DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6751 Steger Drive Cincinnati, OH 45237-3097 (513)679-2700 Fax:(513)679-2772	12/14/2015-1/4/2016* FEI NUMBER 3005664940

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Matthew J. Buderer , Vice President

FIRM NAME	STREET ADDRESS
Buderer Drug Company Inc	26611 Dixie Hwy, Suite 119
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Perrysburg, OH 43551-1765	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 OBSERVED:

OBSERVATION 1

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

Specifically, during aseptic production of human chorionic gonadotropin, (b) (4) [redacted] of the ISO 5 compounding area and (b) (4) [redacted]

OBSERVATION 2

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

Surface, viable air, non-viable air, and personnel monitoring for the ISO 5 area used to produce sterile drug products is not performed at least daily.

OBSERVATION 3

Equipment and utensils are not maintained and sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Matthew B Casale, Investigator	X Matthew B Casale Matthew B Casale Investigator Signed by: Matthew B. Casale -5	1/4/2016

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6751 Steger Drive Cincinnati, OH 45237-3097 (513)679-2700 Fax:(513)679-2772	12/14/2015-1/4/2016*
	FEI NUMBER 3005664940

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Matthew J. Buderer , Vice President

FIRM NAME	STREET ADDRESS
Buderer Drug Company Inc	26611 Dixie Hwy, Suite 119
CITY, STATE, ZIP CODE, COUNTRY Perrysburg, OH 43551-1765	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drug Products

There is no data to support the storage of depyrogenated glassware used in the production of parenteral products in the unclassified (b) (4) area for up to (b) (4) .

OBSERVATION 4

Approved components are not retested or reexamined as appropriate for identity, strength, quality and purity after storage for long periods with subsequent approval or rejection by the quality control unit.

Specifically,

There is no data to support the three month expiration date assigned to (b) (4) used in the production of sterile drug products, including products intended for intrathecal administration.

OBSERVATION 5

Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.

Specifically,

Sterility and endotoxin testing is not performed on each batch of sterile drug product produced, including drug products intended for intrathecal administration.

***DATES OF INSPECTION**

12/14/2015(Mon),12/15/2015(Tue),12/16/2015(Wed),12/18/2015(Fri),12/28/2015(Mon),12/29/2015(Tue),1/04/2016(Mon)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Matthew B Casale, Investigator ☐ Invalid signature X Matthew B Casale Matthew B Casale Investigator Signed by: Matthew B. Casale -5	1/4/2016