DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax:(214)253-5314	7/30/2019-8/9/2019* FEI NUMBER 3012038236

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Rene F. Garza, Chief Executive Officer	
FIRM NAME Stonegate Pharmacy LP	STREET ADDRESS 2501 W William Cannon Dr Ste 203
CITY, STATE, ZIP CODE, COUNTRY Austin, TX 78745-5255	TYPE ESTABLISHMENT INSPECTED 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

Personnel donned gowning apparel improperly, in a way that may have caused the gowning apparel to become contaminated.

Specifically,

A. On 07/30/2019, I witnessed your firm's pharmacy technician's failure to cover exposed skin around the forehead and eyes while producing sterile drug products in your ISO 5 laminar airflow hood, brand name "(b) (4) ", serial number (b) (4) , model (b) (4). Your pharmacy technician's eye and forehead areas entered the ISO 5 sterile environment while producing sterile injectable drug products.

Your firm's pharmacy technician produced the following three sterile drug products on 07/30/2019, Chorionic Gonadotropin 5,000 U/mL Solution, Lot #07292019:92@45, Quantity (b) (4), Testosterone Cypionate (Grapeseed Oil) 40 mg/mL Oil Injection Solution, Lot #07302019:92@4, Quantity (b) (4), and Testosterone USP (Ethyl Oleate) 200 mg/mL Oil Injection Solution, Lot #07302019:67@1, Quantity (b) (4).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jason R Caballero, Investigator	X Jason R Caballero Investigator Signed By: Jason R. Caballero -S Date Signed: 08-09-2019 08:56:21	8/9/2019

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B. On 07/30/2019, I witnessed your firm's pharmacy technician's failure to utilize clean non-sterile booties throughout the day while performing sterile production tasks. Your firm's pharmacy technician exited the sterile suite and anteroom multiple times and donned the same non-sterile booties three times throughout the day. These same non-sterile booties were stored on the floor of the anteroom when not in use. While sterile gowning, your pharmacy technician's sterile gown's draw strings came in contact with the reused non-sterile booties. These same draw strings were tied in front of her torso and she continued to produce drug products and clean the ISO 5 area with the draw strings entering the sterile environment.

C. On 07/30/2019, I witnessed your firm's pharmacy technician's failure to utilize clean non-sterile gowns in your firm's non-sterile production areas. Your employees reuse non-sterile gowns for approximately (b) (4) to (b) (4) days in a row, or according to your pharmacy technician, "until they get really dirty". On 07/30/2019, your firm's pharmacy technician produced the non-sterile drug product Methylcobalamine/Methionine/Inositol/Choline 1/25/50/50, Rapid Dissolve Tablets, Lot #06192019:74@15, Quantity (b) (4) utilizing a reused non-sterile gown.

OBSERVATION 2

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You produced hazardous drugs without providing adequate containment and segregation to prevent cross-contamination.

Specifically,

On 07/30/2019, I witnessed your firm's failure to secure the entry door to your (b) (4) (b) (4) area. Your firm utilized what appeared to be a stack of white napkins to prop up the door to your (b) (4) area while producing Methylcobalamine/Methionine/Inositol/Choline 1/25/50/50, Rapid Dissolve Tablets, Lot #06192019:74@15, Quantity (b) (4). The door to your firm's negative pressure (b) (4) area has fallen twice and your firm has not performed any risk assessment after each occurrence. Your firm does not maintain any maintenance records for said door. According to your pharmacist-in-charge, your firm's (b) (4) area is used primarily for the production of hormone containing drug products. Your firm does not follow any procedures assigned to mitigate drug product cross contamination. The (b) (4) area is adjacent to a drug product storage area and (b) (4) non-sterile (b) (4) hoods in the non-sterile laboratory.

OBSERVATION 3

Equipment was and Materials or supplies were not disinfected prior to entering the aseptic processing areas.

