

Public Health Service Food and Drug Administration	
	Cincinnati District Office Central Region 6751 Steger Drive Cincinnati, OH 45237-3097 Telephone: (513) 679-2700 FAX: (513) 679-2775

March 24, 2016

WARNING LETTER

CIN-16-488024-12

Via United Parcel Service

Neil B. Gallagher, President
Winner Aviation Corp.
1453 Youngstown Kingsville Rd NE
Vienna, OH 44473

Dear Mr. Gallagher:

This letter serves as your formal notification that the U.S. Food and Drug Administration (FDA) has changed the classification of your watering point and aircraft servicing area located at 1453 Youngstown Kingsville Rd NE Vienna, OH 44473 from "Approved" to "Provisional" for interstate carrier use.

On December 18, 2015, the FDA conducted an inspection of your commissary, aircraft servicing area and watering point at your fixed base operation located at the aforementioned address. This inspection was conducted under the authority of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to determine your compliance with the applicable sections of the Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food (CGMP) regulations (21 CFR Part 110) and under the authority of the Public Health Service Act (PHS Act) to determine your compliance with applicable sections of the Interstate Conveyance Sanitation regulations (21 CFR Part 1250), in accordance with 21 CFR Part 1240. The Interstate Conveyance Sanitation regulations were

promulgated pursuant to Section 361 of the PHS Act (42 U.S.C. 264). Regulations promulgated under this section are necessary to prevent the introduction, transmission, or spread of communicable diseases.

At the conclusion of the inspection, the FDA investigator issued a list of Inspectional Observations to your firm; a copy of the FORM FDA 483 is enclosed. To date, we have not received a response to the inspectional observations from the firm. As documented on the Form FDA-483, the following are the significant violations under 21 CFR Part 1250, on which we base the "Provisional" classification:

1. To comply with 21 CFR 1250.67(a), all servicing area piping systems, hydrants, taps, faucets, hoses, buckets, and other appurtenances necessary for delivery of drinking and culinary water to a conveyance must be designed, constructed, maintained, and operated in such a manner as to prevent contamination of the water. However, the back flow prevention (BFP) device in place on the potable water point does not provide adequate protection because the BFP on the general purpose hose downstream from the potable water point is not intended for continuous pressure situations in which it is being used in your facility.

2. To comply with 21 CFR 1250.63, servicing areas must be provided with all necessary sanitary facilities so operated and maintained as to prevent the spread of communicable diseases. However, your sewage disposal site is constructed of gravel and is not graded towards the drain to ensure the adequate sanitary disposal of toilet wastes.

3. To comply with 21 CFR 1250.75(b), servicing areas must be free from contamination of stations/airports by human wastes and connections to sanitary sewers. During the inspection, it was noted that your facility does not flush out the lavatory cart after dumping. Failure to flush out the cart/drain could allow excess sewage waste to drip onto areas that could lead to possible cross-contamination of ice and water. The accumulation of waste in the lavatory service cart could attract flies, which could transmit disease. The cart should be flushed out after each use to avoid waste accumulation in the cart.

4. To comply with 21 CFR 1250.33(a), adequate facilities must be provided for the cleaning and bactericidal treatment of all multiuse eating and drinking utensils and equipment used in the preparation of food and beverages. You do not have any designated equipment to properly sanitize the ice scoop used to bag ice that is distributed to the aircraft. Although this observation was made on a previous inspection, you are still using the hand sink in the employee break room to clean the ice scoop.

Based on these inspectional findings, a "Provisional" classification has been assigned to your watering point and aircraft servicing area located at the Youngstown-Warren Regional Airport in Vienna, OH for a 30-day period, after which time a re-inspection will be conducted. A "Provisional" classification means that the watering point and aircraft servicing area may continue to operate;

however, significant corrections of the observed violations must be made. If significant correction is not made by the time of the next inspection, FDA will reclassify the watering point and aircraft servicing area as "Non-Approved" for carrier use. We note that land and air conveyances engaged in interstate travel must obtain potable water for drinking and culinary purposes from watering points approved by FDA (21 CFR 1240.80) and must use servicing areas that have been approved by FDA (21 CFR 1250.60).

Furthermore, during our inspection, an FDA investigator documented a violation of the CGMP regulation for foods. This violation causes the ice handled in your facility to be adulterated within the meaning of Section 402(a)(4) [21 U.S.C. § 342(a)(4)] of the FD&C Act, in that it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth or rendered injurious to health. Specifically, your firm failed to maintain equipment, containers and utensils used to convey, hold, and store ice in a manner that protects against contamination, as required by 21 CFR 110.80(b)(7). During the inspection, our investigators observed apparent rust and mineral deposits on food contact areas inside the ice bin to the firm's floor mounted ice machine, which may contribute to contamination of the ice.

(b)(4)

Please notify this office in writing within fifteen (15) working days from your receipt of this letter of the specific steps you have taken to correct the violations described above. Include in your response documentation to show correction has been achieved. If you cannot complete all corrections before you respond, state the reason for the delay and when you will complete the corrections. Your response should be sent to Allison C. Hunter, Compliance Officer at the address noted in the letterhead.

If you have any questions with regard to this letter, please contact Allison C. Hunter, Compliance Officer, at (513)679-2700 X 2134 or allison.hunter@fda.hhs.gov.

Sincerely,

/S/

Steven B. Barber

Cincinnati District Director

cc:

John Moliterno, Executive Director

Western Reserve Port Authority

240 North Champion Street

Youngstown, OH 44503

Maurice J. Gallagher, Jr., Chairman/CEO

Allegiant Travel Company

8360 S. Durango Drive
Las Vegas, Nevada 89113

Bryan Bedford, Chairman, President and Chief Executive Officer

Republic Airways Holdings
8909 Purdue Road, Suite 300
Indianapolis, IN 46268