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Food and Drug Administration

October 22, 2001

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

**WARNING LETTER**  
SJN-02-02

**CERTIFIED MAIL**  
**Return Receipt Requested**

Mr. Walid Abdallah  
President  
Natural Source, Inc.  
13 C Lindburg Bay  
P.O. Box 503265  
St. Thomas, U.S.V.I. 00805

Dear Mr. Abdullah:

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. Equipment for processing of bottled drinking water is not always suitable in design for its intended purpose as required by 21 CFR 129.40 (a).

The water piping system has a by-pass valve under the ultraviolet (UV) light disinfecting device and the filling hose. In addition, a "dead leg" (and area of piping with no outlet where water can accumulate) was observed between the ozone water tank and the filling hose.

2. 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.

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3. Failure to maintain records of tests performed on both source and product bottled water as required by 21 CFR 129.80 (h).
4. There were no hand-washing or sanitizing facilities and no toilet facilities in the plant as required by 21 CFR 110.37 (d) & (e).
5. 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 is not enclosed. The doors and windows were not screened to protect against the entry of pests and remained open during processing. The bottling area is located in the same room as the finished goods storage area.

6. There were no records to assure that product water contact surfaces, pipes and equipment used for the processing, handling and storage of product water were adequately cleaned and sanitized as required by 21 CFR 129.37 (1) and 129.80 (d).
7. 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