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

October 15, 2002

WARNING LETTER
SJN-03-01

Certified Mail
Return Receipt Requested

Mr. Abisail Reyes
Owner
La Hacienda Fruit
Box 1890
Hatillo, P.R. 00659

Dear Mr. Reyes:

On 6/20, 26 – 7/2, 9/02, the Food and Drug Administration (FDA) conducted an inspection of your Soft Drink Manufacturing facility, La Hacienda Fruit, Carretera 493 Km 3.1 Bo. Concorvado, Hatillo, PR 00659. Review of the inspectional information and labels of your products: Acerola, Fruit Punch, Guava-Pineapple, Passion Fruit, Tangerine, Tamarind, Sour sop, Sesame seed, Orange, Grapefruit, Grape, and Mavi juice beverages, finds that the products are misbranded within the meaning of Section 403 of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (CFR) Part 101, Food Labeling, as follows:

1. Your juice-drink products are misbranded under 403(i)(2) of the Act because their labels do not contain a statement of the percentage of juice as required by 21 CFR 101.30(b).
2. Your Acerola, Fruit Punch, Guava-Pineapple, Passion Fruit, Mandarin Orange, Sesame Seed, Orange, Grapefruit, and Grape juice products are misbranded under sections 403(i)(2) and 403(k) of the Act because they contain the chemical preservative sodium benzoate, which is not declared on the products' labels. Under 21 CFR 101.22(j), chemical preservatives must be declared on product labels by their common or usual names (e.g., sodium benzoate) along with a description of their function (e.g., "preservative," "to retard spoilage").
3. Your Acerola, Fruit Punch, Guava-Pineapple, Passion Fruit, Mandarin Orange, Sesame Seed, Orange, Grapefruit, and Grape juice products are misbranded under sections 403(i)(2) and 403(k) of the Act because they contain the certified color additives FD&C Yellow No. 6 and FD&C Red No. 40, which are not declared on the products' labels. Under 21 CFR 101.22(k)(1), certified

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color additives must be individually declared in the ingredient statement by their common or usual names (e.g., FD&C Yellow No. 6 and FD&C Red No. 40).

It is your responsibility to assure that all your products are labeled in compliance with all applicable statutes and regulations.

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.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to prevent the recurrence of similar violations. Copies of revised labeling for the products should also be submitted. If corrective actions cannot 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 and Drug Administration, San Juan District Office, 466 Fernandez Juncos Ave., San Juan, PR 00901-3223, Attention: Jorge L. González, Compliance Officer.

Sincerely,



Evelyn Bonnin
Acting District Director