



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-30977
Telephone: (513) 679-2700
FAX: (513) 679-2761

March 15, 2004

WARNING LETTER
CIN-04-20535

Via Federal Express

Charles Thomas Miller
Executive Director
Louisville Regional Airport Authority
101 South 5th Street, Suite 1800
Louisville, KY 40202

Dear Mr. Miller:

This letter serves as your formal notification that the U.S. Food and Drug Administration (FDA) has classified your aircraft servicing facility located at Louisville International Airport, Standiford Field, as "Provisional" for interstate carrier use.

On December 1 and 2, 2003, FDA conducted an inspection of the servicing facility, including your waste disposal site. The inspection found that you have serious deviations from the Interstate Conveyance Sanitation regulations (21 CFR 1250) issued under the authority of the Public Health Service Act. Specifically, the servicing facility is not operated and maintained so as to prevent the spread of communicable disease as required by 21 CFR 1250.63. The inspection revealed the following deficiencies:

1. Spilled waste from lavatory trucks and carts was found on the concrete ramp and grated drain leading into the waste disposal site. (Also observed during the previous inspection).
2. Lavatory waste and pooled water failed to drain properly. On December 1, 2003, the investigator observed an attempt to clean up the site. During the cleaning, the drain became clogged and waste overflowed out of the waste disposal site.
3. A flexible water hose used to wash the site was found lying on the ground near the waste spillage and was not capped.
4. The waste disposal site overhead door was not kept closed to keep out pests when not in use.
5. The disposal site's inner floor and lower walls are not constructed of impervious materials to permit adequate cleaning of spilled lavatory wastes.
6. The site is poorly designed for containing spilled waste and wash water. The site is not properly sloped or curbed, and is in poor repair with cracks and crevices.
7. The site itself is not being frequently cleaned and maintained. Hot water or steam is not available to enhance cleaning efforts.

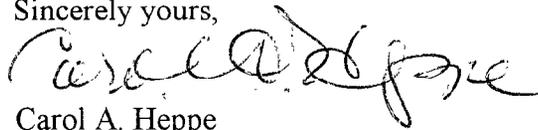
The above objectionable conditions were pointed out and explained to Jonna Upson, Director of Maintenance. A written list of objectionable conditions was issued to Ms. Upson immediately after the inspection.

The deficiencies found at your facility could contribute to the spread of communicable diseases. Based on the inspectional findings, we are classifying your servicing facility as "Provisional" for interstate carrier use. A "Provisional" classification means that the facility may continue to operate; however, correction of deficiencies must be made by the time the facility is re-inspected. If significant corrections are not made by the time of the next inspection, the facility will be reclassified as "Not Approved" for carrier use. A classification of "Not Approved" prohibits the use of your water and waste disposal services by interstate conveyances until the violations have been corrected and the facility has been re-inspected by FDA.

Please advise us in writing within fifteen (15) working days of the receipt of this letter of the actions you have taken to address these deficiencies. Your response should include an explanation of each step being taken to correct the deficiencies and prevent their recurrence.

Your reply should be directed to the attention of Deborah Grelle, Director of Compliance, U.S. Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237 (513) 679-2700 extension 160.

Sincerely yours,



Carol A. Heppe
District Director

Copy:

Mr. Richard L. Pratte
Deputy Executive Director
Louisville Regional Airport Authority
101 South 5th Street, Ste. 1800
Louisville, KY 40202-3108

Ms. Jonna C. Upson
Director of Maintenance
Louisville Regional Airport Authority
4320 Park Boulevard
Louisville, KY 40209