COPY

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	5/30/2018-6/11/2018* FEI NUMBER 3012038236

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mr. Rene F. Garza, CEO	
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 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 I OBSERVED:

OBSERVATION 1

Media fills were not performed that closely simulate aseptic production operations incorporating as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

Media fills conducted by your aseptic technicians do not represent routine production nor do they simulate worst case scenarios or most challenging conditions. For example, your firm produced a batch of Glutathione 5% Inhalation Solution Lot # 04052018:86@39 consisting of (b) (4) each containing (b) (4) of product. In addition, your firm has also produced a batch of Chorionic Gonadotropin 10000IU/ml Solution, Lot # 03202018:94@2 consisting of (b) (4) vials each containing (b) (4) of product. Your firm routinely fills various size vials (2ml-100ml) and batch sizes can be in excess of (b) (4) . Your firm's current media fill test procedure involves placing (b) (4)
(b) (4) .

This is a repeat observation from the previous inspection conducted in 2016.

OBSERVATION 2

Personnel hand washing procedure was conducted in a way that may have cause the gowning apparel to become contaminated.

On 6/5/2018, I observed the sterile technician remove her lab coat, cap and replace her shoe covers prior to entering the clean side of the ISO7 anteroom where she proceeded to wash her hands before sterile gowning. During the hand washing procedure, I observed tap water from the sink splashing the front of her scrubs and

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Patty P Kaewussdangkul, Investigator PPK	X Patty P Kaewussdangkul Investigator Signed By: Patty P. Kaewussdangkul -S Date Signed: 06-11-2018 00:00:18	6/11/2018

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splashing on the floor next to her shoes which were covered with shoe covers. She proceeded to don sterile garments such as a sterile mask, sterile gown, sterile gloves but did not change her shoe covers that may have been contaminated with microbiological organisms found in tap water that splashed on the floor during the hand washing procedure and entered the ISO7 buffer room containing the ISO5 laminar air flow hood.

OBSERVATION 3

(b) (4) are not used properly to verify the adequacy of the sterilization (b) (4)

a) Your firm (b) (4) sterilizes vials of Testosterone in (b) (4) and (b) (4) . The sterile technician stated that (b) (4) (b) (4) . However, your firm does not follow the manufacturer's insert which states that the (b) (4) is to be (b) (4) . Your firm's sterile technician stated that the (b) (4) processed in the (b) (4) . There is no assurance that the vials sterilized by (b) (4) to render the vials of Testosterone in (b) (4) sterile. Approximately (b) (4) prescriptions of Testosterone vials in (b) (4) have been distributed that were (b) (4) sterilized in the (b) (4) since 3/1/2018.

b) Your firm (b) (4) sterilizing Testosterone, Testosterone/Anastrozle and/or Estradiol pellets in the (b) (4) . However, you do not (b) (4) used to house the pellets. The (b) (4) are not processed or subjected to the same conditions as the pellets therefore there is no assurance that the (b) (4) (b) (4) parameters utilized to sterilize the pellets are adequate. Approximately (b) (4) prescriptions of Testosterone, Testosterone/Anastrozole and Estradiol pellets were dispensed since 3/1/2018.

OBSERVATION 4

Stock solutions used in the preparation of sterile finished drug products are not (b) (4) sterilized nor stored in sterile containers.

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Your firm prepares (b) (4), a stock solution that is used as a component in the production of Chorionic Gonadotropin Solution (HCG), an aseptically filled sterile injectable drug product of various strengths such as but not limited to 5,000IU/ml and 10,000IU/ml. The (b) (4) (b) (4) stock solution is not (b) (4) sterile and is not placed in sterile containers. The beyond use date for this stock solution is (b) (4). The following lots of (b) (4): (b) (4) (b) (4) have been prepared without being (b) (4) sterilized nor stored in sterile containers to limit or reduce bioburden to control potential proliferation of bacterial endotoxins and were used in the production of HCG in various strengths. Since 3/1/2018, approximately (b) (4) prescriptions have been fulfilled of various strengths of HCG of which the (b) (4) stock solution was used.

***DATES OF INSPECTION**

5/30/2018(Wed), 5/31/2018(Thu), 6/01/2018(Fri), 6/04/2018(Mon), 6/05/2018(Tue), 6/06/2018(Wed), 6/07/2018(Thu), 6/08/2018(Fri), 6/11/2018(Mon)

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