



October 22, 2001

466 Fernandez Juncos Avenue
Puerta De Tierra
San Juan, Puerto Rico 00901-3223

WARNING LETTER

SJN-02-03

CERTIFIED MAIL

Return Receipt Requested

Ms. Jeannie Benjamin
President
Crown Mountain Natural Water, Inc.
13 C Lindburg Bay
P.O. Box 306918
St. Thomas, U.S.V.I. 00805

Dear Ms. Benjamin:

On May 17 & 18, 2001, the Food & Drug Administration conducted an inspection of your water bottling plant located at 13 C Lindburg Bay, St. Thomas, U.S.V.I. Evaluation of the findings from this inspection reveal that the bottled drinking water produced at your plant is adulterated within the meaning of Section 402 (a)(4) of the Federal Food, Drug and Cosmetic Act (the Act) because it was not manufactured in accordance with the requirements of Title 21, Code of Federal Regulations, Part 129 (21 CFR 129), Processing and Bottling of Bottled Drinking Water and 21 CFR 110, Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food. The deviations found during the inspection include the following:

1. Failure to test source water from a private well for microbiological contamination as required by 21 CFR 129.35 (a)(3).

Source water was sampled from a cistern, after passing through a reverse osmosis filter and not from the well.

2. Failure to take action to prevent continued distribution of product water that tested positive for objectionable microorganisms as required by 21 CFR 110.80.

A sample of product water collected on 4/6/01 was reported positive by a qualitative test for total coliforms and fecal coliforms. The product water manufactured on that date had already been sold. No action was taken to determine the source of the contamination, remove the contaminated production from the market or to implement corrections to prevent future contamination.

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3. Failure to store and maintain single use bottle caps to prevent contamination as required by 21 CFR 129.37 (c).

Bottle caps were stored in an open, unsanitized bucket immediately prior to their placement on finished product water bottles.

4. The water bottling room is not separated from other plant operations either by being located in a sealed area or by use of other adequate protection to preclude contamination of the water and the system, as required by 21 CFR 129.20 (a) & (b).

The room where bottling is performed has sliding glass doors to the outside on 3 walls. These doors remained open and unscreened during the bottling operation. In addition, the door to the toilet facilities opens directly into the bottling area and is not equipped with a self-closing mechanism.

5. Unit containers of product water are not identified with a production code or lot number. In addition, no production records are maintained recording the kind of product, volume, and date produced as required by 21 CFR 129.80 (e).

You should take prompt action to correct these deviations and prevent their recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Regulatory actions include seizure and/or injunction.

Please notify this office in writing within 15 working days of your receipt of this letter as to the specific actions that you have taken to correct the noted violations. Your response should include an explanation of the steps taken to prevent similar violations in the future. If corrective actions can not be completed within 15 working days, state the reason for the delay and the time within which corrective actions will be completed.

Your reply should be sent to the U.S. Food & Drug Administration to the attention of Mary L. Mason, Compliance Officer, at the address listed on the letterhead.

Sincerely


Mildred R. Barber
District Director