



DEPARTMENT OF HEALTH & HUMAN SERVICES

**Public Health Service
Food and Drug Administration**

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

VIA FEDERAL EXPRESS

April 4, 2000

Our Reference Number: 2940077

Michael Z. Kay, President and Chief Executive Officer
Sky Chefs/ Lufthansa, Inc.
524 E. La Mar Boulevard
Arlington, TX 76011
(817) 792-2164

WARNING LETTER

Dear Mr. Kay:

On February 25, 2000, FDA Investigator Janice Lathan conducted an inspection of your catering facility located at 1085 Bible Way, Reno, Nevada 89502, which provides food and beverage services for private aircraft at Reno/Tahoe International Airport. Your operations at this site are in serious violation of the federal regulations for good manufacturing practices (GMP's) which are established in Title 21, Code of Federal Regulations, Part 110 (21 CFR 110), Part 1250 (21 CFR 1250), and Section 361 of the Public Health Service Act. FDA Investigator Lathan's observations were listed on Form FDA 483, Inspectional Observations, and discussed with Mr. David W. Williams, General Manager, at the conclusion of the inspection.

The lack of adequate food protection was demonstrated by the following deficiencies:

1. The cooked jasmine rice was not properly cooled down within a four-hour time period.
2. Bags of frozen shrimp and a box of vegetable soup were found thawing at room temperature.
3. Employees prepared and touched food after touching soiled unsanitized equipment surfaces or personal items and without washing their hands.

4. The chemical concentrations of iodine at four sanitizer stations were measured and found too low to adequately sanitize the utensils and equipment.
5. The surfaces of the mixer-blender, meat slicer, and can opener all had a build-up of old food residues.
6. The food cart shelves in the food preparation area and the refrigerator racks had a build-up of old food residues.
7. Clean utensils were stored on top of soiled pan-liner sheets in the food preparation area.
8. Three 50-gallon trashcans in the food preparation area were overfilled with garbage, and garbage was spilling onto the floor. Trash was not disposed of on a regular schedule.
9. The ground surfaces under both the trash compactor and the container holding soda cans for recycling had a strong foul odor. The ground surface in the loading dock area had a pool of standing murky water and a build-up of trash and garbage.
10. The floor drains in the food preparation area were clogged with old food residue. The floor areas throughout the facility and along the walls were not clean, i.e., areas around the dish washer, food preparation, and refrigerator. The floors in the three refrigerators were cracked, soiled with food debris, and worn from deterioration and disrepair.
11. Two brooms and a wet mop were stored against the wall in the food preparation area. Another broom was stored against the rack near the dish-washing room.

These insanitary conditions and practices are likely to result in adulteration of foods within the meaning of Sections 402(a)(3) and 402(a)(4) of the Food, Drug and Cosmetic Act (the Act). Adulteration of food while held for sale after shipment in interstate commerce is prohibited by Section 301(k) of the Act. The delivery or causing the delivery of adulterated foods into interstate commerce is prohibited by Section 301(a) of the Act.

As mentioned above, the findings were discussed with Mr. David W. Williams, General Manager, at the conclusion of the inspection. Copies of the Form FDA 483, Inspectional Observations, and Form FDA 2420, Food Service Establishment Inspection Report, were issued to Mr. Williams and are being provided to you for your information.

Based on these findings, your operation has been assessed a rating score of 75%, as indicated on Form FDA 2420, and given a "Provisional" classification. A classification of "Provisional" means that if the deficiencies are not corrected within thirty (30) working days from the receipt of this notification, your facility will be placed on "Not Approved" status. A "Not Approved" status means that food and beverages will be

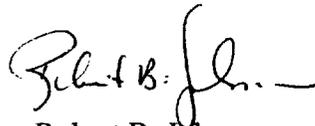
prohibited from use by interstate conveyances until the violations have been corrected and the facility has been reinspected by FDA. A rating score of at least 85% must be maintained at the time of reinspection or your facility will be placed on "Not Approved" status.

You should take prompt action to correct these deficiencies. Failure to do so may result in appropriate regulatory action, such as seizure and/or injunction without further notice. You should notify this office within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the violations, including an explanation of preventive measures taken to preclude recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, cite the reason for the delay and the time by which the corrections will be completed. Your response should be sent 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,



Robert B. Johnson
Acting District Director
San Francisco District

Enclosures:

Form FDA 483, Inspection Observations, dated 2/25/00
Form FDA 2420, Food Service Establishment Inspection Report, dated 2/25/00

Cc:

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