DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 1500 Chicago, IL 60661-4716 (312) 353-5863 Fax:(312) 596-4187 Industry Information: www.fda.gov/oc/industry	09/09/2015 - 10/28/2015* FEI NUMBER 3008688061

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Michael W. Minesinger, President and Owner

FIRM NAME	STREET ADDRESS
American Pharmacy of Illinois, Inc. dba Alwan's Pharmacy	311 N Western Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Peoria, IL 61604-5638	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

The control systems necessary to prevent contamination or mix-ups are deficient.

Specifically,

A. On 09/10/2015, I observed a reddish-orange residue and a clear dried gel-like substance occluding the holes of the top ceiling grate inside the ISO 5 laminar flow hood. This laminar flow hood is used for the production of sterile drug products.

B. On 09/09/2015 and 09/10/2015, I observed that the floor in the sterile compounding room, IV Prep Room, had visible black particles on the floor. I also observed a residue on the outside of the laminar flow hood and an open trash container located on the bottom shelf under the ISO 5 laminar flow hood.

C. On 09/09/2015, I observed the sterile drug processing echnician (b) (4) of the finished sterile drug product (b) (4) with (b) (4). The (b) (4) are not labeled as lint-free.

D. On 09/09/2015, I observed that four different sterile drug products' components were all (b) (4) for the (b) (4). All (b) (4) components for all four products were in unlabeled, (b) (4). The four products produced were: Papaverine 30mg/ml Phentoalmine 2mg/ml Injection, lot I0915F; Tri-Mix #1 (Red) Injection (PGE 5.8mcg/ml Phentoalamine 0.58mg/ml Papaverine 17mg/ml), lot I0915E; Hydroxycobalamin 5mg/ml Injection, lot I0915G; and Methylcobalamine 3mg/ml Injection, lot I0915H. The Papeverine 30mg/ml Phentoalmine 2mg/ml Injection and the Tri-Mix #1 (Red) Injection (PGE 5.8mcg/ml Phentoalamine 0.58mg/ml Papverine 17mg/ml) are clear aqueous solutions that were filled into labeled vials; Hydroxycobalmin 5mg/ml Injection is a dark red solution that was filled in a unlabeled vial; and Methylcobalamine 1mg/ml Injection is a lighter red solution that was filled in an unlabeled vial.

F. On 09/09/2015, I observed that the sterile drug processing technician left the (b) (4) on the ISO 7 IV Prep Room side open during the production of the four sterile products.

AMENDMENT 1

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	Christina A. Miller, Investigator	11/17/2015

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OBSERVATION 2

Clothing of personnel engaged in the processing of drug products is not appropriate for the duties they perform.

Specifically,

On 09/09/2015, I observed the firm's sterile processing technician gown for sterile drug processing operations. The technician entered the (b) (4) room ((b) (4) room) to begin gowning. The technician first (b) (4) . The technician then exited the (b) (4) room and went out into the (b) (4) . The technician then (b) (4) room ((b) (4) room) and (b) (4) ; the technician did not change booties, facemask, and hairnet. The technician then entered the ISO 7 IV Prep Room to begin sterile drug processing operations. I observed the technician produce the following four sterile products: Papaverine 30mg/ml Phentolamine 2mg/ml Injection, lot I0915F; Tri-Mix #1 (Red) (PGE 5.8mcg/ml Phentoalmine 0.58mg/ml Papaverine 17 mg/ml, lot I0915E; Hydroxocobalmin 5mg/ml Injection, lot I0915G; and Methylcobalamine 3 mg/ml Injection, lot I0915H.

OBSERVATION 3

Equipment for adequate control over air pressure, micro-organisms, dust, humidity, and temperature is not provided when appropriate for the manufacture, processing, packing or holding of a drug product.

Specifically, the firm does not ensure that the cleanroom's air quality is maintained through appropriate testing and preventive maintenance. For example,

A. The ISO 5 laminar flow hood HEPA filter air velocity profile test performed on (b) (4) had individual test values that did not meet the contract service provider's air supply specification range ((b) (4)). Four out of the (b) (4) test values were below the minimim specification range (74, 74, 73, and 72). The test value average was within specification ((b) (4)); however, the firm did not investigate the individual OOS test values.

B. The ISO 7 IV Prep Room HEPA filter is not tested for leaks.

C. The ISO 7 IV Prep Room did not meet the contract service provider's room air exchange specifications (actual result 26 APCH; specification is (b) (4) APCH) for both (b) (4) tests.

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OBSERVATION 4

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

Specifically, the firm's environmental monitoring program does not adequately monitor environmental conditions that could impact aseptic processing operations. For example,

A. The firm does not perform viable monitoring inside the ISO 5 laminar flow hood or adjacent ISO 7 IV Prep room.

B. The firm does not perform contact surface sampling. The firm last performed contact surface sampling in (b) (4).

C. The firm does not perform monitoring on personnel. The firm does not sample personnel gloves or other locations on personnel such as arms or chest of gowns during sterile production or while performing media fill studies.

D. The firm does not perform non-viable environmental monitoring during aseptic processing conditions. Non-viable monitoring is performed by a contract service provider (b) (4).

OBSERVATION 5

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically, dynamic smoke studies have not been performed in the ISO 5 laminar flow hood to ensure air patterns are suitable for aseptic conditions. In addition, temperature and pressure are not monitored continuously in the firm's cleanroom complex. The firm (b) (4) (b) (4) (b) (4).

