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	8/13/2018-8/28/2018* FEI NUMBER 3011043554

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Luis R. De Leon, Pharm.D., Owner and Pharmacist-in-Charge	
FIRM NAME Pharm D Solutions, LLC	STREET ADDRESS 1304 S Loop W
CITY, STATE, ZIP CODE, COUNTRY Houston, TX 77054-4010	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

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 are not established, written and followed.

Specifically,

A. Smoke studies performed under dynamic conditions were inadequate to verify the operators or activities do not affect the HEPA unidirectional airflow in the ISO 5 laminar air flow workbench (LAFW) where sterile injectable drugs are compounded. We reviewed videos of smoke studies conducted in January 2018 and July 2018. Studies under dynamic conditions in January 2018 showed a technician injecting a solution into an IV bag in the ISO 5 LAFW. Additionally, studies in July 2018 showed a technician waving their hands and arms around to simulate dispensing motions. No production equipment was present inside each of the ISO 5 LAFWs and no routine production was simulated in both instances. **This is a repeat observation.**

B. Your firm's media fills (MFs) are not being simulated under worst-case activities and conditions that provide a challenge to aseptic operations. On 8/14/18, we reviewed MFs records dated 3/2/18 and found they were not performed under the most stressful and challenging conditions. Specifically, although MFs conducted in 3/2/18 simulated aseptic production into glass vials, IV bags, and syringes, your firm only

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simulated the production of (b)(4) aseptic units per container closure presentation (a total of (b)(4) aseptic units and (b)(4) controls). SOP 9.010 "Media Fill for High Risk Compounding" (Revision 2) is inadequate in that the SOP procedure does not closely simulate your firm's aseptic operations. **This is a repeat observation.**

C. On 8/13/18, we observed the aseptic compounding of Trimix 150 mg/5 mg/50 mcg Lyophilized Powder, lot 08132018:86 and Trimix 150 mg/10 mg/100 mcg Lyophilized Powder, lot 08132018:55. We observed the following deficiencies in aseptic practice:

1. We observed both technicians (b)(6) and (b)(6) blocking the (b) (4) unidirectional HEPA air flow (first clean air) to the open sterile product vials with their right hands and arms while dispensing sterile compounded solution into each vial.

2. We observed technician (b)(6) blocking the (b) (4) unidirectional HEPA air flow (first clean air) with her right hand and arm while partially stoppering the filled product vials.

3. We observed both technicians (b)(6) and (b)(6) working in the ISO 5 LAFW with bare skin exposed around their right cheek areas.

4. We observed technician (b)(6) while working in the ISO 5 LAFW, lean her entire upper body inside the ISO 5 LAFW. We also observed the same technician press her chest against the edge of the ISO 5 LAFW, rested both elbows and lower arms on the LAFW surface, and with her upper body leaned inside the ISO 5 LAFW.

5. With partially stoppered vials still staged inside the ISO 5 LAFW, we observed technician (b)(6) lean her upper body inside the LAFW and over the partially stoppered vials to wipe clean the interior of the LAFW (including the back panel, both side panels, the workbench surface, and the IV hanger bar) with sterile (b) (4)

6. Partially stoppered vials were transported from the ISO 5 LAFW to the (b) (4)

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without ISO 5 protection. The vials were exposed to the ISO 7 quality air during transfer. Specifically, the distance between Hood (b) (4) where Trimix lot 08132018:55 was compounded, and the (b) (4) was about 6 feet. The distance between Hood (b) (4) where Trimix lot 08132018:86 was compounded, and the (b) (4) was about 10 feet.

7. We observed technicians (b) (6) and (b) (6) spray sterile gloves with sterile (b) (4) but did not allow the (b) (4) to dry before returning to work inside the ISO 5 LAFW.

8. Items were sparsely sprayed with sterile (b) (4) without a wipe down before introducing them inside the ISO 5 LAFW during both the non-sterile part and the sterile part of the compounding operations.

