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	6/19/2019-7/1/2019* FEI NUMBER 1000371043

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Stewart I. Edington, President/CEO

FIRM NAME	STREET ADDRESS
Dougherty's Pharmacy	5959 Royal Ln Ste 515
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Dallas, TX 75230-3890	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 OBSERVED:

OBSERVATION 1

Your firm produced drugs while construction was underway in an adjacent area without adequate controls to prevent contamination of the production environment and product.

Specifically,

On 6/19/2019, I observed exposed wires, missing ceiling tiles, paint buckets and clutter during your firm's construction of the non sterile processing areas which were visibly exposed to the firm's surrounding areas. There was no plastic tarp or adequate controls in place to protect possible contamination such as dust and particles to your firm's unclassified lab area which subsequently lead to the ISO7 anteroom and ISO7 buffer rooms containing your ISO5 hoods. According to your Compounding Lab Manager, your firm construction of the non sterile processing areas was initiated on or about 4/3/2019.

OBSERVATION 2

Poor aseptic technique was observed that poses a risk to the asepsis of the critical ISO5 zone in which sterile drugs are processed.

Specifically,

On 6/20/2019, I observed the sterile technician place her forearms and wrists which were covered with non-sterile sleeves and cuffs in the ISO5 biological safety cabinet (BSC) to handle components, containers and initiate aseptic processing of Mitomycin 0.2mg/ml, Lot #20190620@2.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Patty P Kaewussdangkul, Investigator	X Patty P Kaewussdangkul Investigator Signed By: Patty P Kaewussdangkul -S Date Signed: 07-01-2019 11:01:54	7/1/2019

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OBSERVATION 3

Failure to conduct media fill studies to closely simulate aseptic production operations under the worst-case, most challenging and stressful conditions.

Specifically,

Your firm's current media fill procedures do not simulate worst case scenarios or most challenging conditions. Your most recent media fill (aseptic process simulation) conducted qualifies your sterile technicians to aseptically fill a maximum of (b) (4) vials per batch. However, your media fill procedures did not consider aseptic fill of drug product batch sizes in excess of (b) (4) vials. For example,

- (b) (4) vials of Dexamethasone PF 0.1% Ophthalmic Eye Drops, Lot #20190617@11 were aseptically filled on 6/17/2019.
- (b) (4) vials of Papaverine 30mg, Phentolamine 1mg, Alprostadil 20mcg Injection, Lot #20190617@30 were aseptically filled on 6/17/2019.
- (b) (4) vials of Papaverine 30mg, Phentolamine 0.25mg, Alprostadil 10mcg Injection, Lot #20190617@33 were filled on 6/17/2019.

*DATES OF INSPECTION

6/19/2019(Wed), 6/20/2019(Thu), 6/21/2019(Fri), 6/24/2019(Mon), 6/25/2019(Tue), 6/26/2019(Wed), 7/01/2019(Mon)

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