



04-BLT-15

March 4, 2004

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. David M. Thomas  
Director of Operations  
Maryland Port Administration  
2310 Broening Highway  
Baltimore, Maryland 21224

Dear Mr. Thomas:

This letter serves as your formal notification that the U.S. Food and Drug Administration (FDA) has classified certain watering points at the Port of Baltimore as "Provisional."

On November 5-7, 10, 12, 17-19, and December 2, 2003, FDA inspected vessel watering points located at the Port of Baltimore. The inspection found that the facilities for delivery of water to conveyances and the sanitary conditions surrounding such delivery at the specified watering points are not sufficient to prevent the introduction, transmission, or spread of communicable diseases, as required for FDA approval under Title 21, Code of Federal Regulations (CFR), Part 1240.83(a), promulgated under the authority of the Public Health Service (PHS) Act.

The observations made during the inspection were provided to you on a Form FDA-483, Inspectional Observations and on a Form FDA-2521, Inspection Summary – Vessel Watering Point Sanitation Report, completed for each watering point inspected.

Critical deficiencies noted during the inspection of the vessel watering points included:

**Dundalk Marine Terminal**

1. A Reduced Pressure Zone (RPZ) principle backflow preventer, located in a manhole in area [REDACTED] was underwater/submerged.
2. Twenty six (26) of the [REDACTED] vessel watering points inspected, identified below, were in service and lacked adequate backflow prevention devices. Single check valves do not adequately prevent backflow and back-siphonage in high hazard plumbing installations.

- 13-A, 13-S, 13-C (center), 13-N
- 12-SC, 12-C, 12-N (Log #77)
- 11-SC
- 10-S, 10-N,
- 9-S, 9-N
- 8-S, 8-C, 8-N
- 7-S, 7-N
- 4-S (Log #26), 4-N (Log #23)
- 3-S (Log #20), 3-N (Log #17)
- 2-S (Log #14), 2-N (Log #11)
- 1-S (Log #8), 1-C (Log #6), 1-N

3. Twelve (12) of the vessel watering points in service, identified below, lacked proper identification.

- 13-A
- 12-N (Log #77)
- 7-N
- 4-S (Log #26), 4-N (Log #23)
- 3-S (Log #20), 3-N (Log #17)
- 2-S (Log #14), 2-N (Log #11)
- 1-S (Log #8), 1-C (Log #6), 1-N

#### Seagirt Terminal

The nine (9) vessel watering points inspected, identified below, were in service and lacked adequate backflow prevention devices. Single check valves do not adequately prevent backflow and back-siphonage in high hazard plumbing installations.

- 1-C, 1-N, 1-S
- 2-C, 2-N, 2-S
- 3-C, 3-N, 3-S

#### North Locust Point

1. Eight (8) of the vessel watering points inspected, identified below, were in service and lacked adequate backflow prevention devices. Single check valves do not adequately prevent backflow and back-siphonage in high hazard risk facilities.

- Pier 3 (#2), Pier 3 (#3)
- Pier 4 (#1-East side), Pier 4 (#2-East side), Pier 4 (#3-East side), Pier 4 (#4-East side)
- Pier 5 (#3-West side), Pier 5 (#4-West side)

2. The 8 vessel watering points in service lacked proper identification.

#### South Locust Point

1. Seven (7) of the ten vessel watering points inspected, identified below, were in service and lacked adequate backflow prevention devices. Single check valves do not adequately prevent backflow and back-siphonage in high hazard plumbing installations.
  - #1 (Berth 12, near Log#40)
  - #4 (near Berth 11, near Log #33)
  - #6 (Berth 10, near Log #27)
  - #7 (Berth 10, near Log #24)
  - #1 (Berth 9, Logs #16 & 17)
  - #2 (Berth 9, Log #11)
  - #3 (Berth 9, Light #4)
2. All 7 of the vessel watering points in service lacked proper identification.
3. The RPZ principle backflow prevention device, located at hot box #2 (Berth 10), was leaking through its atmospheric vent.

As a result of these inspectional findings, the above-listed Port of Baltimore vessel watering points, located at the Dundalk Marine Terminal, Seagirt Terminal, North Locust Point, and South Locust Point, have been classified as "Provisional." A "Provisional" classification means that you may continue to operate these vessel watering points; however, significant correction of the deficiencies must be made.

The above deficiencies are not intended to be an all-inclusive list of the deficiencies observed during the inspection of the Port of Baltimore vessel watering points. Several non-critical deficiencies were also cited on the Form FDA-483 and Form FDA-2521, issued to the Maryland Port Administration at the conclusion of the inspection. The non-critical deficiencies included: vessel watering points littered with trash and debris, lack of caps and keeper chains, lack of proper protective housing, lack of cut-off valve at hydrants, and hydrant outlets directed vertically.

It is your responsibility to ensure that the vessel watering points operated by the Maryland Port Administration are in compliance with all applicable requirements of 21 CFR Parts 1240 and 1250, the PHS Act, and the Federal Food, Drug, and Cosmetic Act. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action by FDA without further notice.

We request that you notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted deviations and to prevent their recurrence. Your response should include examples of documentation showing that corrections have been achieved. If corrective action can not be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed. A re-inspection of your vessel 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 "Use Prohibited". We note that interstate conveyances must obtain potable water for drinking and culinary purposes from watering points approved by the FDA (21 CFR 1240.80). Therefore, interstate conveyances would not be able to use the water points if they are classified as "Use Prohibited."

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Your reply should be directed to Ms. Vinetta Howard-King, Compliance Officer, U.S. Food and Drug Administration, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21215. If you have any questions, please do not hesitate to contact Ms. Howard-King at (410) 779-5454, extension 413.

Sincerely,



Lee Bowers  
Director, Baltimore District

Cc: Mr. William Grossman  
General Manager, Facility Operations  
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