

FOOD & DRUG ADMINISTRATION
466 FERNANDEZ JUNCOS AVENUE
SAN JUAN, P.R. 00901-3223

May 12, 1997

WARNING LETTER
SJN-97-14CERTIFIED MAIL
RETURN RECEIPT REQUESTEDMr. Angel Luis Rosa
Supervisor of Operations
Puerto Rico Ports Authority
P.O. Box 362829
San Juan, PR 00936-2829

Dear Mr. Rosa:

During an inspection of ship watering points at Pier D, San Juan, Puerto Rico, conducted on May 6-8, 1997, our inspector found deficiencies which are considered violations of the Public Health Service Act and the Interstate Conveyance Sanitation Regulations; title 21, Code of Federal Regulations, 1240.83 (21 CFR 1240.83).

Observations included, but were not limited to, the following deviations:

1. There is no backflow prevention device on the water system at hydrants #'s 2, 3 or 4. This is a critical deviation.
2. The inner surface of the hydrant protective cap at hydrant #1 was not clean. The cap was missing at hydrant #2.
3. Drainage at hydrants #'s 1, 3, and 4 was inadequate. Dirty, standing water was observed on the uncleaned pier surface beneath those hydrants.
4. Water valve leaks were in evidence at hydrants #'s 1 and 3.
5. Keeper chains were noted to be in poor condition at hydrants #'s 1 and 4.

The Inspectional Observations, as listed on a Form FDA 483, were discussed with you. A copy of the FDA 483 is included for your review.

Mr. Angel Luis Rosa
May 12, 1997

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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 applicable requirement of the Public Health Service Act and applicable regulations.

As a result of these observations, the watering points at Pier D are classified "NOT APPROVED" for servicing interstate carriers. A re-inspection to verify accomplishment of corrective actions will be scheduled as soon as you notify this office in writing of their completion.

You should 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 action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, 466 Fernandez Juncos Avenue, Puerta de Tierra, San Juan, Puerto Rico 00901-3223, Attention: John M. McInnis, Compliance Officer.

If you require any assistance in understanding the contents of this letter, or if you desire a meeting with members of our staff, please contact Mr. McInnis, at (787) 729-6894.

A copy of this letter is being forwarded to the agent for any interstate carrier identified as being serviced at these watering points.

Sincerely,


Samuel Jones
District Director

Enclosure:

FDA Form 483 as noted

cc:

Dr. Hernan Sulsona
Director
Puerto Rico Ports Authority
P. O. Box 362829
San Juan, Puerto Rico 00936-2829

Mr. Angel Luis Rosa
May 12, 1997

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