DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax:(407) 475-4768 Industry Information: www.fda.gov/oc/industry	12/15/2015 - 01/22/2016* FEI NUMBER 3010621916

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: William L. Lagamba, Manager

FIRM NAME	STREET ADDRESS
Drug Depot, Inc., dba APS Pharmacy	34911 Us Hwy 19 N Ste 600
CITY, STATE, ZIP CODE, COUNTRY	TYPE 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 WE OBSERVED:

OBSERVATION 1

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

Specifically,

A. For the following four out of four products I reviewed, (b) (4) are used for the sterilization for the following drug products labeled as sterile:
   1. Methylcobalamin (1 mg/mL)
   2. Human Chorionic Gonadotropin (HCG) (3500 IU/vial and 5000 IU/vial)
   3. Testosterone Cypionate (200 mg/mL)
   4. Sermorelin (15 mg/vial)

B. The (b) (4) (b) (4) and the practice of (b) (4) container/closures in (b) (4) has have not been validated. This includes the storage hold times for these container/closures. In addition, there are no written calibration procedures or actual calibration documentation available for your (b) (4) and (b) (4) This includes lack of (b) (4) documentation for the (b) (4) .
   1. The (b) (4) (b) (4) is used for all glassware and finished product vials (b) (4) (b) (4) while preparing sterile drug products.
   2. The (b) (4) is used for sterilizing finished drug products (i.e., testosterone pellets), finished product vials, rubber vial stoppers, and utensils used in the filling of sterile drug products.
   3. (b) (4) , laboratory glassware, finished product vials, and stoppers are (b) (4) that is (b) (4)

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C. Partially stoppered vials are exposed to less than ISO 5 quality air during the (b) (4)

OBSERVATION 2

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

Specifically,

A. I observed the following aseptic deficiencies during the preparation of sterile drug products:
   1. Personnel are not sanitizing items (e.g., bags containing vials, syringes, and glassware) prior to placing them into the laminar flow hood (ISO 5).
   2. Personnel are placing their head inside the laminar flow hood while preparing sterile drug products.

B. The media fills documented as being conducted by your technicians within the ISO 7 room and under the laminar flow hoods (ISO 5) were found to be deficient in that they do not accurately simulate current production processes and conditions that represent the most stressful/challenging conditions and optimize detection of any microbiological contamination. For example, there is no media fill data for your current operation of filling approximately (b) (4) glass Human Chorionic Gonadotropin vials (b) (4) for a prepared batch that uses (b) (4) glass vials, stoppers, caps that are sterilized in-house.

OBSERVATION 3

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

A. Air (viable and non-viable) sampling within all classified areas is not performed during daily operations. Personnel stated that sampling is only performed every (b) (4) (b) (4)

B. There is no continuous or at least periodically monitoring of air pressure differentials during production from the ISO 7 room containing the ISO 5 hoods and the prep room (ISO 7) to the surrounding non-classified pharmacy area.

C. For all classified areas, personnel stated that dynamic airflow pattern studies (i.e., smoke studies) had not been conducted in the laminar flow hoods inside your ISO room.

D. Surface sampling within your laminar flow hoods is not conducted during daily operations. Personnel stated that a (b) (4) sample is taken (b) (4) on a (b) (4) basis.

E. Personnel monitoring within all classified areas is not adequate based on the following:
   1. Personnel monitoring (e.g., fingertip sampling) is not conducted during daily operations. Personnel stated that sampling is only conducted every (b) (4).
   2. Your personnel's gowning materials have never been sampled after preparation of sterile drug products.

OBSERVATION 4

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically,

A. Personnel use non-sterile disinfectants (e.g., (b) (4)) to clean the laminar flow hoods where sterile drug products are prepared.

B. No sporicidal agent is used to clean your classified areas, including the laminar flow hood where sterile drug products are prepared.

