



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

Telephone: 787-729-6894
FAX: 787-729-6658

June 29, 1999

WARNING LETTER
SJN-99-10

HAND DELIVERED

Mr. Roberto Romero
President
Cerro La Marquesa, Inc.
Avenida Esmeralda #53, Suite 114
Guaynabo, Puerto Rico 00969

Dear Mr. Romero:

On 6/2,4,9/99, the Food and Drug Administration (FDA) conducted an inspection of your water bottling plant located at Rd. #834, Km.4.2., Bo. Sonadora, Guaynabo, PR. The inspectional findings and product label review revealed that your product is adulterated within the meaning of Section 402(a)(4) and misbranded within the meaning of Section 403(a)(1) of the Federal Food, Drug, and Cosmetic Act; and in violation of Title 21, Code of Federal Regulations, Parts, 129 (Processing and Bottling of Bottled Drinking Water), 165.110 (Standard of Identity for Bottled Water) and 101 (Food Labeling) as follows:

1. Source water is not being analyzed for chemical contaminants, radiological contaminants or for microbiological contaminants. [21 CFR 129.1].
2. Analyses have not been conducted on the product water after processing and prior to bottling in order to assure the uniformity and effectiveness of the filtration process performed by your plant. The product water is not being analyzed for microbiological purposes or for chemical, physical or radiological purposes. Records are not being kept of the type and date of physical inspections, conditions found, and the performance and effectiveness of the filtration and ultraviolet treatment equipment used for the treatment of the source water into product water [21 CFR 129.80(a) and 165.110(b)(2), (3), (4)].
3. Sanitizing operation of the 5-gallon containers is inadequate. Source water being used for both the sanitizing solution and the first rinse is not tested as required. Records are not being kept of analyzes of the sanitizing solution, and the chlorine test kit used only provides for a maximum reading of 10 ppm. The sanitizing solution preparation procedure does not ensure that the suggested

chlorine concentration (50ppm to 200 ppm) is obtained. Testing of the sanitizing solution is done only at the beginning of the operation and monitoring of the solution is not performed during the operation. [21 CFR 129.80 (1) (c) , (d) &(3)].

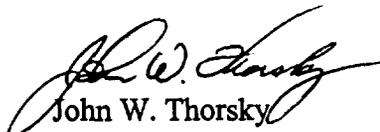
4. Sanitizing of the pipe system is inadequate. The amount of approximately 28 fl. Oz. of commercial chlorine "Clorox" is used to sanitize approximately 2 miles of 2" pipeline. Chlorine concentration and exposure time have not been established. [21 CFR 129.1].
5. The lot code system for the 5-gallon containers is being placed in the bottle cap where it is discarded when the bottle is placed in a water cooler. [21 CFR 165.3(a)(1)].
6. The product label is false and misleading in that it indicates that the water is sterilized when in fact there is no process to assure product sterility. [21 CFR 165.110(a)(2)(vii)].

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 correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. 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: Daniel Gonzalez, Director of Compliance.

Sincerely,


John W. Thorsky
Acting District Director