



DEPARTMENT OF HEALTH & HUMAN SERVICES

g1821d

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

WARNING LETTER
2002-DT-05

October 12, 2001

Mr. Richard Anderson, CEO
Northwest Airlines, Inc.
5101 Northwest Drive
St. Paul, Minnesota 55111

Dear Mr. Anderson:

On September 26-27, 2001, FDA investigator LTJG Carolyn J. Oyster inspected your aircraft support facilities at the Detroit Metropolitan Airport. As an operator of interstate aircraft conveyances, you are subject to the provisions of the Public Health Service Act Section 361(a) (42 USC 264), and Title 21 Code of Federal Regulations Parts 1240 (Control of Communicable Disease) and 1250 (Interstate Conveyance Sanitation).

During the inspection, the FDA investigator observed shortcomings in your system that are deviations from interstate conveyance sanitation and the significant requirements of the Interstate Travel Program (watering points). The FDA investigator presented your firm with a form FDA-483 that provides the investigator's evaluation of your firm's performance regarding various aspects of Interstate Conveyance Sanitation and Control of Communicable Disease requirements for watering points. These deviations cause your products to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) because of the following:

1. You must have all servicing area piping systems, taps, faucets, hoses, and other appurtenances necessary for delivery of the drinking and culinary water to a conveyance be designed, constructed, maintained and operated in such a manner as to prevent contamination of the water in accordance with 21 CFR 1240.83(a)(2) and 1250.67(a). However, your firm failed to have a backflow preventer within a close proximity to 2 of 7 potable water closets that are used to transport potable water from the airport to Northwest aircraft. Your F-9 and F-12 potable water closets' backflow preventers were over 130 feet from the closets.

Your firm failed to maintain clean and sanitary potable water stations in 7 of 7 water closets (F-2, F-9, F-12, F-14, C-24, D-15 and D-4 water room) and in 1 of 1 water trucks inspected. For example:

- a. 7 of 7 inspected hoses used to provide potable water to the aircraft did not have a protective end cap on the hose or a connected keeper chain.
- b. Your water truck 44724, license #DTW-8103, was driving in the rain through splashing groundwater with no protective end cap on the potable water exit which was less than 3 feet from the ground, directly behind the 2 back wheels, nor was there a keeper chain. In addition, the truck's 2 fill valve were opened to the sky with no protective cover or keeper chain.
- c. F-Terminal (2, 9, 12, 14) potable water mechanical mechanisms on the hose wheel were observed to have a brown-colored, non-food-grade grease on them and were less than 6 inches from open potable water hoses.
- d. F-Terminal (12) potable water hose was observed to have duct tape on it to keep it from leaking water. FDA does not recognize duct tape as an easily cleanable surface.
- e. F-Terminal (14) was observed to have a leaking packing nut valve as well as a highly dented front cover that does not allow proper closure.

The above objectionable conditions were pointed out and explained to Mr. Thomas P. Neylon, Jr. who was the most responsible person on-site at the time of the FDA inspection. The above-identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations. Because of the insanitary conditions that were observed by FDA Investigator LTJG Oyster, your potable water facilities and equipment are now classified as **PROVISIONAL**.

A reinspection will be conducted to determine if the objectionable conditions have been corrected. If the reinspection reveals adequate corrections have not been made, your facility will be reclassified as **NOT APPROVED**. **NOT APPROVED** potable water facilities cannot be used by an interstate aircraft conveyance company. Airline companies engaged in interstate commerce may obtain potable water only from facilities approved by the U.S. Food and Drug Administration.

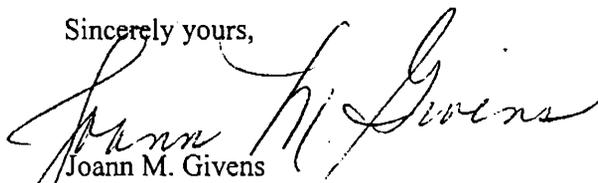
We request that you take prompt action to correct this situation. Failure to do so may result in further enforcement action. Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their occurrence. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Also, please include copies of any available documentation demonstrating that corrections have been made.

Mr. Richard Anderson, CEO
Northwest Airlines, Inc.

October 12, 2001
Page 3

Your reply should be sent to the attention of Mr. David M. Kaszubski, Director
Compliance Branch, U.S. Food and Drug Administration, 1560 East Jefferson Avenue,
Detroit, Michigan 48207.

Sincerely yours,



Joann M. Givens
District Director
Detroit District

CC: Mr. Robert E. Ball, Station Master/Vice President
Northwest Airlines, Inc.
Detroit Metro Airport
Detroit, MI 48242