DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661	2/27/2017-3/17/2017* FEI NUMBER 3010840309

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Gary L, Hanley, O.D. , Chief Executive Officer

FIRM NAME	STREET ADDRESS
SterRx	141 Idaho Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Plattsburgh, NY 12903-3987	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 WE OBSERVED:

OBSERVATION 1

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

Specifically,

a) You do not monitor the air quality for non-viable particles within the critical fill zone (ISO 5 environment) during Blow Fill Seal production operations for the sterile ophthalmic drug production of 1% Cyclopentolate HCl, 1% Tropicamide, and 2.5% Phenylephrine HCl.

b) You have not certified at the point of use the (b) (4) during Blow Fill Seal production operations for the sterile ophthalmic drug production of 1% Cyclopentolate HCl, 1% Tropicamide, and 2.5% Phenylephrine HCl.

c) The surfaces within the critical fill zone (ISO 5 environment) are not sampled as part of your environmental monitoring program.

d) You do not perform any monitoring of personnel engaged in Blow Fill Seal manufacturing operations of sterile ophthalmic drug products.

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Chad N Thompson, Investigator Rachael A Moliver, Investigator 3/17/2017 X Chad N Thompson Chad N Thompson Investigator Signed by: Chad N. Thompson - S	3/17/2017

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a) Validation of the product (b) (4), as conducted in the (b) (4) for the (b) (4) dated: 2/16/17, is inadequate because:

1) The firm did not evaluate which product is the worst-case representative product for the (b) (4) validation. No analysis or rationale as to why or how the firm determined to use (b) (4) as the worst-case representative product versus (b) (4) is provided in the report.

2) Evaluation of the (b) (4) using (b) (4) did not include the firm's standard practice of (b) (4) ((b) (4)). Rather, the firm (b) (4) without evaluating its effect when exposed to the compounded product.

b) Media fills did not represent the most challenging conditions, specifically, the duration of the manufacturing run.

OBSERVATION 3

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the equipment to produce aseptic conditions.

Specifically,

a. Cleaning validation is inadequate and fails to demonstrate that the (b) (4) cleaning material can effectively be recovered from surfaces of the firm's equipment. Inconsistent recovery results, not meeting the acceptance criteria, were observed among (b) (4) different analysts conducting (b) (4) in the Final Summary Report (b) (4) Results; Protocol for (b) (4) of (b) (4) (b) (4).

i. The results of this study fail to satisfy the requirements of Protocol (b) (4) (b) (4) Studies of (b) (4) ((b) (4) which requires (b) (4) (b) (4) (b) (4) as (b) (4) achieved results that satisfy the acceptance criteria.

ii. CAPA (b) (4) (opened on 2/16/17, due 4/28/17) was initiated to observe and determine if there are differences in (b) (4)

b. The current practice for the frequency for cleaning (b) (4) is (b) (4) however, SOP PRD305, entitled "CLEANING AND MAINTAINING (b) (4) ," Version: A, Effective Date: 08 Dec 2015, calls for (b) (4) (Section 1.1 and Section 3.1).

OBSERVATION 4

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

Specifically, the raw data was not available for Research & Development (b) (4) completed to (b) (4) of (b) (4) for the ophthalmic drug products: 1% Cyclopentolate HCl, 1% Tropicamide, and 2.5% Phenylephrine HCl.

OBSERVATION 5

The labels of your outsourcing facility's drug products are deficient.

Specifically, the following information is not found on some of your drug product labels:

a) The statements "This is a compounded drug" and "Office use only";
b) The address and phone number of your facility;
c) The date that the drug was compounded;
d) Storage and handling instructions;
e) The national drug code number, if available.

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Examples of drug products that do not contain this information:

- Cyclopentolate HCl 1% 0.5 ml-Printed Label for Vial
- Phenylephrine HCL 2.5% 0.5 ml- Printed Label for Vial
- Tropicamide 1% 0.5 ml- Printed Label for Vial

***DATES OF INSPECTION**

2/27/2017(Mon),2/28/2017(Tue),3/01/2017(Wed),3/02/2017(Thu),3/03/2017(Fri),3/06/2017(Mon),3/07/2017(Tue),3/08/2017(Wed),3/17/2017(Fri)

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