

5/14/98



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

7752M

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94102-7070
Telephone: 510-337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

April 23, 1998

Our Reference No.: 29-52642

Kazu Hayashida, Director
State Department of Transportation
869 Punchbowl Street
Honolulu, Hawaii 96813

WARNING LETTER

Dear Mr. Hayashida:

On April 7, 1998 FDA Investigator Randall P. Zielinski conducted an inspection of the watering point and service area where lavatory carts are emptied at Kona International Airport in Kailua-Kona, Hawaii. Your operations at this site are in serious violation of the federal regulations for interstate conveyance sanitation, Part 1250 (21 CFR 1250), and Section 361 of the Public Health Service Act. Observations made by FDA Investigator Zielinski were listed on the FDA 483, Inspectional Observations, and discussed with Mr. Myron Shimamoto, Supervisor, at the conclusion of the inspection.

Lack of adequate protection for the drinking water supply at the airport was evidenced by the lack of a testable backflow prevention device on the potable water fill line used by the airlines to fill their potable water carts; the potable water fill hose is exposed to contamination in its outdoor location because it lacks a cabinet to enclose the hose and nozzle; toilet paper was observed on the ground adjacent to the potable water hose line; the area where the toilet paper was observed is a loose volcanic rock pad which can't be properly hosed down for cleaning and doesn't drain to a sanitary sewer; the sewer cover used for dumping of lavatory wastes was surrounded by toilet paper and blue water spillage and lacks facilities to properly clean the area and dispose of the waste water.

These conditions are likely to result in contamination of drinking water and could lead to a serious disease outbreak on aircraft serviced at this airport.

The findings were discussed with Mr. Myron Shimamoto at the conclusion of the inspection, and copies of the FDA 483, Inspectional Observations, were provided to him. A copy of the FDA 483 is being provided to you for your information.

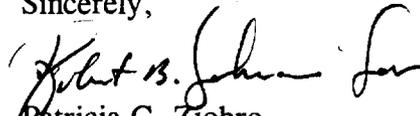
Based on these findings, your facility has been classified "Provisional". A Provisional classification means that if the deficiencies are not corrected within thirty (30) working days from the receipt of this notification, your facility will be placed on "Not Approved" status. A "Not Approved" status means that potable water and lavatory service facilities will be prohibited from use by interstate conveyances at the Kona International airport.

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 the receipt of this letter of the specific steps you have taken to correct the violations. If corrective action cannot be completed within thirty (30) 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

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

Sincerely,



Patricia C. Ziobro
District Director
San Francisco District

Enclosure: FDA 483

cc: Mr. Frank Kamahele, Manager
Kona International Airport
P.O. Box 1660
Kailua-Kona, HI 96745