9. We observed both technicians (b) (6) and (b) (6) come out of the ISO 7 Clean Room, pass through the ISO 7 prep room, then come to the ISO 7 Ante Room (where gowning occurs) to collect and retrieve sterile items (i.e., sterile tubings, (b) (4), utensils) and non-sterile raw materials and equipment (i.e., (b) (4) (b) (4) (b) (4) IV bag, (b) (4) We observed both non-sterile and sterile items touch their sterile overalls. The technicians later returned to the ISO 7 clean room resuming sterile compounding operations without re-gowning.

D. Your firm is using non-pharmaceutical grade component in the compounding of sterile drugs. For example: the formulation for sterile, lyophilized Trimix drug products includes the component "(b) (4) USP"; however, a non-pharmaceutical grade component, (b) (4) was observed to be used as a substituted for "(b) (4) USP" in Trimix lots 08132018:86 and 08132018:55 on 8/13/18.

OBSERVATION 2

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The quality control unit lacks the responsibility and authority to approve and reject all in process materials and drug products.

Specifically,

A. Your firm failed to reject batches of sterile drug product that did not meet specifications for potency. Your firm uses (b) (4) (b) (4) for HCG potency testing with acceptance criteria of (b) (4)% to (b) (4)%. Also, the potency testing of Lipo MIC-12 has acceptance criteria of (b) (4)% to (b) (4)%. Examples of drug products still within expiry that either failed or are without potency testing were released and distributed include but are not limited to:

Lot Number	Drug Product	Test Failed	% Potency
07192018:13	HCG 5000 IU	No Potency Result	NA
06262018:00	HCG 5000 IU	Potency	58.7
06072018:03	HCG 12,000 IU	Potency	77.6
07162018:84	HCG 4000 IU	Potency	38.7
06192018:36	HCG 4000 IU	Potency	53.8
05082018:39	HCG 5000 IU	Potency	66.4
08012018:46	HCG 5000 IU	Potency	36.5
07192018:64	HCG 12,000 IU	No Potency Result	NA
06192018:36	HCG 4000 IU	Potency	53.8
03212018:27	Lipo MIC-12	Potency	78.5, 79.7, 80.8 (3 repeat testing)
07302018:65	Lipo MIC-12	Potency	89.0

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B. Your firm does not perform 100% visual inspection of all sterile drug products prior to release. With the exception of Testosterone products which are 100% inspected; visual inspection is performed on randomly selected units of each batch. Additionally, visual inspections are performed without the use of contrasting backgrounds and a calibrated light source. Also, your firm has no documented training or qualification for technicians or pharmacists who routinely perform visual inspection. On 8/20/18, Owner/Pharmacist JCD was observed performing visual inspection for Testosterone lot 08162018:63/A using a (b) (4) light. He was observed to pick up two vials at a time, inverted the vials once, more if necessary, and held it up to the light to inspect for "floaters".

C. Your procedure for the release of sterile drug products is deficient. Your current practice for the release of (b) (4) and (b) (4) sterilized drugs are subject to a third-party laboratory (b) (4)-day sterility tests for batches over (b) (4) units; however, your firm do not always review testing results prior to distribution of these (b) (4) and (b) (4) sterilized drugs.

D. Your firm failed to reject drug products that failed (b) (4) test. For example: Your (b) (4) Log Sheet shows (b) (4) result of (b) (4) for the (b) (4) that was used to (b) (4) Glutamine injection, lot 07182018:49 (Expiry 9/16/18). Additionally, your firm did not send this lot for sterility testing. Glutamine injection, lot 07182018:49 was distributed.

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OBSERVATION 3

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

Specifically,

Your firm's environmental monitoring (EM) and personnel monitoring (PM) of the IOS 5 areas are inadequate. For example,

A. On 8/13/18, we observed the aseptic compounding of Trimix 150 mg/5 mg/50 mcg Lyophilized Powder, lot 08132018:86 and Trimix 150 mg/10 mg/100 mcg Lyophilized Powder, lot 08132018:55. Your firm did not perform either surface monitoring or viable active air monitoring of the ISO 5 LAFWs (b) (4) sterile drug product was compounded. The EM performed (b) (4) includes the passive air sampling of (b) (4) inside the ISO 5 LAFW. We also observed the (b) (4) placed in the (b) (4) where no compounding activities occurred.

B. On 8/13/18, we observed technicians (b) (6) and (b) (6) sampled only one of the gloves, not both gloves, using (b) (4) at the (b) (4).

