DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Cincinnati District 6751 Steger Drive Cincinnati, OH 45237 (513) 679-2700 Industry Information: www.fda.gov/oc/industry	07/17/17 - 07/24/17
	FEI NUMBER 3005664940

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Matthew J. Buderer, Vice President

FIRM NAME	STREET ADDRESS
Buderer Drug Company, Inc.	26611 North Dixie Highway, Suite 119
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Perrysburg, OH 43551	Producer of Sterile Drug Products

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:

1) Your firm released drug product in which the strength differs from, or its purity or quality falls below, that which it purports or is represented to possess. Specifically, tiny white particulates were seen in retained sample vials from all batches of Sodium Tetradecyl Sulfate, Straight Chain 3% 30ml Vascular Injection MDV produced to date. No investigation was performed to determine the cause of these failures.

2) Personnel donned gowning apparel improperly, in a way that may have caused the gowning apparel to become contaminated and were observed with exposed skin during aseptic processing. The gowns worn by the technician producing sterile drug products are non-sterile, including the sleeves that actually enter the ISO 5 area and the gowns are removed, (b) (4) ISO 8 area, and then re-used throughout the day.

3) Pressure differentials between areas with different air classifications were not monitored prior to or during sterile drug production. Specifically, there is a gap in the doors on both sides of the pass-through between the ISO 7 cleanroom and the supporting unclassified prep area that allows palpable airflow between the areas.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Jazmine Still	Matthew Casale, Investigator Jazmine Still, Investigator	07/24/2017