



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

*m3893n*

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Food and Drug Administration  
Waterview Corporate Center  
10 Waterview Blvd., 3rd Floor  
Parsippany, NJ 07054

WARNING LETTER

**Via Telefax**  
**Original via Certified Mail**  
**Return Receipt Requested**

File # 00-NWJ-43

June 28, 2000

Michael E. Harkins  
President  
Delaware River and Bay Authority  
I-295 @ Delaware Memorial Bridge  
New Castle, DE 19720

Dear Mr. Harkins:

The Food and Drug Administration (FDA) conducted inspections of two motor vessels of the Cape May Lewes Ferry fleet during June 12-14, 2000. The vessels inspected were the MV *Twin Capes* and the MV *Cape May*. During those inspections, our investigators collected evidence of violations of the Public Health Service Act [Section 361], the Food, Drug and Cosmetic Act [Section 402(a)(4)], and Title 21 -- Code of Federal Regulations [Sections 110, 1240 and 1250].

The violations included:

1. Potentially hazardous food is not prepared, stored, displayed or serviced at required temperatures.\* Potentially hazardous food is defined as food of plant or animal origin requiring temperature control because it is in a form that will support rapid growth of infectious or toxigenic microorganisms. Potentially hazardous food must be held either at <41°F for chilled foods or >140°F for hot foods. Our investigators took internal temperatures of foods prepared, stored or held for service onboard and found the following temperatures:

Chef salad with ham -- 57°F (twice)  
Chef salad with turkey -- 56°F and 57°F  
Chef salad with hard-cooked eggs -- 53°F and 56°F  
Half-n-half -- 43°F and 47°F  
Hot dogs -- 132°F  
Uncooked sausage patties -- 50°F and 63°F  
Pork roll -- 52°F

Hard-cooked eggs -- 43°F  
Crumbled bleu cheese -- 42°F  
Cream cheese -- 46°F  
Roast beef/turkey/ham deli meats -- 47°F/50°F/56°F, respectively  
Pepper/Swiss/provolone deli sliced cheeses -- 52°F/51°F/52°F, respectively  
Hamburgers/cheeseburgers -- 128°F/105°F, respectively

Many of these improper temperatures were caused by equipment that was either faulty or incapable of holding product at adequate temperatures. This includes refrigerators and heat lamps. Also, partially cooked chicken patties were not reheated to proper temperatures prior to serving. In addition, food was not chilled within acceptable times following cooking. Meatballs and sausage & peppers were not cooled to <41°F within two hours of preparation. Both products displayed temperatures in excess of 41°F, including meatballs prepared the day before the inspection.

2. Plumbing systems in use are inadequate, in that equipment fails to ensure no backflow of waste water occurs, thereby contaminating potable water supplies.\* No backflow devices were present on high pressure hoses that use potable water. Drain hoses for soda dispensers were observed to be submerged in waste water.
3. Employees working in direct contact with food or food-contact surfaces were observed to use poor or inadequate hygienic practices.\* Food preparation employees did not change gloves when handling different food items or non-food items. Employees not wearing gloves did not wash their hands when soiled. Employees did not have adequate hair restraints and wore jewelry. Supervisory personnel present to monitor food-preparation employees did not detect the above practices and, upon questioning, were unaware of the sanitary significance of proper hygienic practices.
4. The facilities used in preparing and holding food demonstrated insanitary or dangerous conditions.\* Toxic industrial cleaners were stored adjacent to food-contact surfaces, including cups, forks, spoons, napkins, aluminum foil, and deli tissues. Flies were observed in the food preparation area of the Cape May.
5. Food-contact surfaces (including utensils and equipment) displayed rusting, soil residues or buildup. Other food-contact utensils were improperly stored in between uses, contributing to potential bacterial growth or cross-contamination.
6. Refrigeration equipment is not operated at a sufficiently low temperature to maintain proper food refrigeration temperatures ( $\leq 41^{\circ}\text{F}$ ) and to compensate for temperature rises due to frequent access. Reach-in refrigerators did not contain temperature-indicating devices. Also, the door to the *Cape May's* forward bar refrigerator does not seal properly upon closing. In addition, refrigeration equipment has not been calibrated to assure accurate temperatures.
7. Your firm had no sanitizer strips or other means to determine or monitor the concentration of sanitizer solutions used to sanitize utensils, equipment or food-contact surfaces. Our

investigators found wash water used to clean equipment had a temperature of 100°F. The acceptable temperature is  $\geq 110^{\circ}\text{F}$ .

8. Your employees placed a pan over the unprotected tops of raw sausage patties. The bottom of that pan, when placed on a food contact surface, could thereby cross contaminate that surface and any food prepared or stored on that surface.
9. Single-service storage containers were re-used to store other products not originally contained in such containers.
10. Your employees reheated a customer's unwrapped, half-eaten sandwich. That sandwich was not prepared onboard by any of your facilities.
11. Non-food contact surfaces were observed to be unclean. These included the walls and floors in eating areas, utensil holders, ice bins, soda dispenser nozzles and drain covers.

Asterisked items (\*) indicate critical conditions where, if violations are present, they would significantly contribute to the potential of foodborne illness.

The seriousness of these deficiencies would normally require FDA to classify your food preparation operation as Use-Prohibited. However, due to the apparent adequacy and promptness of your corrective actions, as documented in the information provided to this office by Chief Operating Officer Jeffery Lewis, your food preparation operation is classified as *"Provisional Status."*

It is your responsibility as an interstate conveyance to ensure that your operations are not in violation of the law. The violations specified in this letter may not include all deficiencies present with your vessel or land commissaries.

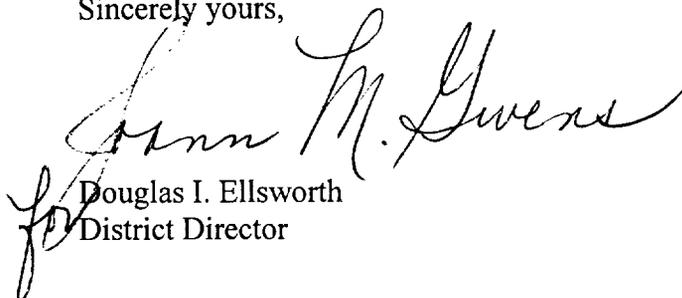
You have 30 days to correct the above violations, as well as any other violations you have knowledge of. Corrections should include the installation of equipment and adoption of procedures for your entire fleet to prevent future violations. If you fail to perform these corrections within the time allotted, FDA may execute serious regulatory actions, which can include:

- Classification of your operation as *"Use-Prohibited,"* where we will notify conveyances of your violations and deny their use of your facilities, or
- Permanent injunction of operations.

You should notify this office in writing within 15 working days from receipt of this letter of any and all corrections previously unreported to us. You may direct your reply to the attention of: Kirk D. Sooter, Compliance Officer, U.S. Food and Drug Administration, 10 Waterview Boulevard, Third Floor, Parsippany, New Jersey 07054.

We are enclosing for your benefit FDA's Guide to Inspections of Interstate Carriers and Support Facilities. Please pay particular attention to the Catering Point/Commissary section (page 19 of the guide).

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Douglas I. Ellsworth". The signature is written in black ink and is positioned above the printed name and title.

Douglas I. Ellsworth  
District Director

Enclosure