DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115 Industry Information: www.fda.gov/oc/industry	7/31/2017-8/15/2017* **FEI NUMBER** 3013444075

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Jan R. Gerber, Owner/ President & CEO

FIRM NAME	STREET ADDRESS
Custom RX, LLC	3510 N Ridge Rd, Suite 900
CITY, STATE AND ZIP CODE	**TYPE OF ESTABLISHMENT INSPECTED**
Wichita, KS 67205-1224	Producer of Sterile and Non-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
You failed to prevent contamination while working in the aseptic production area (ISO 5 hood).

Specifically,

A) On 08/02/2017, I observed an aseptic operator produce sterile Magnesium Chloride Hexahydrate (PF), 5ml vial 200 mg/ml injectable. During production, I notice the operator spray his gloves with sterile (b) (4) over open vials. The open vials contained finished sterile drug product.

B) Your media fills are not representative of your aseptic production operations. The media fills conducted aseptically (b) (4). Specifically, your firm produces sterile drug products using bulk drug substances with volume sizes of up to (b) (4) ml. For example:
- On 06/29/2017, you produced (b) (4) ml of Ascorbic Acid (PF, Corn Free) 500 mg/ml injectable. The product was filled in 50ml vials with lot number 06292017@6. You produced a total of (b) (4)

OBSERVATION 2
you failed to adequately clean or disinfect the ISO 5 hood and equipment used in production.

Specifically,

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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Rita Kabaso	Rita K. Kabaso, Investigator	08/15/2017

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A) Smoke studies utilizing (b) (4) base smoke were conducted in the ISO 5 hood on 12/20/2016 and 06/26/2017. Upon completion of smoke studies, there is no documentation indicating the production area was cleaned to remove smoke residue. The following sterile drug products were produced after the completion of the smoke study re-certification in the ISO 5 hood:

- On 12/20/2016 – Acetylcysteine ophthalmic 10% solution lot 12202016@41 and Acetylcysteine ophthalmic 20% solution lot 12/20/2016@42.
- On 06/26/2017 – Trimix 30/1/0.02 mg/ml injectable lot 06262017@25.

B) On 7/30/2017, during the sterile facility tour, I noticed a bottle of '(b) (4) ', a commercialized liquid detergent used for dishwashing. The liquid dishwashing soap was witnessed on the sink in the Ante Room (ISO 8 room). Your firm's management informed me the soap was used to wash glassware to be used in the sterile hood.

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	Ritakabaso	Rita K. Kabaso, Investigator	08/15/2017