

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 60 Eighth Street NE Atlanta, GA 30309 404-253-1161 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 07/31/2017 - 08/04/2017
	FEI NUMBER 3012184662

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
 TO: Douglas R. Yoch, Owner / Pharmacist in Charge

FIRM NAME Stanley Specialty Pharmacy Compounding and Wellness Center	STREET ADDRESS 3120 Latrobe Dr. Suite 200
CITY, STATE AND ZIP CODE Charlotte, NC 28211	TYPE OF ESTABLISHMENT INSPECTED 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

Environmental monitoring was not performed in your aseptic processing areas.

Specifically,

(b) (4) samples collected within the ISO 8 (b) (4) and (b) (4) areas, ISO 7 (b) (4) room, and (b) (4) ISO 5 laminar flow hoods, are ~~only~~ collected on a (b) (4) basis after cleaning.
Spr 08/04/2017

OBSERVATION 2

Disinfecting agents and cleaning pads or wipes used in the ISO 5 aseptic processing areas are not sterile.


Specifically,

Your firm uses a non-sterile, non-sporocidal disinfectant (b) (4) with non-sterile wipes for all surfaces within the ISO classified areas, including in the ISO 5 laminar flow hoods where aseptic processes are conducted.

OBSERVATION 3

There is insufficient data to support the percentage of preservative used to ensure anti-microbial effectiveness in multi-dose stock solutions which are used to formulate finished product.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Seneca Toms, Investigator Bonita Chester, Investigator	DATE ISSUED 08/04/2017
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