



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

San Juan District
Compliance Branch
466 Fernandez Juncos Avenue
San Juan, Puerto Rico 00901-3223
Telephone: 787-474-9500
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June 1, 2004

WARNING LETTER
SJN-04-08

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Jorge L. Hernández
Owner
Refrescos Yaguez, Inc.
Parque Industrial Guanajibo
W.F. Brennan #1055
Mayaguez, PR 00682

Dear Mr. Hernández:

From December 4 thru 17, 2003, investigators from the Food and Drug Administration (FDA) inspected your juice drink manufacturing facility located at Parque Industrial Guanajibo, Mayaguez, PR. This inspection was conducted as a follow-up to an April 2003 inspection. At the conclusion of the December 2003 inspection, a Form FDA 483, Inspectional Observations, was issued, and one of our investigators discussed the observations with you. This inspection documented violations of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (CFR). You can find the Act and FDA regulations through links on FDA's home page at www.fda.gov.

We have reviewed the product labels and formulation sheets collected during the December 2003 inspection and have identified several violations of the Act and applicable regulations. These violations cause your products to be adulterated and/or misbranded, as discussed below.

Several of your products contain color additives that are not declared in the ingredient statement on the product's label. Under 21 CFR 101.22(k)(1), a color additive subject to certification under section 721(c) of the Act shall be declared by the name of the color additive, as specified in the color additive's listing regulation in part 74 or part 82 of the CFR. The name may be abbreviated to omit the "FD&C" prefix and the term "No." (e.g., Red 3 instead of FD&C Red No. 3). Although color additives not subject to certification (e.g., the caramel color used in Refrescos Yaguez Tamarindo) need not be declared by the name specified in the applicable listing regulation, 21 CFR 101.22(k)(2) requires that

they be declared, e.g., as “artificial color,” or “color added.” Products you manufacture that are adulterated and/or misbranded because they contain undeclared color additives are as follows:

- Your product Yaguez Supreme Parcha is adulterated within the meaning of section 402(c) of the Act, in that it contains a color additive which is unsafe within the meaning of section 721(a)(1)(A) of the Act. Under section 721(a)(1)(A), a color additive subject to certification is deemed unsafe unless it is used in conformity with its listing regulation, including any conditions of use prescribed in the regulation. Your use of FD&C Yellow No. 5 in Yaguez Supreme Parcha does not comply with the applicable listing regulation, which specifically requires that FD&C Yellow No. 5 be declared as an ingredient on the label of any food for human use that contains it [21 CFR 74.705(d)(2)]. Yaguez Supreme Parcha is also misbranded within the meaning of section 403(i)(2) of the Act in that the label fails to declare FD&C Yellow No. 5, FD&C Yellow No. 6, and FD&C Red No. 40.
- Your products Yaguez Supreme Fruit Punch, Yaguez Supreme Acerola, and Refrescos Yaguez Guava-Piña are misbranded within the meaning of section 403(i)(2) of the Act, in that the labels fail to declare FD&C Red No. 40.
- Your Refrescos Yaguez Tamarindo is misbranded within the meaning of section 403(i)(2) and 403(k) in that the label fails to declare the presence of added caramel color.

You were previously advised about the failure to declare the certified color additives in Yaguez Supreme Parcha and Yaguez Supreme Fruit Punch at closing of the inspection conducted on April 2003, in which you promised our investigator prompt correction of labeling deficiencies.

Your products Refrescos Yaguez Acerola, 128 fl oz, Refrescos Yaguez UVA, 128 fl oz, Refrescos Yaguez Guava-Pina, 128 fl oz, Refrescos Yaguez Limon, 128 fl oz, and Refrescos Yaguez Tamarindo, 128 fl oz, are misbranded within the meaning of section 403(r)(1)(A) of the act. The labels bear the claim “low calorie;” however, the products do not meet the requirements for “low calorie” as defined in 21 CFR 101.60(b)(2). The nutrition label for these products declares 60 calories per 240 ml. The definition for “low calorie” requires, in part, that the food not provide more than 40 calories per 240 ml reference amount customarily consumed for beverages.

