CFR 101.22(k)(1)], and your products contain colors certifiable as FD&C Yellow No. 5, FD&C Yellow No. 6 and FD&C Red No. 40, but the labels fail to declare the presence of these colors [403(i)(2) and 21 CFR 101.4].
3. Your "Refresqueria Jerry" juice and drink beverage labels are false in that the products contain chemical preservatives, e.g. sodium benzoate, and/or a beverage mix that contains a chemical preservative, but the labels fail to declare both the presence of the chemical preservatives and a description of the function of the preservatives [403 (a), 403(i)(2), 403(k), 21 CFR 101.4 and 21 CFR 101.22(j)].
4. Your beverage products are misbranded because the labeling states that the beverages contain fruit juice, but they do not bear a statement, with appropriate prominence on the information panel, of the total percentage of fruit juice [403(i)(2) and 21 CFR 101.30]. These beverages contain fruit juice from fruit pulp concentrate yet the total percentage of such fruit juice is not declared.
5. The "Refresqueria Jerry" Piña (pineapple) and Toronja (grapefruit) beverage drinks are misbranded in that they are labeled as containing fruit pulp when they are made from beverage drink mix powder that contains natural and artificial flavors, not fruit juice derivatives. These beverage labels must declare all of the ingredients of the products [403(a) and 21 CFR 101.4].

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The labels on your "Refresqueria Jerry" beverages are misleading in that they depict a vignette that displays recognizable (characterizing) flavors of fruit (e.g., a pineapple, oranges, cherries, etc.). This implies that all of the fruits shown are in the products. However, some of your drink mix powders do not contain characterizing flavors, e.g. Pineapple Drink mix. Your beverages that contain natural and/or artificial flavors that simulate characterizing flavors are required to declare the common or usual name(s) of those characterizing flavor(s), along with the word(s) "artificial" or "artificially flavored" [21 CFR 101.22(i)].

Although the principal display panels of your products declare a flavor designation, e.g., Guava, Grapefruit, etc., they do not bear a statement of identity that describes the food, e.g. juice, drink, beverage, etc. [21 CFR 101.3]. Also, the flavor designation for the products, e.g. Guava-Piña, Toronja, etc., should not appear inside of the "Nutrition Facts" box [21 CFR 101.9(d)].

Our Investigator observed drums of fruit pulp both inside and outside of the storage refrigerator. Your beverages that contain juice or juice derivatives (e.g. concentrate, pulp, etc.) require a warning statement if they have not been processed as defined in 21 CFR 101.17(g). Our Investigator provided you with written guidance regarding the requirements under this regulation. In lieu of a warning statement on the product labels, you can comply with the warning statement requirement until November 1999, by providing signs or placards [21 CFR 101.17(g)(4)(i), 21 CFR 101.17(g)(4)(ii)].

Furthermore, our Investigator observed that you do not have a system in place by which you are able to ensure safe levels of ingredients are added to the products. For example, you must ensure that the sodium benzoate used in the products does not exceed good manufacturing practice, which is currently a maximum level of 0.1 percent [21 CFR 184.1733].

The above violations, some of which concern certain new labeling requirements, are not meant to be an all-inclusive list of deficiencies at your plant. Other labeling violations can subject the food to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by FDA.

You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory action without further notice. These 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. If corrective action cannot be completed within 15 days, state the reasons for the delay and the time at which the corrections will be completed.

Your reply should be directed to Andres Toro, Compliance Officer at 466 Fernandez Juncos Ave, Puerta de Tierra, San Juan, P.R. 00901. If you have any questions concerning the violations noted please contact the above named Compliance Officer at telephone number (787) 729-6894 ext. 2131.

Sincerely



Mildred R. Barber
District Director