C. Viable active air sampling is only being performed under static conditions every (b) (4) during the clean room certification by an outside vendor.

D. Your firm performed viable surface monitoring of randomly selected locations in the ISO 7 areas on a (b) (4) basis. However, your firm lacks written descriptions, justifications, and maps for how each EM location was determined.

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E. Your firm has not established alert level limits or provided scientific justification for action level limits for your EM and PM program.

F. The magnehelic gauges used to monitor the positive air pressure differentials of the ISO 5 LAFW to the ISO 7 Clean Room have not been calibrated and are not on a routine preventative maintenance program.

G. During the inspection, we found dried up and cracked EM (b) (4) plates inside your firm's incubator; (b) (4) Model (b) (4) Your firm lacks documented studies to show damaged (b) (4) media can support the growth of microorganisms. For example: On 8/14/18, we observed two (b) (4) contact plates inside the incubator each labeled "Bottom Shelf supply cart ante, 8.2.18" and "Floor ® sink, 8.2.18". We noticed both (b) (4) appeared dry and have shriveled away from the edge of the plates. Also, on 8/17/18, we found operator fingertips (b) (4) contact plates for Trimix Lot 08132018:86 and Lipo-Mic 08132018:75/A in the incubator. We observed both (b) (4) plates appeared dry and cracked. Additionally, on 8/17/18, we observed (b) (4) passive air sampling plate for Trimix Lot 08132018:86 appeared dried up and also shriveled away from the edge of the plate. No microbial growth was observed on the above (b) (4) media.

This is a repeat observation.

OBSERVATION 4

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

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Specifically,

Your firm did not test high-risk compounded drug product batches that were less than (b) (4) units for endotoxin and potency. Unvalidated in-house method is used for sterility testing. For example: drug product batches under (b) (4) units not tested prior to release including but not limited to Trimix Alprostadil/Phentolamine/Papavarin lots 08062018:52 and 08012018:08. **This is a repeat observation.**

OBSERVATION 5

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

Specifically,

E. Your firm does not test the preservative content in batches at time of release. Majority of your firm's compounded drug products contain (b) (4) ; a preservative. Examples of drug products contain (b) (4) are Trimix, Testosterone, and Lipo MIC-12.

F. Your firm lacks dissolution testing for Testosterone pellets to ensure the pellets do not immediately dissolve, that they remain integral, the active ingredient is released appropriately and at an acceptable rate. Additionally, your firm do not have method suitability for testing potency for your Testosterone pellets.

G. Your firm does not ensure the pH of the finished product meets written

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specification prior to release. For example:

a. Testosterone Cypionate/Proprinate lot 02272018:63/A was labeled to contain pH of "5.5 to 7.5"; however, there is no record to show the pH was measured for this product prior to release.

b. On 8/17/18, I reviewed batch record of Trimix Lot 08012018:08 Alprostadil / Phentolamine / Papavarin, 10 ML 40 MCG/1 MG/30 MG Injectable with BUD of 9/30/18. This batch was released on 8/1/18. The batch instruction specifies the pH of solution should be between (b) (4) and (b) (4); however, the firm's pH of solution was documented as 3.26. Pharmacist JCD stated that (b) (4) if the solution pH is (b) (4) and it was his professional judgement to determine pH 3.26 is acceptable.

OBSERVATION 6

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,

There is no assurance you have control over the lyophilization of sterile drug products produced at your facility. For example:

A. There is no assurance the lyophilization system utilized by your firm is suitable for compounding of drug products. The User's Manual for

(b) (4) ; model (b) (4) and (b) (4) ; model (b) (4) describes the intended use which is for laboratory use to facilitate the lyophilization process.

B. Your lyophilization process for processing of sterile drug product is deficient. Your firm utilized a "(b) (4) freeze-drying system by (b) (4) (b) (4) . After (b) (4) the vials are (b) (4) (b) (4) . Your firm processed sterile lyophilized drugs using this process from October 2016 to April 2018.

