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	6/5/2018-7/17/2018*
	FEI NUMBER 3008688061

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Michael W. Minesinger, RPH & JD , Pharmacist-in-Charge and Owner

FIRM NAME	STREET ADDRESS
American Pharmacy of Illinois, Inc. dba Alwan Pharmacy and Compounding Center	311 N Western Ave
CITY, STATE, ZIP CODE, COUNTRY Peoria, IL 61604-5638	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

Non-sterilized and Non-depyrogenated equipment was used in sterile drug production.

Specifically,

The non-sterile amber bottles, rubber stoppers, and aluminum seals are not purchased sterilized and pyrogen-free and no steps are taken to remove possible pyrogens before the following drug products are sterilized in the (b) (4) . The non-sterile amber bottles, rubber stoppers, and aluminum seals were used for the following sterile human drug products.

1. Hydroxyprogesterone 250 mg/ml Injection, produced on 1/12/18, 50 ml, Lot # A1218Z, expires on 7/12/18, Rx # (b) (6) , and other prescriptions.

2. Progesterone 100 mg/ml Injection, produced on 2/8/18, 50 ml, Lot # B08180, expires on 8/8/18, Rx # (b) (6) and other prescriptions.

3. Hydroxyprogesterone 250 mg/ml Injection, produced on 2/8/18, 50 ml, Lot # B0818Z, expires on 8/8/18, Rx # (b) (6) , and other prescriptions.

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	Debra I Love, Investigator Debra I. Love X	7/17/2018

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4. Progesterone 100 mg/ml Injection, produced on 4/25/18, 50 ml, Lot # D2518E, expires on 10/25/18, Rx # (b) (6) , and other prescriptions.

OBSERVATION 2
Materials or supplies were not disinfected prior to entering the aseptic processing areas.

Specifically,

On 6/5/2018, I observed the pharmacy technician with (b) (4) vials of sterile (b) (4) used to prepare the sterile drug product, GHRP-2 1mg/ml/GHRP-6 1mg/ml/Sermorelin1 mg/ml Injection, 7 ml, Lot F0518K, Exp. 8-4-18, Rx# (b) (6) . After the pharmacist sprayed his gloves with disinfectant, I observed the pharmacist disinfect one of the vials by (b) (4) with a (b) (4) motion.

OBSERVATION 3
You produced highly potent drugs without providing adequate cleaning of utensils to prevent cross-contamination.

Specifically,

The (b) (4) is used to mix bulk drug substances used to produce non-sterile drug products. This equipment is cleaned with a laboratory grade cleaner and rinsed with tap water and could be difficult to

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clean and possibly cause cross-contamination when different bulk drug substances for non-sterile drug products are placed within it for mixing. It was used to produce the following non-sterile drug products.

1. Quetiapine 100 mg/ml Suspension, Lot # G1218H, produced 7/12/18, expiration 1/12/19, Rx # (b) (6)

2. Guaifenesin SR 600 mg Capsules, Lot # G0318W, produced 7/3/18, expiration 1/3/19, Rx #(b) (6)

3. Amlopidine Besylate 1 mg/ml Oral Suspension, Lot # F2818B, produced 6/28/18, expiration 8/23/18, Rx #(b) (6)

OBSERVATION 4
Your facility design allowed the influx of poor quality air into a higher classified area.

Specifically, the(b) (4) the non-classified non-sterile room and the classified ISO 7 room is constructed of(b) (4) material instead of material that is suitable for a clean room. This(b) (4) items such as weigh boats containing bulk drug substances, sterile needles, sterile empty vials, vials containing sterile (b) (4) and other required materials needed to produce sterile drug products. Unclassified air from the non-sterile production room could possibly enter the(b) (4) when the door is opened and materials are (b) (4) This air could possibly enter the classified ISO 7 room when the door is opened on the classified ISO 7 room side to (b) (4) for production in the ISO 5 hood.

1. On 6/5/18, I observed the preparation of a sterile drug product, GHRP-2 1mg/ml/GHRP-6 1mg/ml/Sermorelin1 mg/ml Injection, 7 ml, Lot F0518K, Exp. 8-4-18, Rx #(b) (6)

2. On 6/6/18, I observed the preparation of the following sterile drug products.

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- HCG 5,000 un/ml Injection, 5 ml, Lot F0618L, Exp. 7/21/18, Rx #(b) (6) , and one other prescription.
- Papaverine 30 mg/ml/Phentolamine 1mg/ml/Alprostadil 10mcg/ml Injection, 22 ml, Lot F0618M, Exp. 7/21/18, Rx # (b) (6) and other prescriptions.
- MIC (Methionine 25 mg/ml/Inositol 50 mg/ml/ Choline 50mg/ml) with Lidocaine HCL 2% Injection Solution, 16 ml, Lot F0618N, Exp. 7/21/18, Rx # (b) (6)

3. On 6/14/18, I observed the preparation of the following sterile drug products.
   - HCG 2,000 un/ml Injection, 23 ml, Lot F1418O, Exp. 7/29/18, Rx # (b) (6) and other prescriptions.
   - Triple Mix 30-1-10 Injection, 11 ml, Lot F1418P, Exp. 7/29/18, Rx # (b) (6) and another prescription.
   - Papaverine 30 mg/ml/Phentolamine 1mg/ml/Alprostadil 10mcg/ml Injection, 27 ml, Lot F1418Q, Exp. 7/29/18, Rx #(b) (6) .

OBSERVATION 5
You used a non-pharmaceutical grade component in the formulation of a drug product.

Specifically, non-pharmaceutical grade(b) (4) was used to produce the following human non-sterile finished drug products.

1. Dental Anesthetic Gel, 65 ml, Lot B1518B, produced 2/15/18, expires 8/15/18, Rx # (b) (6) , (b) (4) mixed with (b) (4) was used in the formula.

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	Debra I Love, Investigator X Debra I Love Investigator Signed By: 1306157402 Date Signed: 07-17-2018 17:28:57	7/17/2018

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2. Losartan 2.5 mg/ml Suspension, Lot E3118N, produced 5/3/18, expires 6/28/18, Rx # (b) (6) (b) (4) was used in the formula.

Specifically, your firm has no assurance that the endotoxin level of your intrathecal drug products are safe, since you do not have any endotoxin data and your firm doesn't perform endotoxin testing for the finished product. These preparations are made using non-sterile starting material. Furthermore, there is no endotoxin testing data for your API. The following intrathecal finished human drug products were produced.

- Hydromorphone HCL 10 mg/ml Isotonic Injection, Lot # E0118K, produced 5/1/18, expiration 5/2/18, Rx #(b) (6) .
- Hydromorphone HCL 10 mg/ml and Bupivacaine HCL 25 mg/ml Intrathecal Injection, Lot B2818I, produced 2/28/18, expiration 3/1/18, Rx #(b) (6) .
- Hydromorphone HCL 10 mg/ml, Bupivacaine HCL 14 mg/ml, and Clonidine 50 mcg/ml Intrathecal Injection, Lot # E2418U, produced 5/24/18, expiration 5/25/18, Rx # (b) (6)
- Hydromorphone HCL 30 mg/ml and Clonidine HCL 1.8 mg/ml Isotonic Injection, Lot E2118N, produced 5/21/18, expiration 5/24/18, Rx #(b) (6)

***DATES OF INSPECTION**
6/05/2018(Tue), 6/06/2018(Wed), 6/07/2018(Thu), 6/08/2018(Fri), 6/11/2018(Mon), 6/12/2018(Tue),

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