



*magon*

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

September 20, 1999

**WARNING LETTER**

SJN-99-17

**Certified Mail**

**Return Receipt Requested**

Mr. Rafael Contes  
Owner  
Refresqueria Victoria  
HC-67 Box 13040  
Bayamon, P.R. 00956

Dear Mr. Contes:

On April 14, 16, 23, 28 and May 27, 1999, the Food and Drug Administration (FDA) conducted an inspection of your fruit beverage manufacturing plant located at the address listed above. Review of the inspectional information and labels for your fruit beverage products finds that the products are misbranded within the meaning of section 403 (i)(2) of the Federal Food Drug and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (CFR), parts 101, 102 and 108 as follows:

1. None of the Juicy Juicy Fruit drink products manufactured by your firm contain a statement of the percentage of juice as required by 21 CFR 101.30 (b).
2. The principal display panel for your juice products does not bear a statement of identity that describes the food. For diluted fruit beverages, the name given to the product must meet the requirements of 21 CFR 102.33 and 101.3.
3. The products Juicy Juicy Fruit Fruit Punch™, Juicy Juicy Fruit Acerola™, Juicy Juicy Fruit Kiwi-Strawberry™ and Juicy Juicy Fruit Frutas are misbranded because they contain the color additive F D & C Red #40 and the presence of this color

Rafael Contes

9/20/99

page 2

4. The products Juicy Juicy Fruit China™ and Juicy Juicy Fruit China Concentrado™ are misbranded because they contain the food additive saccharin and the labels of these products do not indicate the presence or amount of saccharin in accordance with 21 CFR 180.37 (f)(2). The labels for these products also do not contain the warning statement: "USE OF THIS PRODUCT MAY BE HAZARDOUS TO YOUR HEALTH.THIS PRODUCT CONTAINS SACCHARIN WHICH HAS BEEN DETERMINED TO CAUSE CANCER IN LABORATORY ANIMALS", which is required by section 403 (o)(1) of the Act for products which contain saccharin.
5. Our inspection also reports that sodium benzoate is added to the fruit drink products during manufacturing. The ingredient statements on the labels of the products which contain sodium benzoate should declare the presence of this additive in accordance with 21 CFR 101.22 (c)
6. All of the above mentioned juice drink products are also misbranded because the labels do not comply with the labeling requirement that juices not specifically processed to prevent, reduce or eliminate the presence of pathogens bear the warning statement set forth in 21 CFR 101.17. Although the preservative sodium benzoate is reportedly used in all of the products, your firm has not obtained any scientific data to assure that the sodium benzoate provides a 5-log reduction of pathogens.

We also note that none of the product labels contain a nutritional labeling statement. 21 CFR 101.9 requires that nutrition information be provided on the labeling of all food products. A list of exemptions from this requirement is included in 21 CFR section 109(j). If you believe your firm is entitled to an exemption from the nutritional labeling requirements, a notice of the reasons for such exemption should be filed with:

Office of Food Labeling  
Center for Food Safety and Applied Nutrition  
Food & Drug Administration  
200 C St. SW  
Washington, D.C. 20204

in accordance with the instructions found in 21 CFR 101.9 (j)(18).

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.

Rafael Contes

9/20/99

page 3

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, including an explanation of each step being taken to prevent the recurrence of similar violations. Copies of revised labeling for the products should also be submitted. If corrective actions can not be completed within 15 working days, state the reason for delay and the time within which corrections will be completed.

Your reply should be sent to the Food & Drug Administration, San Juan District Office, 466 Fernandez Juncos Ave., San Juan, PR 00901-3223, Attention: Mary L. Mason, Compliance Officer.

Sincerely,

  
Mildred R. Barber  
District Director