DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Dr., Suite 205 Lenexa, KS 66214 (913) 495-5100	10/23/2017-11/16/2017* FEI NUMBER 1972829

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kristina N. Bryowsky, Director of Pharmacy

FIRM NAME	STREET ADDRESS
SSM Health Care St. Louis dba SSM St. Clare Health Center	1015 Bowles Avenue
CITY, STATE, ZIP CODE, COUNTRY Fenton, MO 63026	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

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

Investigations of an unexplained discrepancy did not extend to other batches of the same drug product.

Specifically, the scope of your initial investigation performed on 7/28/2017 for the (b) (4) process media fill failure did not extend to all sterile drug products produced via this process. Norepinephrine 8mg in 250mL of D5W bag is produced via the (b) (4) process. You only assessed Norepinephrine batches made post 7/12/2017. Some examples of Norepinephrine batches produced prior to 7/12/17 include:

Lot#	Date Produced	Expiration Date
170703-017	7/3/2017	10/1/2017
170628-001	6/28/2017	9/26/2017
170614-007	6/14/2017	9/12/2017
170606-006	6/6/2017	9/4/2017
170530-001	5/30/2017	8/28/2017

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Tiara N Brown-Crosen, Investigator	DATE ISSUED 11/16/2017

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Dr., Suite 205 Lenexa, KS 66214 (913) 495-5100	10/23/2017-11/16/2017* FEI NUMBER 1972829
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Kristina N. Bryowsky, Director of Pharmacy	
FIRM NAME	STREET ADDRESS
SSM Health Care St. Louis dba SSM St. Clare Health Center	1015 Bowles Avenue
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fenton, MO 63026	Outsourcing Facility

OBSERVATION 2

Buildings used in the manufacture, processing, packing or holding of drug products are not maintained in a clean and sanitary condition.

Specifically, on 10/24/2017 during the production of Phenylephrine HCl 1000 mcg in 0.9% Sodium Chloride 10 mL syringe Lot# 171024-014, I observed reddish-orange discoloration throughout (b) (4) (b) (4) ISO 5 LAFHs. In addition, a gray substance was observed behind the HEPA filter frame in the (b) (4) ISO 5 LAFH.

OBSERVATION 3

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

Specifically, the firm's monitoring program for the ISO 5 hood in the IV room used to produce sterile drug products such as Phenylephrine HCl 1000 mcg in 0.9% Sodium Chloride 10mL Lot# 171024-014 and Morphine Sulfate 50mg in 0.9% Sodium Chloride 50mL Lot#171002-006 does not include:

a. At least daily environmental monitoring for active viable air in the ISO 5 area during production. You only monitor viable air counts in-house with a settling plate during production. Active viable air monitoring is only conducted every (b) (4) by a contract service provider.
b. At least daily surface monitoring of the work surface inside the ISO 5 LAFH during periods of production or at the end of operations. Surface monitoring is only performed (b) (4)
c. Routine monitoring of personnel gowns during operations. Personnel gloved fingertip monitoring is only performed.
d. Established alert and action limits for personnel gloved fingertips and settling plates.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Tiara N Brown-Crosen, Investigator		DATE ISSUED 11/16/2017

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Dr., Suite 205 Lenexa, KS 66214 (913) 495-5100	10/23/2017-11/16/2017* FEI NUMBER 1972829
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Kristina N. Bryowsky, Director of Pharmacy	
FIRM NAME	STREET ADDRESS
SSM Health Care St. Louis dba SSM St. Clare Health Center	1015 Bowles Avenue
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fenton, MO 63026	Outsourcing Facility

This is a Repeat Observation from FDA inspection ending on 8/14/2014.

OBSERVATION 4

Results of stability testing are not used in determining expiration dates.

Specifically, you released 8 lots of Nicardipine 25mg in 250mL of NS from (b) (4) to (b) (4) without sufficient stability data to support the beyond use date (BUD) of 90 days. The following lots of Nicardipine 25mg in 250mL of NS were released:

Lot #	Date Produced	Expiration Date	Date Released
151007-4356	(b) (4)		
151029-4528			
151103-4553			
151110-4614			
151217-4947			
151230-5093			
160114-5292			
160126-5509			

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Tiara N Brown-Crosen, Investigator		DATE ISSUED 11/16/2017

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Dr., Suite 205 Lenexa, KS 66214 (913) 495-5100	10/23/2017-11/16/2017*
	FEI NUMBER 1972829

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kristina N. Bryowsky, Director of Pharmacy

FIRM NAME	STREET ADDRESS
SSM Health Care St. Louis dba SSM St. Clare Health Center	1015 Bowles Avenue
CITY, STATE, ZIP CODE, COUNTRY Fenton, MO 63026	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

OBSERVATION 5

Aseptic processing areas are deficient regarding systems for maintaining equipment used to control the aseptic conditions.

Specifically, on 10/24/2017 during the production of Phenylephrine HCl 1000 mcg in 0.9% Sodium Chloride 10 mL syringe Lot# 171024-014, I observed yellow and red vinyl type tape on the work surfaces inside the (b) (4) ISO 5 LAFHs, respectively. This does not appear easily cleanable or sanitizable. Furthermore, there are no procedures for changing of, cleaning or sanitizing of this vinyl type tape.

OBSERVATION 6

Procedures describing in sufficient detail the controls employed for the issuance of labeling are not written.

Specifically, you do not have a written procedure that explains the receipt, identification, storage, handling, sampling, and examination of finished product labels for sterile drug products such as Phenylephrine HCl 1000 mcg in 0.9% Sodium Chloride 10mL Lot# 171024-014 and Morphine Sulfate 50mg in 0.9% Sodium Chloride 50mL Lot# 171002-006.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Tiara N Brown-Crosen, Investigator	x	DATE ISSUED 11/16/2017