C. Your firm did not perform 100% visual inspection of your lyophilized, sterile drug products prior to distribution. On 8/17/18, three of (b) (4) lots of released lyophilized product stored in your refrigerator and freezer were observed to be collapse, cracked, or shrunk. These released lyophilized, sterile drug products were:

1. Trimix 150 mg/5 mg/50 mcg, lot 04042018:44;
2. Trimix 150 mg/10 mg/100 mcg, lot 06122018:06; and
3. Sermorelin-Ipamorelin 18 mg/15 mg, lot 07272018:31.

D. Your firm did not adequately validate your lyophilization process for each lyophilized drug product prior to commercial production to ensure your drug production process yield consistent results. Changes and adjustments to the

lyophilization cycles settings were determined by a pharmacist using their professional judgement and performed as needed. For example:

1. On 4/10/18, your firm reported variations in product volume as the root cause for the lyophilization failure for Trimix lots "032018:83" and 03292018:61. Your firm subsequently adjusted the program settings by using a standard set point of (b) (4) °C. Additionally, your record states for "additional failures we will follow the manufacturers guideline to set the (b) (4) (b) (4) ."

2. On 5/14/18, your firm reported the final phase of (b) (4) being (b) (4) " as the root case for lyophilization failure for HCG lot 05082018:39. Your firm subsequently implemented the maximum final (b) (4) temperature not to exceed (b) (4) °C.

3. On 5/21/18, Trimix lot 05212018:44 failed lyophilization. Your investigation determined the need to adjust the (b) (4) and (b) (4) (b) (4). Your records states a pharmacist directed the technicians to run new cycle specifications.

E. The recording device on your lyophilizer is deficient. The digit printout of the lyophilization cycle for Trimix 750 mg/25 mg/250 mcg, lot 08092018:93 provided for review on 8/14/18 shows the processing of the lot from 8/14/18 at 4:03 to (b) (4) at (b) (4).

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Your production logs for lyophilized products show the production of (b) (4) lots of lyophilized products between 10/4/16 and 8/21/18.

OBSERVATION 7

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

Specifically,

A. The cleaning agents for cleaning of the sterile drug production area are deficient. For example:

1. There is no expiration date on the sterile (b) (4) prep pads that are used in the ISO 5 LAFWs. On 8/13/18 and 8/20/18 operators were observed to use sterile (b) (4) prep pads on the IV bags in the LAFWs.

2. Non- sterile disinfectants (b) (4) and (b) (4) Cleaner and non-sterile nonwoven (b) (4) dry wipes are used to clean the ISO 7 clean room furniture and equipment, including but not limited to: tables, chairs, carts, mixer, (b) (4) and outside of the (b) (4) These items are then cleaned with sterile (b) (4) and non-sterile wipes.

B. The cleaning of the sterile drug production suite is deficient. For example:

1. On 8/15/18, we observed fiber-like material hanging from the HEPA filter housing of Hood (b) (4) (b) (4) model (b) (4) . You produced

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(b) (4) vials of LIPO MIC-12, lot 08132018:75/A on the (b) (4) model (b) (4) on 8/15/18.

2. Your firm lacks justification for conducting both the non-sterile part and the sterile part of the compounding operations in the same ISO 5 LAFW. On 8/13/18, during the production of Trimix 150 mg/5 mg/50 mcg Lyophilized Powder, lot 08132018:86 and Trimix 150 mg/10 mg/100 mcg Lyophilized Powder, lot 08132018:55, we observed in each of the ISO 5 LAFW, technicians (b) (6) and (b) (6) weighed out non-sterile (b) (4) and (b) (4). Afterwards, in the same ISO 5 LAFWs, both technicians continued to perform the sterile part of the compounding operation by (b) (4) the compounded drug solution, dispensing them into sterile vials, and partially stoppered them without first thoroughly cleaning and disinfecting the LAFWs.

3. On 8/13/18, Technician (b) (6) was observed using a non-sterile nonwoven (b) (4) dry wipes with sterile (b) (4) to clean inside the (b) (4) (b) (4); model (b) (4) prior to loading partially stoppered vials of Trimix 150 mg/5 mg/50 mcg, lot 08132018:86 and Trimix 150 mg/10 mg/100 mcg, lot 08132018:55 for lyophilization.

