

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER

FDA Kansas District Office
8050 Marshall Drive, Suite 205
Lenexa, KS 66214
913-495-5100

Industry Information: www.fda.gov/oc/industry

DATE(S) OF INSPECTION

7/31/2017, 8/1/2017, 8/8/2017, and
8/14/2017.

FEI NUMBER

3013446837

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Jay R. Bryant-Wimp, Pharmacist in Charge

FIRM NAME

Accurate Rx Pharmacy Consulting, LLC dba Accurate Rx Pharm

STREET ADDRESS

103 Corporate Lake Drive, Suite B

CITY, STATE AND ZIP CODE

Columbia, MO 65203-7290

TYPE OF ESTABLISHMENT INSPECTED

Producer of sterile drugs

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

Observation 1:

Your ISO 5 classified workstation where sterile product are prepared is located within a non-classified room.

Specifically,

A. Your (b) (4) "compounding aseptic (b) (4)" is not located in a controlled environment/ room in order to prevent the risk of contamination. On 7/31/2017, during the production of saline water bags, the (b) (4) was observed to be equipped with (b) (4) and is therefore not completely enclosed to the environment. Additionally, (b) (4) is not used every day and it is turned off when it is not in use. (b) (4) for cleaning and disinfection.

B. The ISO 5 classified area is in close proximity to the sink and no barriers exists between the sink and the "compounding aseptic (b) (4)" to prevent risk of contamination.

SEE
REVERSE
OF THIS
PAGE

EMPLOYEE(S) SIGNATURE



EMPLOYEE(S) NAME AND TITLE (Print or Type)

Veronica Fuentes, Investigator

DATE ISSUED

8/15/2017