



DEPARTMENT OF HEALTH AND HUMAN SERVICE

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Food and Drug Administration  
San Juan District  
Compliance Branch  
466 Fernández Juncos Ave.  
San Juan, PR 00901-3223

Telephone: 787-474-9500  
FAX: 787-729-6658

October 26, 2004

**WARNING LETTER**  
**SJN-05-01**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Miguel Lugo  
Owner  
Refrescos Lugo  
#AA 4 Sta. Juanita Ave.  
Bayamón, P.R. 00956-4644

Dear Mr. Lugo:

On July 7 thru 9, 2004, an investigator from the Food and Drug Administration (FDA) inspected your firm located at Sta. Juanita Ave. #AA 4, Bayamón, P.R. This inspection was conducted as a follow-up to a January 2003 inspection. The inspection documented repeated 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](http://www.fda.gov).

We have reviewed the product labels collected for the following products:

- Jugos Lugo Parcha (64floc, 128floc) and Lugo Light Parcha (64floc)
- Jugos Lugo Limon (64floc, 128floc) and Lugo Light Limon (64floc, 128floc)
- Jugos Lugo China (64floc, 128floc) and Lugo Light China (16floc, 64floc)
- Jugos Lugo Toronja (64floc, 128floc) and Lugo Toronja Light (64floc, 128floc)
- Jugos Lugo Tamarindo (16floc, 64floc)
- Jugos Lugo UVA (16floc, 64floc, 128floc)
- Jugos Lugo MAVI (64floc, 128floc)
- Jugos Lugo Guanabana (64floc, 128floc)
- Jugos Lugo Fruta (64floc, 128floc)
- Refrescos Lugo Acerola (64floc, 128floc) and Lugo Light Acerola (64floc, 128floc)
- Lugos Guava-Pina (64floc, 128floc)
- Fruit Price Toronja (16floc)
- Fruit Price Limon (16floc)
- Fruit Price China (16floc)
- Fruit Price UVA (16floc)

Upon review of the labels and during the inspection we identified several violations of the Act and applicable regulations. These violations cause your products to be misbranded under section 403 of the Act, 21 U.S.C. 343, as discussed below.

1. Several of your products contain color additives that are not declared in the ingredient statements of the products' labels. Under 21 CFR 101.22(k)(1), a color additive subject to certification under section 721(c) of the Act, 21 U.S.C. 379e(c), 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 40 instead of FD&C Red No. 40). Although color additives not subject to certification (e.g., the caramel color used in Jugos Lugo Mavi) 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 misbranded because they contain undeclared color additives are as follows:
  - Your products Lugo Light Parcha, Jugos Lugo Acerola, Lugo Light Acerola, and Jugos Lugo Frutas contain a color additive subject to certification (i.e., FD&C Red No. 40) which was not declared on the products' labels as required by 21 CFR 101.22(k)(1). Failure to declare certified color additives causes a product to be misbranded under sections 403(i)(2) and 403(k) of the Act, 21 U.S.C. 343(i)(2) and 343(k).
  - Your Jugos Lugo Mavi and Jugos Lugo Tamarindo drinks, which both contain the color additive caramel, are misbranded under sections 403(i)(2) and 403(k) of the Act, 21 U.S.C. 343(i)(2) and 343(k), in that their labels fail to indicate that a color additive was used in the products, as required by 21 CFR 101.22(k)(2).
2. All of your products listed on page one (with the exception of Jugos Lugo MAVI) are misbranded under Sections 201(n) and 403(a) of the Act, 21 U.S.C. 321(n) and 343(a), because information required by or under authority of this Act to appear on the label or labeling does not appear thereon. As specified in 21 CFR 172.804(d) (2), the label of any food containing aspartame must state [redacted] Your products contain aspartame, but do not include the required statement.
3. All of your products listed on page one are misbranded under section 403(i)(2) of the Act, 21 U.S.C. 343(i)(2), in that the labels do not declare the common or usual name of each ingredient as specified in 21 CFR 101.4. For example, according to the information collected by our investigator, your Lugo Light China drink is made with the ingredient [redacted] which itself is composed of two or more ingredients. Unless these ingredients are exempt (See, for example, 21 CFR 101.100), they must be declared on the finished product label. In addition, according to the formulations you provided, many of your products are made with the preservative [redacted] Preservative ingredients must be declared on the label by common or usual name and also must bear a separate description of the preservative's function, in accordance with 21 CFR 101.22(j).
4. Your Fruit Price Toronja, Limo, China, and UVA flavors; Lugo Guava-Pina flavor; and Lugo Light Acerola, Toronja, and Limon flavors are misbranded under section 403(e)(2) of the Act, 21 U.S.C. 343(e)(2), as the labels do not bear an accurate statement of quantity of the contents in terms of fluid ounces, as required by 21 CFR 101.105(a).
5. Your Jugos Lugo Parcha, Jugos Lugo Limon, Jugos Lugo China, Jugos Lugo Toronja, Jugos Lugo Tamarindo, Jugos Lugo Uva, Jugos Lugo Mavi, Jugos Lugo Guanabana, and Jugos Lugo Acerola are beverages that contain more than 0% and less than 100% juice; however, the term

- juice in the name of the food is not qualified to inform the consumer that the product is less than 100 percent juice in accordance with 21 CFR 102.33(a).
6. The products labeled with the term "light" Lugo Light Parcha, Lugo Light Limon, Lugo Light China, Lugo Light Toronja, and Lugo Light Acerola, fail to include the identity of the reference food and the comparative caloric and fat content in the reference food as required by 21 CFR 101.56(b)(3) and 101.13(j)(2). Because these products satisfy the provision in 21 CFR 101.56(b)(3) (iii), the percentage reduction would not need to accompany the claim on these products.

The above violations are not meant to be an all-inclusive list of deficiencies in your products and their labeling. Other violations can subject the products to legal action. It is your responsibility to ensure that all products distributed by your firm are in compliance with all applicable statutes and regulations enforced by the FDA.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction.

Please note that your labels bear information both in English and Spanish. According to 21 CFR 101.15(c), these labels may bear information exclusively in English, or, in the Commonwealth of Puerto Rico or in a Territory where the predominant language is one other than English, exclusively in the predominant language (in this case, Spanish). However, where labels bear information in both English and another language, all required information must appear in both languages.

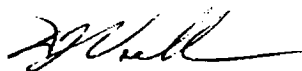
Please also note, as discussed at the conclusion of the inspection, your firm is required to register with FDA in order to comply with 21 U.S.C. § 350d.

Regarding the voluntary recall of Acerola, Parcha, and Fruta drinks for re-labeling purposes, please provide information as to the outcome of this recall to Ivonne Ayala at the address below.

Please notify the San Juan District office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, please state the reason for the delay and the time within which corrections will be completed.

Your reply should be sent to the U.S. Food and Drug Administration, San Juan District Office, 466 Fernández Juncos Ave., San Juan, P.R. 009091-3223, Attention: Jorge L. González, CSO/Compliance Officer.

Sincerely,



Donald J. Voeller  
District Director  
San Juan District