OBSERVATION 6

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

Specifically,

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A. The firm has not validated the (b) (4) that are used to sterilize drug products such as Hydroxyprogesterone Injection and Progesterone Injection. The firm also does not have an established procedure for the (b) (4) sterilization process nor does the firm document (b) (4) sterilization.

B. The firm has not validated the (b) (4) used to sterilize the drug product, Medroxyprogesterone Eye Drops. The firm also does not have an established written procedure for the (b) (4) sterlization process nor does the firm document (b) (4) sterilization.

C. The firm has not validated the (b) (4) used to sterilize the drug component (b) (4) which is used in the production of Corticotrophin 80 units/mL Injection. (b) (4)

D. The firm did not adequately validate that the firm's current aseptic processing conditions will not introduce the potential for microbial contamination. The firm's media fills did not adequately simulate the most complex processing conditions that could provide a challenge to aseptic conditions. For example, the firm's current media fill study procedure includes only (b) (4) whereas some of the firm's production operations may include a minimum of (b) (4)

OBSERVATION 7

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

Specifically, the firm's current process for Corticotrophin 80 Units/mL Injection does not prevent the potential introduction of microbial contamination. For example, Corticotrophin 80 Units/mL Injection is produced by (b) (4)

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OBSERVATION 8

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

Specifically, not every batch of sterile drug product produced by the firm is sterility tested and/or tested for pyrogens. In 2015, only (b) (4) batches of sterile drug products have been tested for sterility and only (b) (4) batches of sterile drug products have been tested for pyrogens. The firm approximates that its produces (b) (4) sterile drug products per month. The firm produces sterile drug products that are administered intrathecal, intravenously, and intramuscular.

OBSERVATION 9

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

Specifically, the firm does not use a sporicidal agent to clean the floor, walls, and ceiling of the ISO 7 IV Prep Room; the firm currently uses (b) (4). The firm also does not use sterile (b) (4) during its cleaning and disinfection of the ISO 5 laminar flow hood and ISO 7 IV Prep Room; the firm currently uses (b) (4).

OBSERVATION 10

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release.

Specifically, the firm does not test its sterile drug products for potency as part of its final approval and release. In 2015, only (b) (4) batches of sterile drug products have been tested for potency. The firm approximates that its produces (b) (4) sterile drug products per month.

OBSERVATION 11

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

Specifically,

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A. The firm does not have a stability program for its sterile drug products. The firm has not conducted studies to support the expiry dates assigned to its sterile drug products. The following are examples of sterile drug products and their assigned expiry dates:

- Hydroxyprogesterone 250mg/ml Inj. is stored at room temperature and assigned a six month expiry date;
- Corticotrophin 80 Units/ML Injection is refrigerated and assigned a sixty day expiry date;
- Papaverine 30mg/ml Phentoalamine 1 mg/ml Injection expiry date at refrigerated temperature is sixty days and its expiry date when stored frozen is 180 days;
- Quad Mix 30-1-10-.15 Injection expiry date at refrigerated temperature is sixty days and its expiry date when stored frozen is 180 days.

B. On 09/09/2015, I observed expired drug product components in the room temperature storage area in the (b) (4) room. The firm does not have data to support the stability of the components' past their expiration dates.

OBSERVATION 12

Time limits are not established when appropriate for the completion of each production phase to assure the quality of the drug product.

Specifically, the firm has not conducted hold time studies to support the (b) (4) that are further used in the production of sterile finished drug products. For example,

- Tacrolimus (b) (4) (b) (4) the assigned expiration date is (b) (4);
- Cyclosporine (b) (4) (b) (4) the assigned expiration date is (b) (4);
- Clonidine (b) (4) (b) (4) the assigned expiration date is (b) (4);
- Alprostadil (b) (4) (b) (4) the assigned expiration date is (b) (4);
- and Phentoalamine (b) (4) (b) (4) the assigned expiration date is (b) (4).

OBSERVATION 13

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically,

A. The firm does not always provide instructions nor document all operations that are performed to produce a sterile drug product such as sterilization methods and/or filling and packaging operations.

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For example,

1. The Hydroxyprogesterone Injection formula worksheets do not include instructions or process parameters for (b) (4) sterilization. The (b) (4) sterilization process is not documented on the formula worksheet or on any other document.

2. The Hydroxyprogesterone Injection formula worksheets do not include filling and packaging operations. The sterile drug processing technician stated that (b)(4) will first (b) (4) [redacted]. These filling and packaging operations are not documented on the formula worksheet nor any other document.

B. Formula worksheets do not include descriptions or lot numbers of the containers and closures that are used during packaging.

C. Component lot numbers and expiration dates are not always recorded on formula worksheets.

D. Theoretical and actual yields are not always documented on formula worksheets.

E. The technician's initials and the verifier's initials are not always recorded on the formula worksheets.

OBSERVATION 14

Employees engaged in the processing of a drug product lack the training required to perform their assigned functions.

Specifically, the firm's pharmacist that oversees sterile drug operations has not been trained in sterile drug operations. The firm's sterile drug processing technician has not received sterile drug operations training since (b) (4)

*** DATES OF INSPECTION:**
09/09/2015(Wed), 09/10/2015(Thu), 09/11/2015(Fri), 09/16/2015(Wed), 10/15/2015(Thu), 10/28/2015(Wed)

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