DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404) 253-1161 Fax:(404) 253-1202 Industry Information: www.fda.gov/oc/industry	02/18/2014 - 02/26/2014* FEI NUMBER 3010078549

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Chalmas C. Stewart, Co-Owner

FIRM NAME	STREET ADDRESS
Stewart Compounding Pharmacy	101 Broadfoot Avenue
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fayetteville, NC 28305	Producer of Sterile and Non-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 WE OBSERVED:

OBSERVATION 1

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

Specifically,

A. Hydroxyprogesterone Caproate Lot #01132014 + 16756@6 was sterilized via [redacted] (b) (4) on 1/13/2014 at [redacted] (b) (4). However, the [redacted] (b) (4) were not documented to support that the process is capable of producing a sterile product. The equipment use log only identifies the product and the [redacted] (b) (4).

B. Verification studies performed on the [redacted] (b) (4) were insufficient due to the following reasons:

1. The study only represents a [redacted] (b) (4) and not the sterilization of actual or simulated finished product.
2. The [redacted] (b) (4) used to perform the verification studies is not [redacted] (b) (4) (b) (4) or documented.

OBSERVATION 2

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

Specifically,

A. The [redacted] (b) (4) used for the sterilization of finished products during aseptic processing has not been qualified to ensure adequate (b) (4) [redacted] and (b) (4) [redacted]. The verification studies executed on 4/17-18/13 does not sufficiently validate the sterilization process in that:

1. The current procedure (SOP 8.010, v1) requires [redacted] (b) (4) [redacted]

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Tamara J. Henderson, Investigator Bonita S. Chester, Investigator B.C.	02/26/2014

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[redacted] whereas the verification studies were ran at the following [redacted]

[redacted]

2. The monitoring data [redacted] from the verification studies could not be verified to ensure that the [redacted] were met.

3. The design of the studies do not incorporate the use of simulated compounded product.

4. The [redacted] used in the studies are not appropriate for the firm's sterilization [redacted] The COA for the [redacted] states that the [redacted] met specifications [redacted] The firm's minimum requirements for sterilization is [redacted].

B. Your firm lacks documentation showing that your sterile products have been 100% visually inspected for particulate matter, container/closure defects, phase separation, and meets the appropriate color.

C. There is no scientific justification to support the specific concentration of [redacted] as an effective antimicrobial agent in the processing of Hydroxyprogesterone Caproate Lot #01132014 + 16756@6.

D. There is no environmental sampling conducted for viable/non viable particulates during aseptic processing in the ISO 5 air flow hood.

OBSERVATION 3

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

Specifically,

The gowning procedure for the processing of sterile products does not require the donning of sterile gowning that would prevent the transmission of microbes from personnel engaged in aseptic processing into the sterile products.

*** DATES OF INSPECTION:**
02/18/2014(Tue), 02/19/2014(Wed), 02/20/2014(Thu), 02/21/2014(Fri), 02/26/2014(Wed)

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