Your products Yaguez Supreme Fruit Punch, 8 fl oz, Yaguez Supreme Acerola, 64 oz, Yaguez Supreme Mandarina, 16 and 64 fl oz, Yaguez Supreme Limon, 128 fl oz, Yaguez Supreme UVA, 64 fl oz, Yaguez Supreme China, 16 fl oz, Yaguez Supreme China, 64 fl oz, and Yaguez Supreme Parcha, 16 fl oz, are misbranded within the meaning of section 403(i)(2) in that they are beverages that purport to contain juice but they fail to declare the percentage juice on the label [see 21 CFR 101.30].

Several of your products are misbranded within the meaning of section 403(e)(2) of the Act, in that the labels do not declare the net quantity of contents on the principal display panel [see 21 CFR 101.105]. The products are as follows:

- Refrescos Yaguez Acerola 128 fl oz
- Refrescos Yaguez Uva 128 fl oz
- Yaguez Supreme Acerola 64 fl oz
- Refrescos Yaguez Guava-Piña 128 fl oz
- Refrescos Yaguez Tamarindo 128 fl oz
- Yaguez Supreme Uva 64 fl oz
- Yaguez Supreme Mandarina 64 fl oz
- Refrescos Yaguez Limon 128 fl oz
- Yaguez Supreme China 64 fl oz

Failure to promptly correct these violations and prevent future violations may result in regulatory action without further notice, such as seizure or injunction. As a food manufacturer, it is your responsibility to ensure that your products meet all the requirements of the Act and the regulations promulgated thereunder.

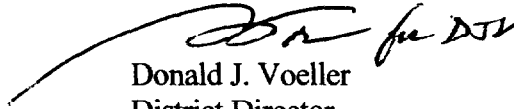
We also note that several of your products do not fully comply with the nutrition labeling format specified in FDA's regulations. For example, your products Refrescos Yaguez Acerola 128 fl oz, Refrescos Yaguez Uva 128 fl oz, Refrescos Yaguez Guava-Piña 128 fl oz, Refrescos Yaguez Tamarindo 128 fl oz, and Refrescos Yaguez Limon 128 fl oz do not list "sugar" in the correct position in the Nutrition Facts panel [see 21 CFR 101.9(c)]. The labels for these products use the simplified format provided in 21 CFR 101.9(f). We remind you that when using the simplified format, if nutrient content claims (e.g., "Low Calorie") are made in the product's label or other labeling, the statement "Not a significant source of _____" (with the blank filled in as specified in 21 CFR 101.9(f)(4)) must be included at the bottom of the Nutrition Facts panel.

Several of your product labels fail to include the common or usual name for ingredients in accordance with the requirements of 21 CFR 101.4(a). For example, your Yaguez Supreme China (64 fl oz) does not list the presence of "aceite de china" in the ingredient statement, although the formulation sheet for this product lists "aceite de china" as an ingredient. In addition, the ingredient statements for several of your products list the ingredient "Pulpa de Fruta" (fruit pulp), which is a general term that describes a group of ingredients, not a specific common or usual ingredient name. The ingredient statement should list the specific type of fruit pulp used in the product (e.g., lemon pulp).

Your product Refrescos Yaguez UVA declares "Color Amarillo #5 y #6" on the label; however, the formulation sheet for this product does not include FD&C Yellow No. 5 or FD&C Yellow No. 6. It is your responsibility to make sure the labeled ingredient information for all of your firm's products reflects accurately what ingredients are actually present.

We request a response in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the violations listed above, including an explanation of each step being taken to prevent the recurrence of the violations. Your written reply should be addressed to the Food and Drug Administration, Attention: Miguel A. Hernández, Compliance Officer, 466 Fernández Juncos Avenue, San Juan, and Puerto Rico 00901.

Sincerely,

A handwritten signature in black ink, appearing to read 'D. J. Voeller', with a long, sweeping underline that extends to the left.

Donald J. Voeller
District Director
San Juan District