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A. On 07/30/2019, I witnessed your firm's pharmacy technician's failure to disinfect a bottle of sterile water prior to entering the ISO 5 area. Your firm utilizes sterile water as the primary cleaning step for the ISO 5 area. Said bottle of sterile water entered the ISO 5 environment without being wiped/disinfected with (b) (4) sterile (b) (4). According to your pharmacist-in-charge, the exterior of said bottle is not sterilized from the manufacturer. Said bottle of sterile water is reused throughout each day of production.

B. On 07/30/2019, I witnessed your firm's pharmacy technician's failure to disinfect blue vial stickers prior to entry into the ISO 5 sterile environment. These blue vial stickers were applied to all drug product vials produced in the laminar airflow hood. Said blue stickers entered the ISO 5 environment without being wiped/disinfected with (b) (4) sterile (b) (4). The blue stickers are staged directly above your laminar airflow hood.

Your firm's pharmacy technician produced the following three sterile drug products on 07/30/2019, Chorionic Gonadotropin 5,000 U/mL Solution, Lot #07292019:92@45, Quantity (b) (4) Testosterone Cypionate (Grapeseed Oil) 40 mg/mL Oil Injection Solution, Lot #07302019:92@4, Quantity (b) (4) and Testosterone USP (Ethyl Oleate) 200 mg/mL Oil Injection Solution, Lot #07302019:67@1, Quantity (b) (4).

OBSERVATION 4

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The ISO 5 classified aseptic processing areas had difficult to clean and particle-generating equipment or surface.

Specifically,

On 07/30/2019, I witnessed your firm's failure to properly store unsealed prefilters awaiting installation into your laminar airflow hood ISO 5 environment, (b) (4) (b) (4) , serial #(b) (4) , model #(b) (4). Said unsealed prefilters were stored directly on the ground in your anteroom room and then moved to the non-sterile area of the laboratory, near a trash can.

OBSERVATION 5

Your firm released drug product in which the strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

Specifically,

1. On 07/30/2019, I witnessed your firm's failure to maintain calibration records for your (b) (4) , brand name "(b) (4)", serial number (b) (4) , utilized to test your sterile injectable drug products. Your (b) (4) calibration records date only back to June 27th, 2019. Your firm's calibration (b) (4) for your (b) (4) , do

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not specify expiration dating and only represent (b) (4) calibration points (b) (4) and (b) (4).

2. On 07/30/2019, I witnessed your firm's failure to utilize a calibratable thermometer in your freezer that is dedicated to drug product storage. This is where your firm stores sterile injectable solutions pending distribution. All of your freezer temperature records/logs are based on this non-calibratable "(b) (4)" brand thermometer. I witnessed the storage of your firm's drug product, Methionine/Inositol/Choline//MB12/HB12/B1/B2/B3/B5/B6/MB9/LIDOCAINE 12.5/25/50/6.25/6.25/50/5/50/5/5/5MG/ML/2% Combination Injectable Solution, Lot # 6189498-07222019:90@26, Quantity (b) (4), in said freezer.

3. Your firm failed to utilize starting materials that provide sterility assurance and are indicated for injectable use. Your firm utilizes grapeseed oil in your drug product, Testosterone Cypionate (Grapeseed Oil) 40 mg/mL Oil Injection Solution, Lot #07302019:92@4, Quantity (b) (4) without any sterility assurance or indication for injectable use from the manufacturer.

Your firm's Methylcobalamin/Hydroxocobalamine/Folinic Acid/P5P 6.25/6.25/5/6.25 mg/mL Sterile Injectable Solution, directly associated with a consumer complaint submitted against your firm, necessitates pH level testing prior to release and storage in the above mentioned freezer at appropriate temperatures for drug product stability.

***DATES OF INSPECTION**
7/30/2019(Tue), 7/31/2019(Wed), 8/01/2019(Thu), 8/02/2019(Fri), 8/05/2019(Mon), 8/06/2019(Tue), 8/07/2019(Wed), 8/08/2019(Thu), 8/09/2019(Fri)

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