



Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Andrew Axelrod, CEO
Love and Quiches, Ltd.
178 Hanse Avenue
Freeport, NY 11520

July 20, 2004

Ref: NYK-2004-22

Dear Mr. Axelrod:

On May 6 and 10, 2004, the Food and Drug Administration (FDA) conducted an inspection of your facility, located at 178 Hanse Avenue, Freeport, NY, which provides bakery products to airlines and airline caterers. The observations made during the inspection revealed that your facility is in violation of Current Good Manufacturing Practice (CGMP) regulations in manufacturing, packing, or holding human food, which are set forth at Title 21, Code of Federal Regulations, Part 110 (21 C.F.R. Part 110). In addition, the inspection revealed that your facility is in violation of Section 361 of the Public Health Service Act and the Interstate Conveyance Sanitation regulations, which are set forth at 21 C.F.R. Part 1250.

At the conclusion of the inspection, Investigator Ortiz-Latinsky presented you with the Inspectional Observations (Form FDA 483) and the Food Establishment Inspection Report (copies enclosed), and discussed the findings with you. The deficiencies of concern were as follows:

1. The failure to provide a device that would prevent backflow from or cross-contamination between piping systems, as required by 21 C.F.R. §§110.37(b)(5) and 1250.30(d). The inspection specifically observed that your facility did not have a backflow prevention device on the main water line and on the Straham hoses in the pots and pans washing area and dishwashing area.
2. The failure to provide adequate, convenient hand-washing facilities with running water at a suitable temperature, as required by 21 C.F.R. §§110.37(e) and 1250.38. The inspections specifically observed:
 - No hand-washing station at the melting oven area, cake decorating area, pots and pans washing area, sample packaging area, and the scaling area.
 - The hand-washing station was not accessible in the pre-baking production area; there was a cart and a bucket blocking it.

- No hot water at the automatic hand-washing stations in the pre-baking production area and no hot water in the women's toilet room.
3. The failure to have safe and adequate sanitizing agents that routinely render equipment and utensils clean and provide sufficient cleaning and sanitizing treatment, as required by 21 C.F.R. §§110.35(d)(5) and 1250.33. The inspection specifically observed:
 - The chlorine sanitizer at 0 ppm at the pots and pans washing area and 10 ppm at the icing/pots and pans washing area. Chlorine sanitizer should read between 50 to 100 ppm.
 - The quaternary ammonia sanitizer at the icing/pots and pans washing area was 300ppm. Quaternary ammonia sanitizer should read 200 ppm.
 - Equipment and utensils were not being washed with detergent at the pots and pans washing area. All equipment and utensils are to be washed, rinsed and sanitized in that order to prevent contamination.
 4. The failure to maintain food that support rapid growth of undesirable microorganisms in a manner that prevents the food from becoming adulterated, as required by 21 C.F.R. §§ 110.80(b)(3) and 1250.27. The inspection specifically observed that pasteurized eggs were left sitting out during the employee lunch break. The investigator tested the eggs and found them at a temperature of 53 degrees Fahrenheit. The eggs should be held under refrigeration during employee breaks.
 5. The failure to have a water supply sufficient for the operations intended, and the failure to have running water at a suitable temperature, and under pressure as needed, as required by 21 C.F.R. §§ 110.37(a) and 1250.30(c). The inspection specifically observed:
 - The water flow pressure in the dishwashing machine was found to be 35 psi. It should have been between 15 and 25 psi:
 - The final rinse gauge for the dishwashing machine was observed at 120 degrees Fahrenheit. It should have been 180 degrees Fahrenheit.
 - The wash temperature gauge of the dishwashing machine was inoperable.
 - The dishwashing machine was not provided with an ips valve.

The list of inspectional observations identified above is not intended to be an all-inclusive list of 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. 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. An assignment of "Not

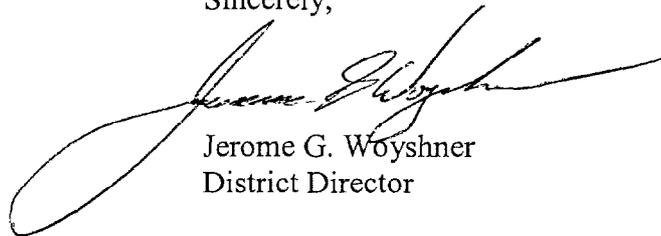
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Approved" status for food service facilities means that food and beverages from this facility may not be used by interstate conveyances until the violations have been corrected and the facility has been re-inspected by FDA.

You should notify this office in writing within 15 working days of the receipt of this letter. In your written response to FDA, you should outline the specific steps that you have taken to prevent a recurrence of the cited deficiencies. If corrective action cannot be completed within the 15 days, state the reason for the delay and the date by which the corrections will be completed. Also, please include copies of any available documentation that corrections have been made.

Your response should be sent to the attention of: Bruce A. Goldwitz, Compliance Officer, Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, NY 11433. If you have any questions, you can call Mr. Goldwitz at (718) 340-7000, ext. 5582.

Sincerely,

A handwritten signature in black ink, appearing to read "Jerome G. Woyshner", with a large, sweeping flourish extending to the left.

Jerome G. Woyshner
District Director

Enclosures: Form FDA 483 and Food Establishment Inspection Report dated May 6 and 10, 2004.