



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

91364d

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

Via Federal Express

Our ref: 2956447

June 4, 2001

Renee Medina, Owner and President
Lucky Tours
1111 Mission Street
San Francisco, CA 94103

WARNING LETTER

Dear Mr. Medina:

On May 22 and 23, 2001, Food and Drug Administration Investigator Lorna F. Jones conducted an inspection of your bus watering point and waste service area located at 355 Selby Street, San Francisco. Your operations at this site are in serious violation of the federal regulations for interstate conveyance sanitation, found in Title 21, Code of Federal Regulations Part 1250 (21 CFR 1250), and section 361 of the Public Health Service Act. As a result of these inspectional findings, this facility has been classified as "Provisional."

The investigator observed the lack of back-flow prevention device on the potable water line. The hose connected to the potable water line is attached to chemicals used for cleaning the buses.

This letter is not intended to be an all-inclusive list of deficiencies at your facility, and it is your responsibility to ensure adherence to each requirement of the regulations. You should assure that all Lucky Tours facilities are in compliance with the regulations.

At the conclusion of the inspection, Investigator Jones issued Form FDA 483, Inspectional Observations, to Walt Pietila, mechanic, and discussed it with him. On May 31, Investigator Jones discussed these findings with Phyllis C. Reyes and Ned Masetti, supervisors, by telephone. A copy of the FDA 483 is enclosed for your information.

Failure to take prompt corrective action may result in appropriate regulatory action, such as 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 Suzanne Schenck, Compliance Officer, at the above address.

Sincerely yours,



Dennis K. Linsley
Director, San Francisco District

Enclosures: FDA-483

cc: Phyllis C Reyes, Supervisor
Lucky Tours