

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

DISTRICT ADDRESS AND PHONE NUMBER 60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax: (404)253-1202	DATE(S) OF INSPECTION 6/6/2016-7/7/2016*
	FBI NUMBER 3012184662

**NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED**  
Douglas R. Yoch , Owner/ Pharmacist In Charge

<b>FIRM NAME</b> Stanley Specialty Pharmacy Compounding and Wellness Center	<b>STREET ADDRESS</b> 3120 Latrobe Dr Ste 200
<b>CITY, STATE, ZIP CODE, COUNTRY</b> Charlotte, NC 28211-2185	<b>TYPE ESTABLISHMENT INSPECTED</b> Producer of 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 OBSERVED:**  
**OBSERVATION 1**  
Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

Your firm does not conduct environmental or personnel monitoring during or after sterile operations. Current procedures only require personnel monitoring (fingertip sampling) (b) (4) Viable surface monitoring within the classified areas, including (b) (4) , is performed only (b) (4) , (b) (4)

**OBSERVATION 2**  
Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically,

Employees performing manipulations in the production of drug products required to be sterile do not wear sterile gowning. When fully gowned, operators have exposed skin on their neck, face, and forehead while working within the ISO 5 laminar air flow hoods.

**OBSERVATION 3**  
Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include validation of the sterilization process.

<b>SEE REVERSE OF THIS PAGE</b>	<b>EMPLOYEE(S) SIGNATURE</b> Bonita S Chester, Investigator	<b>DATE ISSUED</b> 7/7/2016
		<input checked="" type="checkbox"/> Bonita S Chester Bonita S Chester Investigator Signed by Bonita S. Chester's

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Producer of Sterile Drugs

Specifically,

Your firm performs (b) (4) of aseptic processes: (b) (4) Media fills that have been conducted do not simulate actual production or include the most challenging conditions or manipulations to demonstrate that employed practices are reproducible and are not contributory to the microbiological contamination of the finished product.

**OBSERVATION 4**

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

Specifically,

Your firm uses a (b) (4) as a sporicidal agent to clean and disinfect floors, ceilings, pass-thru boxes, and within the the ISO 5 laminar air flow hood. There is no scientific data to support the concentration and contact time being used to achieve sporicidal disinfection.

**\*DATES OF INSPECTION**

6/06/2016(Mon),6/07/2016(Tue),6/08/2016(Wed),6/09/2016(Thu),7/07/2016(Thu)

**SEE REVERSE  
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Bonita S Chester, Investigator

DATE ISSUED

7/7/2016

Bonita S Chester

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Investigator  
Signed by Bonita S. Chester -S