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San Francisco District  
1431 Harbor Bay Parkway  
Alameda, CA 94502-7070  
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

Our Reference: 3001237452

March 8, 2004

Ms. Sandra R. Freeman, Partner  
Mr. Timothy M. Cass, Partner  
Cassandra LLC  
344 – 20<sup>th</sup> Street, Suite 35  
Oakland, California 94612

**WARNING LETTER**

Dear Ms. Freeman and Mr. Cass:

On February 9, 2004, FDA conducted an inspection of your facility, located at 344 – 20<sup>th</sup> Street, Suite 35, Oakland, California, which provides meal services to several chartered jet airlines. The observations made during the inspection revealed that your facility is in violation of Section 361 of the Public Health Service Act, the Interstate Conveyance Sanitation regulations at Title 21, Code of Federal Regulations, Part 1250 (21 CFR § 1250), and the Good Manufacturing Practice regulations at 21 CFR § 110. FDA's observations were listed on Form FDA 483, List of Inspectional Observations, a copy of which was provided to and discussed with Ms. Freeman at the conclusion of the inspection. A copy of the Form FDA 483 is enclosed for your reference.

During the inspection, the following observations were noted:

1. Your firm failed to accomplish all food-handling operations so as to minimize the possibility of contaminating food, drink, or utensils (21 CFR § 1250.32(a)).
2. Your firm failed to have personnel responsible for identifying sanitation failures or food contamination who have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food (21 CFR § 110.10(c)).
3. Your firm failed to hold foods that can support the rapid growth of undesirable microorganisms in a manner that prevents the food from becoming adulterated within the meaning of the Act. Compliance with this requirement may be accomplished by any effective means, including maintaining hot foods at 140°F or above (21 CFR § 110.80(b)(3)). Specifically,

- A container of noodles that was six inches deep was nested in another container of noodles creating a mass of food 12 inches deep. The temperature of the noodles was 58°F after six hours.
  - Chicken was left on top of the fryer two hours after cooking. The temperature of the chicken was 101°F.
  - The temperature of cooked beans for burritos was at 117°F while being held for hot delivery to an airline.
  - The internal temperature of a cooked roast was at 75°F more than two hours after cooking.
4. Your firm failed to protect raw materials and other ingredients to ascertain that they are stored under conditions that will protect against contamination (21 CFR § 110.80(a)). Specifically,
- Uncovered raw chicken was stored on a shelf next to cooked noodles, cheeses, beef, and shrimp mix.
  - Foods in the walk-in refrigerator were not covered.
5. Your firm failed to clean food-contact surfaces, including utensils and food-contact surfaces of equipment, as frequently as necessary to protect against contamination of food (21 CFR § 110.35(d)). Specifically, the food contact surfaces of the cutting block, [REDACTED] meat slicer, ice machine, knives, and cutting boards were all contaminated with food residue and grease.
6. Your firm failed to have personnel conform to hygienic practices to protect against contamination of food (21 CFR § 110.10(b)). Specifically,
- FDA observed no hand-washing by any employee during the entire inspection.
  - FDA observed an employee handling soiled equipment, cleaning materials, and boxes and then, handling cooked food.
  - FDA observed a dish room employee scrape dirty dishes and then, without washing his hands, remove clean dishes from the dish machine.
  - FDA observed employees consuming coffee while cooking food.
  - FDA observed an employee touch his nose with his hand and then handle cooked broccoli.
  - FDA observed employees handling ready-to-eat food with their bare hands.
7. Your firm failed to identify, hold, and store toxic cleaning compounds and sanitizing agents in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials (21 CFR § 110.35(b)(2)). Specifically, FDA observed spray bottles of cleaning chemicals stored without labels.
8. Your firm failed to clean non food-contact surfaces of equipment used in the operation of your food-processing facility (21 CFR § 110.35(d)(3)). Specifically, FDA observed an ice-cream scoop stored on the dirty top of the ice machine.

9. Your firm failed to properly maintain equipment (21 CFR § 110.40(a)). Specifically, the inside of the ice machine door lacks a gasket and is broken and cracked.
10. Your firm failed to store single-service containers in a manner that protects against contamination of food or food-contact surfaces (21 CFR § 110.35(d)(4)). Specifically, FDA observed single-service food containers stored uncovered in contact with un-sanitized surfaces.
11. Your firm failed to properly maintain all plant equipment to protect food and food-contact surfaces (21 CFR § 110.40(a)). Specifically, the garbage grinder was removed in the food production area, resulting in the sewage pipe being left open and uncapped.
12. Your firm failed to provide backflow prevention on the spray nozzle of your hose when the hose is placed in a bucket or below the flood rim of the sink (21 CFR § 110.37(b)(5)).
13. Your firm failed to maintain the floor of the walk-in refrigerator in a sanitary condition (21 CFR § 110.35(a)). Specifically, FDA observed puddles of raw meat juices on the floor of the walk-in refrigerator.
14. Your firm failed to keep the walls of your facility in good repair (21 CFR § 110.20(b)(4)). Specifically, FDA observed holes in the walls throughout the facility.

The list of inspectional observations, identified above, is not intended to be an all-inclusive list of the conditions observed at your facility. It is your responsibility to assure adherence with all applicable statutes and regulations enforced by FDA.

Based on the inspectional findings, we are classifying your facility as "Provisional" for interstate carrier use for a period of thirty days. A "Provisional" classification means that the facility may continue to operate; however, significant correction of violations must be made by the expiration date. On or about that date, a re-inspection of this facility will be conducted to assure that corrections meet FDA requirements. If significant corrections are not made by the time of the next inspection, this facility will be reclassified as "Not Approved" for carrier use. Assignment of "Not Approved" status for food service facilities means that food and beverages from this facility may not be used by interstate conveyances until the violations have been corrected and the facility has been re-inspected by FDA.

You should notify this office in writing, within fifteen working days of the receipt of this letter, of the specific steps that you have taken to prevent a recurrence of the cited deficiencies. Your response should include an explanation of each step being taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 30 days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made. Your response should be directed to:

Randall P. Zielinski, CSO/ITS  
U.S. Food and Drug Administration  
1431 Harbor Bay Parkway  
Alameda, CA 94502-7070

You may wish to fax your response to Mr. Zielinski at (510) 337-6703.

Sincerely,



Celeste M. Corcoran  
Acting District Director  
San Francisco District

Enclosure: Form FDA 483