

Public Health Service Food and Drug Administration	
	Seattle District Pacific Region 22215 26 th Avenue SE, Suite 210 Bothell, WA 98021-4425 Telephone: 425-302-0340 FAX: 425-302-0402

May 13, 2016

OVERNIGHT DELIVERY

SIGNATURE REQUIRED

In reply refer to Warning Letter SEA 16-11

Bradley D. Tilden

Chairman and Chief Executive Officer

Horizon Air Industries, Inc.

19251 International Boulevard

Seattle, Washington 98188

WARNING LETTER

Dear Mr. Tilden:

On December 10 and 17, 2015, January 6 and 8, 2016, and February 11 and 19, 2016, the U.S. Food and Drug Administration (FDA) conducted an inspection of your watering point, commissary, and lavatory servicing facilities, and four of your passenger aircraft located at Seattle-Tacoma Airport, 17801 International Boulevard, Seattle, Washington, 98158. Your passenger aircraft operate in interstate traffic between Washington, Idaho, Montana, Oregon, California, and Canada. This comprehensive inspection was conducted 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 Code of Federal Regulations, Part 1250 (21 CFR 1250). These 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, on January 8, 2016, the FDA investigator issued a list of Inspectional Observations (FDA-483) to your firm. We acknowledge your written responses, dated January 28, 2016 and March 7, 2016. We also met with you, per your request, on March 24, 2016. Corrective actions appear to have adequately addressed the inspectional observations, except for one, which we discuss below. As documented on the Form FDA 483, the following significant violation under 21 CFR Part 1250 was noted on your aircraft.

1. To comply with 21 CFR 1250.38, toilet and lavatory facilities of suitable design and construction shall be provided for use of food-handling employees, and hand washing facilities must include soap, sanitary towels, and hot and cold running water, or warm water in lieu of hot and cold running water. However, on December 10 and 17, 2015, our investigators observed that each aircraft boarded was equipped with one lavatory, and each lavatory was constructed without hand-wash sinks. You confirmed that your firm has a fleet of 52 Q400 aircraft in your fleet, which are all constructed without hand-wash sinks in the lavatories. Toilet facilities without accompanying proper hand-washing facilities available on aircraft for use by food service personnel can increase the potential spread of communicable disease.

Your response is not adequate because you continue to provide beverage service on certain aircraft that does not have the hand-washing facilities required under 21 CFR 1250.38. Directing your employees to wash their hands in the airport between flights or to use hand sanitizer does not meet the requirements for suitable lavatory facilities for food-handling employees. We recommend that you discontinue the use of ice and serve only food and beverages that are in closed containers.

The violation cited in this letter is not intended to be an all-inclusive list of violations that exist at your facility. You should take prompt action to correct the violation noted in this letter. We remind you that it is your responsibility to assure adherence with all requirements of the regulations at this facility, and any other facilities involving interstate travel and sanitation under your control.

We may take further action if you do not promptly correct this violation. It is your responsibility to ensure that all requirements of the PHS Act, the Federal Food, Drug, and Cosmetic Act, and their implementing regulations, are being met.

In addition to the violation described above, we have the following comment. Our investigator noted that there were no certificates of sanitary construction posted on your aircraft. If certificates of sanitary construction have been issued by FDA for your aircraft, they must be prominently posted on the aircraft to comply with 21 CFR 1240.20.

You should respond in writing within fifteen (15) working days of receiving this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include each step that has been

taken or will be taken to correct the violations and prevent their recurrence. You should also include in your response any documentation or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, you should explain the reason for your delay and state when you will correct any remaining violations.

Please send your response to the U.S. Food and Drug Administration, Seattle District, 22215 26th Avenue SE, Suite 210, Bothell, Washington, 98021-4421, to the attention of LCDR Cynthia White, Compliance Officer. If you have any questions regarding this letter, please contact LCDR White at (425) 302-0422.

Sincerely,

/S/

Miriam R. Burbach

District Director

cc: Bradley D. Tilden

Chairman and Chief Executive Officer

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