C. No documentation was provided demonstrating disinfectant efficacy either by the firm or cleaning solution manufacturer

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CITY, STATE, ZIP CODE, COUNTRY Palm Harbor, FL 34684-1921	TYPE ESTABLISHMENT INSPECTED Producer of sterile drugs

OBSERVATION 5

Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically, I observed inconsistent and inadequate gowning practices during this inspection as described below:

A. Gowning qualifications have not been conducted for your pharmacy personnel that prepare drug products in your ISO 7 room under the laminar flow hoods (ISO 5).

B. The following non-sterile gowning components are used while preparing sterile drug products:
   - Gown
   - Facemask
   - Hairnet

C. Personnel stated they use (b) (4) . I observed personnel slide their hands from top to bottom of their gowns, after they hung them on the hooks in the gowning room.

OBSERVATION 6

Each batch of drug product purporting to be sterile is not laboratory tested to determine conformance to such requirements.

Specifically,

A. Your firm has not validated sterility testing to ensure substances in your product formulations do not interfere with the test and if they can detect low levels of organisms. In addition growth promotion testing is not conducted for media used for sterility testing in-house.

B. Your firm has never performed testing to determine the preservative (i.e., (b) (4) content for any of the sterile drug products I reviewed:
   - Methylcobalamin (1 mg/mL)
   - Testosterone Cypionate (200 mg/mL)

C. Your firm has never tested the reconstitution time for any of the sterile lyophilized drug products

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I reviewed:

- Human Chorionic Gonadotropin (HCG) (3500 IU/vial)
- Human Chorionic Gonadotropin (HCG) (5000 IU/vial)
- Sermorelin (15 mg/vial)

OBSERVATION 7

Drug products do not bear an expiration date determined by appropriate stability data to assure they meet applicable standards of identity, strength, quality and purity at the time of use.

Specifically,

A. No documentation (potency and sterility data) could be provided to support your labeled beyond use date for the sterile drug products that I reviewed:

Drug product	BUD (days)
Methylcobalamin (1 mg/mL)	90
Human Chorionic Gonadotropin (HCG) (3500 IU/vial)	180
Human Chorionic Gonadotropin (HCG) (5000 IU/vial)	180
Human Chorionic Gonadotropin (HCG) pre-filled syringe (200 IU/syringe)	45
Testosterone Cypionate (200 mg/mL)	180
Testosterone Cypionate pre-filled syringe (200 mg/mL)	90
Sermorelin (15 mg/vial)	180
17-A-OH-Progesterone caproate (PF) (250 mg/mL)	90
Procaine HCl 2%	30

B. There is no antimicrobial effectiveness testing for sterile drug products that your firm prepares that contain preservatives (e.g., (b) (4)) over the labeled shelf life:
   - Methylcobalamin (1 mg/mL)
   - Testosterone Cypionate (200 mg/mL)

C. There is no written testing program designed to assess the stability characteristics of drug products.

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OBSERVATION 8

Each lot of a component, drug product containers, and closures liable to objectionable microbiological contamination is deficiently subjected to microbiological tests before use.

Specifically,

A. Your firm has no qualified vendor program and no documentation could be provided showing you have qualified any of your non-sterile bulk drug substance (e.g., (b)(4) or component suppliers.

B. Your firm has not verified that Certificate of Analysis (CoA) test results are reliable for any incoming bulk drug substance used in the preparation of sterile drug products.

OBSERVATION 9

Drug product containers and closures were not clean and sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use.

Specifically,

A. Your firm's practice of (b)(4) lab glassware, vials and stoppers with non-sterile (b)(4) has not been verified that this process does not leave behind a chemical residue or introduce particles inside these containers and closures.

B. Your firm does not depyrogenate vial stoppers that are used in the packaging of finished sterile drug products prepared at your facility.

* DATES OF INSPECTION:
12/15/2015(Tue), 12/16/2015(Wed), 12/17/2015(Thu), 01/05/2016(Tue), 01/22/2016(Fri)

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