DEPARTMENT OF HEALTH AND HUMAN SERVICES

94997d

Public Health Service
Food and Drug Administration
Central Region

New Jersey District
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Parsippany, NJ 07054

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WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

September 17, 2004

File # 04 -NWJ-19

Mr. Mark Phillips
Co-owner
Horizon Cruises LLC
1500 Harbor Blvd.
Weehawken, NJ 07087

Dear Mr. Phillips:

This letter serves as your formal notification that the U.S. Food and Drug Administration (FDA) has classified the food service facility on your vessel, *The Horizon*, as "Provisional" for interstate carrier use.

On June 16 & 18, 2004, The Food and Drug Administration (FDA) conducted an inspection of the food service operation on board your vessel, *The Horizon*. The inspection revealed that your facility is in violation of FDA's Interstate Conveyance Sanitation regulations, Title 21, Code of Federal Regulations, Part 1250 (21 CFR 1250), issued under the authority of the Public Health Service Act (42 U.S.C. § 264), and the Good Manufacturing Practice regulations (21 CFR 110).

At the conclusion of the inspection, our investigators provided your Director of Operations, Michael Pierro, with a List of Inspectional Observations (FDA Form 483) and a Food Service Establishment Inspection Report (FDA Form 2420). Their findings were also discussed with Mr. Pierro at that time. Upon further review, we find the following serious deviations from the interstate conveyance sanitation regulations:

- All perishable food or drink must be kept at or below 50 °F, except when being prepared or kept hot for serving, to comply with 21 CFR 1250.27. However, potentially hazardous foods that could support the rapid growth of microorganisms of public health significance were not held and stored in such a manner as to minimize the potential growth of microorganisms. For example, our investigators observed that grilled chicken, chicken fingers and riblets (some of which were prepared on the day prior to the inspection) were stored in your [redacted] reach-in refrigerator at temperatures ranging from 54 ^{0}F to 61 ^{0}F. Additionally, the ambient air temperature in this refrigeration unit was observed to have reached as high as 60 ^{0}F during the course of the inspection.

- All multiuse eating and drinking utensils shall be thoroughly cleaned in warm water and subjected to an effective bactericidal treatment after each use, to comply with 21 CFR 1250.33. However, the equipment and procedures used for both the mechanical and manual sanitization of soiled dishware and utensils were inadequate to ensure effective sanitization. For example, sanitizer concentrations in the mechanical dishwasher were measured at < 50 PPM. FDA recommends a minimum sanitizer concentration of at least 150 PPM to ensure an effective sanitization process with sufficient lethality to microorganisms of public health significance. Similarly, the dispenser used to meter and supply sanitizer to your three-compartment sink was not operating properly. This dispenser supplied a sanitizer concentration of < 100 PPM, which was not adequate to ensure that an effective sanitization process was administered to the foodservice equipment and utensils commonly washed in this sink. Our investigators further noted that your firm did not have sanitizer strength test strips available on-site, so no measurements of sanitizer strength were taken by your firm to verify the adequacy of your sanitizer solutions.

- You must ensure that there is no backflow or cross connection between potable water systems and any other systems, to comply with 21 CFR 1250.82(e). However, your firm failed to provide a backflow prevention device on the faucet of the three-compartment sink, where a garden hose with spray nozzle was attached.

- You must identify, hold, and store toxic cleaning compounds and sanitizing agents in a manner that protects against the potential cross-contamination of food, food-contact surfaces, or food-packaging materials, to comply with 21 CFR 110.35(b). However, our investigators observed an unlabeled spray bottle of sanitizer in the dishwashing area. Additionally, two aerosol cans of stainless steel cleaner/polish were observed stored in contact with coffee and teabags.

- All food-handling operations must be conducted in a manner that minimizes the possibility of contaminating food, drink, or utensils, to comply with 21 CFR 1250.32(a).However, wiping cloths were observed stored atop food preparation tables when not in use and were not stored in a sanitizing or bactericidal solution. Similarly, cooking implements and utensils used during the food preparation process were observed stored in a container of water at room temperature which contained no sanitizer or bactericidal solution. These practices allow for microbial growth on items which could subsequently be a source of contamination if allowed to come into contact with food or food preparation surfaces.

The above-listed observations are not intended to be an all-inclusive list of deviations from the regulations. You are responsible for ensuring that your facility is in compliance with the law. You also have a responsibility to use procedures to prevent further violations of all applicable FDA regulations.

The deficiencies found on your vessel could contribute to the spread of communicable diseases. Based on our inspectional findings, we are classifying the food service facility on your vessel as "Provisional" for interstate conveyance use for a period of thirty (30) days. A "Provisional" classification means that the facility may continue to operate; however, significant corrections of violations must be completed within that timeframe. On or about that date, a re-inspection of this facility will be conducted to assure that all corrections meet FDA requirements. If significant corrections are not implemented by the time of the next inspection, this facility may be reclassified as "Use-Prohibited." Assignment of "Use-Prohibited" status for food service facilities means that food and beverages from this facility may not be used until the violations have been corrected and the facility has been re-inspected by FDA.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. Your response should include an explanation of each step being taken to correct the violation, and prevent a reoccurrence. You may wish to include in your response documentation concerning procedures you have implemented or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when the corrections will be completed.

Your response to this letter should be directed to the U.S. Food and Drug Administration, Attention: Richard D. Manney, Compliance Officer at the address and telephone number listed above.

If you have questions regarding any issue in this letter, please contact Mr. Manney directly.

Sincerely,

Diana Amador-Toro for

Douglas I. Ellsworth
District Director
New Jersey District