



DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

94833d

One Montvale Avenue
Stoneham, Massachusetts 02180
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WARNING LETTER

NWE-27-04W

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

June 17, 2004

Craig Coy, CEO
Massachusetts Port Authority
One Harborside Drive
Suite 200S
East Boston, Massachusetts 02128

Dear Mr. Coy:

This letter serves as your formal notification that the U.S. Food and Drug Administration (FDA) has classified your vessel watering points located in the Black Falcon Cruise Terminal at One Black Falcon Avenue, Boston, Massachusetts, as "Provisional" for interstate carrier use.

On April 28-29, 2004 and May 5, 2004, an FDA investigator conducted an inspection of your vessel watering point. The inspection found that you have a serious deviation from the Interstate Conveyance Sanitation regulations (21 CFR 1240) issued under the authority of the Public Health Service Act. The deficiency is as follows:

- You must make provisions to prevent backflow from the vessel to the pier potable water system(s) to comply with 21 CFR 1240.86. However, the inspection revealed that none of the vessel potable watering points are equipped with backflow prevention devices.

As a result of this inspectional finding, the Black Falcon Cruise Terminal vessel watering point has been classified as "Provisional" for interstate carrier use for a period of thirty (30) days. "Provisional" classification means that watering points may continue to operate; however, significant corrections of the deficiency must be made within the designated time period. On or about that date, a re-inspection of your watering points will be conducted to assure corrections have been made and meet FDA requirements. This re-inspection will determine if your future classification will be "Approved" or "Not Approved." A "Not Approved" classification means that vessels are prohibited from using your watering points.

Please provide this office in writing, within fifteen (15) working days of receipt of this letter, a description of the actions you have taken to correct the deficiency and to assure that such deficiency will not recur. Your response should be directed to Food and Drug Administration, Attention: Bruce R. Ota, Compliance Officer, One Montvale Avenue, Stoneham, Massachusetts 02180. If you have questions regarding any issues in this letter, please contact Mr. Ota at (781) 596-7762.

Sincerely,



Gail D. Costello
District Director
New England District