

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER US Customhouse Rm900 2nd & Chestnut St Philadelphia, PA 19106 (215) 597-4390 Ext:4200 Fax:(215) 597-0875	DATE(S) OF INSPECTION 6/13/2017-6/29/2017*
	FEI NUMBER 3006101483

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Pradeep Chilakapati , Staff Pharmacist

FIRM NAME SaveWay Compounding Pharmacy, Inc.	STREET ADDRESS 31 Albe Drive Suite 1
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CITY, STATE, ZIP CODE, COUNTRY Newark, DE 19702-1360	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drug Products
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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, pressure differentials between the (b) (4) Room^{(b) (4)} ISO 7) and (b) (4) Room (ISO 8) with different air classifications were not monitored prior to or during sterile drug production. This is a repeat Observation.

***DATES OF INSPECTION**
 6/13/2017(Tue),6/14/2017(Wed),6/15/2017(Thu),6/19/2017(Mon),6/20/2017(Tue),6/22/2017(Thu),6/29/2017(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Anita R Michael, Investigator	DATE ISSUED 6/29/2017
		<input checked="" type="checkbox"/> Anita R. Michael Anita R. Michael Investigator Signed by: ANITA R. MICHAEL-S