DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Industry Information: www.fda.gov/oc/industry	07/09/2018-07/13/2018
	FEI NUMBER 3010621916

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: William L. LaGamba, Owner

FIRM NAME	STREET ADDRESS
Drug Depot, Inc. dba APS Pharmacy	34911 US Hwy 19 N, Suite 600
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Palm Harbor, FL 34684-1921	Producer of 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:

1. Personnel were observed conducting aseptic manipulations that blocked the movement of first pass air around an open unit, whether before or after it is filled with sterile product.

Specifically, on 07/09/2018 I observed a sterile technician filling vials of Testosterone Cypionate/ Anastrozole*GS*Oil 200MG/0.5MG/ML RM Injectable lot number 486380, in a (b) (4) laminar ISO 5 classified bio-safety cabinet, break first pass unidirectional air flow at least four times by placing hands over an open top of the (b) (4) while (b) (4) drug product in a syringe during the fill operation. Since the January 2017 there have been (b) (4) sterility failures which may be an indication of insanitary conditions.

2. The ISO-classified area has difficult to clean, particle-generating, or visibly dirty equipment or surfaces.

Specifically, caulking around joints of the ISO 5 area between the laminar flow hood and (b) (4) and on ceilings in the non-hazardous and hazardous areas were not smooth.

3. Hazardous drugs were produced without providing adequate containment, segregation, and/or cleaning of work surfaces, utensils, and/or personnel to prevent cross-contamination.

Specifically, since December 2017 lots of hazardous Human Choronic Gonadotropin (HCG) were filled and (b) (4) in the non-hazardous ISO 5 classified area of the facility.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Seneca D. Toms -S	Seneca D. Toms, Investigator	07/13/2018