



June 2, 2003

WARNING LETTER
SJN-03-11

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Lazaro Canto
Owner
Professional Aircraft Services
Luis Muñoz Marín Airport
P. O. Box 362829
Carolina, Puerto Rico 00937

Dear Mr. Canto:

On April 4 and April 7, 2003 an inspector of the US Food and Drug Administration (FDA) conducted an inspection of your ramp services mobile potable water tank unit located at Luis Muñoz Marín International Airport, Carolina, PR, (airport), that provides potable water to [REDACTED]. The inspector documented deviations that show your facility is in violation of the Interstate Conveyance Sanitation regulations at Title 21, Code of Federal Regulations Part 1250 (21 CFR 1250), and the Control of Communicable Diseases regulations Part 1240 (21 CFR 1240), which were promulgated pursuant to the Public Health Service Act 42 U.S.C. section 264(a). These deviations cause your potable water to be adulterated within the meaning of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). The inspector's observations were listed on Form FDA 483, List of Inspectional Observations, a copy of which was provided to, and discussed with, you at the conclusion of the inspection.

The deviations reported on the potable water mobile tank (mobile tank) were as follows:

1. The water inlet line that feeds to the mobile tank is not adequately designed in that a piece of garden hose with an attached piece of copper pipe (nozzle) was used. The nozzle of the water inlet line was not equipped with a protective cap nor any similar device to protect it from becoming contaminated by insects or other pests, or coming in contact with filth (21 CFR 1240.83 & 1250.67).
2. The mobile tank unit's overflow system, consisting of a 90 ° drainage pipe was not equipped with a protective cap nor any similar device to protect it from becoming contaminated by insects or other pests, or coming in contact with filth (21 CFR 1240.83 & 1250.67).

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3. A water leak was observed from a potable water pipe connected to the water pump located at the hose storage cabinet. Stagnant water was observed on the cabinet floor. The hose nozzle that is used to delivery the potable water to the aircraft was not equipped with a protective cap nor any similar device to prevent it from coming in contact with the floor or other foreign material; therefore, exposing the water contact surface to potential contamination with filth, insects and other pests (21 CFR 1240.83 & 1250.67).
4. There was no evidence to show that the mobile tank, hoses, and auxiliary devices used to deliver the portable water are cleaned and sanitized regularly (21 CFR 1240.83 & 1250.67).
5. The mobile tank was not identified with a sign reading "Potable Water" to differentiate it from the mobile waste tanks (21 CFR 1240.83 & 1250.67).

Based on the inspectional findings, we are classifying your facility as "Provisional" for interstate carrier use for a period of thirty (30) days. A "Provisional" classification means that the facility may continue to operate; however, significant correction of violations must be made by the expiration date. On or about that date, a reinspection of this facility will be conducted to assure that corrections meet FDA requirements.

The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your facilities comply with all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action may include seizure and/or injunction.

Please notify this office in writing; within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be directed to: Food and Drug Administration, Attention: Mr. Andres Toro, Acting Director of Compliance Branch, at 466 Fernandez Juncos Avenue, San Juan, P.R. 00901-3223. If you have questions regarding any issue in this letter, please contact Mr. Jose F. Pedró, Acting Compliance Officer at 787-474-9550.

Sincerely,


Donald J. Voeller
District Director