DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse, Rm 900 2nd & Chestnut St Philadelphia, PA 19106 (215) 597-4390 Fax:(215) 597-0875 Industry Information: www.fda.gov/oc/industry	08/31/2015 - 10/02/2015* FEI NUMBER 3006101483

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Ms. Brenda L. Pavlic, Owner/Director of Sterile Operations

FIRM NAME	STREET ADDRESS
SaveWay Compounding Pharmacy, Inc.	31 Albe Drive Suite 1
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Newark, DE 19702-1360	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 the system for monitoring environmental conditions.

Specifically, routine/daily environmental or personnel monitoring is not done during sterile compound operations. This includes personnel, surface, and air monitoring. Monitoring is only performed (b) (4) (b) (4) approximately every (b) (4) months. There is no assurance or data to support that an aseptic environment exists during routine/daily sterile compounding operations. Also, the curtain that separates the ISO class 7 buffer-room (b) (4)) from the ISO class 7 ante-room has never been evaluated for microbial contamination and is not part of the firm's environmental monitoring program. There is no written procedure that describes or requires the routine cleaning and sanitization of this curtain.

Additionally, there is no assurance positive pressure differential is maintained between the ISO Class 7 ante/buffer room zone, which (b) (4) used for sterile compounding, and the adjacent unclassified segregated compound set-up room. In that, room pressure is not monitored in the segregated compounding room.

OBSERVATION 2

Clothing of personnel engaged in the processing of drug products is not appropriate for the duties they perform.

Specifically, the cleanroom gowns are not appropriate for aseptic processing. They are porous, thin, see-through, and easily torn. There is no assurance that these cleanroom gowns are sterile. The gowns are (b) (4) prior to use, but there was no data to show the (b) (4) used by the firm actually sterilizes the gowns. The firm's gowning procedures do not include a hood or goggles, so there is exposed skin on the neck and face during aseptic processing. Also, the facemasks that are used by the firm, are not sterile.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Paul L. Bellamy, Investigator Paul L. Bellamy	10/02/2015

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CITY, STATE, ZIP CODE, COUNTRY Newark, DE 19702-1360	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drug Products

OBSERVATION 3

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

Specifically, media fill simulations performed by the firm do not represent worst-case conditions. There is no requirement that media simulations be performed after compounding operations/steps or with maximum personnel in the cleanroom.

OBSERVATION 4

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established.

Specifically, the smoke studies that were conducted as part of the (b) (4) Cleanroom Certification by (b) (4) for the ISO class 7 buffer-room did not evaluate air-flow patterns during dynamic conditions, only static conditions. There was no data or study to show that air-flow patterns were adequate when personnel was in the buffer-room or when the ISO Class 5 Hood was in use.

OBSERVATION 5

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

Specifically, the firm's (b) (4) sanitization procedures for the cleanrooms do not specify contact times for disinfectants and sporicidal agents. So there is no assurance adequate surface contact times are used during routine cleanings. Also, the (b) (4) that are used during sanitization are not labeled as sterile.

OBSERVATION 6

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically, the firm does not have sterility data to support the "beyond use dates" of the following preservative-free sterile preparations: Dexamethasone Ophthalmic Solution and Methylcobalamin Injection. These preparations are given a "beyond use dates" of 180 days for Dexamethasone and 120 days Methylcobalamin.

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OBSERVATION 7

Written records are not made of investigations into the failure of a batch or any of its components to meet specifications.

Specifically, there was no written investigation into OOS Potency results that were obtained for Dexamethasone lot 20111006@17 and Methylcobalamin lots 20141205@7 and 20141704@1 preparations. These preparations were not distributed, but there was no investigation that evaluated or determined the cause of the OOS results or proposed corrective and preventative actions.

*** DATES OF INSPECTION:**
08/31/2015(Mon), 09/01/2015(Tue), 09/02/2015(Wed), 09/03/2015(Thu), 09/04/2015(Fri), 09/11/2015(Fri), 09/23/2015(Wed), 10/01/2015(Thu), 10/02/2015(Fri)

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