



October 20, 1997

WARNING LETTER  
SJN-98-02

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Mr. Johnny Morales,  
Director  
Port of Ponce  
Santiago de Los Caballeros #10  
Ponce, Puerto Rico 00734

Dear Mr. Morales:

On September 30, 1997, the Food and Drug Administration inspected your facility located at Santiago de los Caballeros #10, Ponce Puerto Rico 00734.

The observations made during this inspection are in violation of the Public Health Service Act and the Food Drug and Cosmetic Act requirements specified under Title 21, Code of Federal Regulations, Parts 1240 and 1250.

The inspection revealed the following critical violations:

1. The backflow prevention device is inadequately installed. The single check valve is installed under continuous pressure on hydrants numbered 3, 5, and 9. The check valve is located before, instead of after the last control.
2. Stagnant water was observed inside the hydrant number three. In addition, the drain hole was obstructed with debris and soil sedimentation.

The inspectional observations identified above, are not intended to be an all-inclusive list of the conditions observed at your facility. It is your responsibility to assure adherence with all requirements of the regulations.

Mr. Johnny Morales  
October 20, 1997

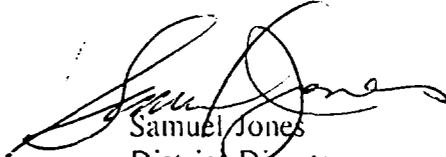
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Based on the inspectional findings we are classifying your facility as PROVISIONAL for interstate carrier use for a period of thirty (30) days. A "PROVISIONAL" classification means that the facility may continue to operate; however, significant correction of violations must be made by the expiration date. On or about that date, a re-inspection of this facility will be conducted to assure that corrections meet FDA requirements. If significant corrections are not made the time of the next inspection, the facility will be reclassified as NON-APPROVED for carrier use.

Please advise this office within fifteen (15) days of the receipt of this letter the measures you have implemented to correct the violations. Your response should include a discussion of any delays you foresee in achieving correction, and a deadline by which correction can be expected.

Please direct your response to Carmelo Rosa, Acting Compliance Officer at the address listed above. Should you require any assistance in understanding the contents of this letter or if you desire a meeting with the agency staff Mr. Rosa can be reached by telephone at (787) 729-6894.

Sincerely,



Samuel Jones  
District Director

Enclosures:

Copy of form FDA-2521  
Copy of 21 CFR 1250

cc:

Mr. Francisco Pomal  
President  
Board of Directors