



April 2, 2003

**WARNING LETTER**  
**SJN-03-07**

**Certified Mail**  
**Return Receipt Requested**

Mr. Fernando E. Ramirez Gelpi  
President  
Tropical City Industries, Inc.  
P.O. Box 7466  
Ponce, Puerto Rico 00732-7466

Dear Mr. Ramirez:

Our investigator, Hector J. Colon Torres, on January 16, 17, 21 and 23 inspected your water bottling and ice plant facility, Tropical City Industries, Inc., located at Ponce Puerto Rico. During the course of his inspection, he noted significant deviations from Food and Drug Administration's regulations as set forth in Title 21 Code of Federal Regulations (CFR) Part 129, "Processing and Bottling of Bottled Drinking Water" and, specifically, 21 CFR §129.1 "Current Good Manufacturing Practice." Further your facility's water bottling operation failed to comply with 21 CFR § 165.110(b)(2)(i) and (ii), the microbiological standards for bottled water. These deviations, which were set forth in an Inspectional Observations Form (FDA-483) presented to your company's president on January 23, 2003 and which cause your drinking water and ice products to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) are as follows:

1. During December 2002, analytical results for your bottled drinking water sold under the label "La Senorial" in one gallon and sixteen ounce sizes showed the presence of Coliform organisms. The analytical methods used did not provide quantitative information for Coliform organisms, as required by 21 CFR § 129.80(g)(3) and 21 CFR § 165.110(b)(2)(i) and (ii). Further review of analytical results showed that on September 28, 2002 Acualab de Puerto Rico, Inc. reported a positive result for the presence of Coliform organisms and identified the presence of E.coli organism, in your bottled drinking water sold under the label "Polarstil" in five gallon containers. In addition, on three separate days during the year 2002, your ice product analytical results also showed the presence of Coliform organisms and on two different days the "gallon valve" analytical results also showed the presence of Coliform organisms. Corrective action records were not provided to our investigator during the inspection. Therefore there is no assurance of the quality of the bottled drinking water and ice products manufactured at your facility.

2. You are not analyzing your bottled drinking water for bacteriological purposes at the required minimum of once a week as set forth in 21 CFR § 129.80(g)(1). Your current practice of performing the analysis once every two weeks is inadequate.
3. You fail to analyze the source water once a week for microbiological contaminants as required by 21 CFR § 129.35(3). Your current practice of performing the analysis once a year is inadequate.
4. You fail to perform, at least once every three months, a bacteriological swab and /or rinse count from at least four containers and closures selected just prior to the filling and sealing operations as required by 21 CFR § 129.80(f) and the microbiological analyses required by 21 CFR § 129.80(f) are not being performed. .
5. You have failed to assure that the multiservice containers are adequately sanitized. The five gallon bottle washing machine does not provide exposure of the product water-contact surface at minimum intensity of the sanitizing agent solution as required by 21 CFR § 129.80(b)(2) and § 129.80(d)(3). Our inspector's review of the bottle washing machine use record revealed that there were no entries setting forth the time duration during which the product water contact surface was exposed to the sanitizing agent.
6. You have failed to keep records of the type and date of physical inspection of your equipment, the conditions observed, and the performance and effectiveness of such equipment as required by 21 CFR § 129.80(a).
7. You have failed to keep records of the physical maintenance, inspections, conditions found, and the performance of the mechanical washer equipment as required by 21 CFR § 129.80(b)(1).
8. You have failed to take effective measures to maintain the equipment used in your ice product manufacturing operation in an acceptable condition as required by 21 CFR § 110.80(b)(1).
9. You have failed to maintain your equipment in a manner that protects against contamination of your products as required by 21 CFR § 110.80(b)(7).
10. You have failed to take effective measures to protect against the introduction of metal or other extraneous material in your products as required by 21 CFR § 110.80(b)(8).

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Current Good Manufacturing Practices (CGMP) In Manufacturing, Packaging, or Holding Human Food and the microbiological standards for bottled water. You should take prompt action to correct your violations, discussed above, and you should establish procedures whereby such violations do not recur. Failure to

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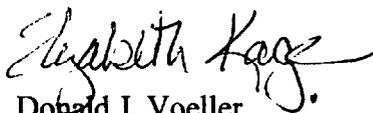
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promptly correct these violations may result in regulatory action without further notice in accordance with the Act. Possible actions include seizure and/or injunction.

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 cannot be completed within 15 working days, state the reason for the 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, Puerto Rico 00901-3223, attention: Mr. Carlos A. Medina, Acting Compliance Officer.

Sincerely yours,



for Donald J. Voeller  
District Director