4. You firm did not establish contact time requirements for the sterile disinfectants (b) (4) and (b) (4) that are used in the ISO 5 LAFWs. SOP 5.003 "Laminar Airflow Hoods – Use, Certification, and Cleaning" (no revision, no date) only mentions the use of lint free wipe and sterile (b) (4) for the cleaning of ISO 5 LAFW. SOP 5.003 does not describe disinfectant contact time

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requirements. The manufacturer's directions for use for (b) (4) require a minimum of (b) (4) minutes contact time. The (b) (4) technical data sheet does not specify a contact time.

This is a repeat observation.

OBSERVATION 8

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

Specifically,

Your firm's (b) (4) and (b) (4) sterilization cycles have not been validated to ensure the cycles are capable of producing sterile compounded drug products. On 8/14/18, we reviewed (b) (4) validation records dated 6/8/18. We also reviewed (b) (4) calibration reports dated 1/25/18. We found only the temperature mappings for both equipment and the (b) (4) for the (b) (4) were performed. Your firm did not conduct sterilization cycle validation specific to compounded drug products. The (b) (4) ((b) (4)) is used to (b) (4) sterilize Phenol 5%, 7%, and all rubber stoppers and stopper caps. Additionally, the (b) (4) ((b) (4) (b) (4)) is used to sterilize Testosterone Cypionate and Testosterone Cypionate/Proprinate bulk drug product. On 8/13/18, technicians were observed to place leftover rubber stoppers from compounding into a new (b) (4) intended for re-sterilization in the (b) (4) The firm did not provide scientific justification on how many times rubber stoppers can be re-sterilized. **This is a repeat observation.**

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OBSERVATION 9

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

Specifically, non-smooth areas that are difficult to clean were observed in the clean room. For example:

A. On 8/15/18, apparent rust inside a grooved area measured approximately two inches long on each side where the leg connects to the work surfaces was observed on the front right side of the (b) (4) LAFW, Hood (b) (4) (b) (4) model (b) (4).

B. On 8/15/18, non-smooth welded surfaces were observed inside the LAFWs where the legs connect to the work surface on Hoods (b) (4) and (b) (4) (b) (4) models (b) (4) and (b) (4), respectively.

C. On 8/15/18, apparent chips and non-smooth surfaces were observed at the lip of the top and middle tray inside the (b) (4) (b) (4); model (b) (4).

OBSERVATION 10

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

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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	8/13/2018-8/28/2018* FEI NUMBER 3011043554

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Luis R. De Leon, Pharm.D., Owner and Pharmacist-in-Charge	
FIRM NAME Pharm D Solutions, LLC	STREET ADDRESS 1304 S Loop W
CITY, STATE, ZIP CODE, COUNTRY Houston, TX 77054-4010	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

A. Your firm lacks environmental monitoring excursion investigations. For example, your firm does not identify a probable root cause and does not assess product impact.

1. On 3/8/17, a swab sample was collected from your firm's LAFW. Examination on 3/20/17 showed 9 cfus were recovered from the LAFW. From 3/8/17 to 3/20/17, (b) (4) batches of sterile injectable products were compounded.

2. On 1/30/17, a swab sample and a viable passive air sample were collected from your firm's LAFWs. Examination on 2/2/17 showed 1 cfu was recovered from each of the samples. From 1/30/17 to 2/2/17, (b) (4) batches of sterile injectable products were compounded.

B. Your firm lacks investigations for yeast and mold species recovered from your firm's clean room facility. Your firm uses (b) (4) to monitor ISO 7 areas for yeast and mold growth. However, your firm lacks procedure in the monitoring, identification, and acceptance criteria for yeast and mold species recovered from the clean room facility.

1. On 6/9/16, 3 cfus were recovered from your firm's ISO 7 Ante Room sink floor.

2. On 4/18/16, 3 cfus were recovered from your firm's ISO 7 Ante Room floor.

OBSERVATION 11

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

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On 8/13/18, we observed the aseptic compounding of Trimix 150 mg/5 mg/50 mcg Lyophilized Powder, lot 08132018:86 and Trimix 150 mg/10 mg/100 mcg Lyophilized Powder, lot 08132018:55. We observed the following deficiencies.

A. We observed both technicians (b) (6) and (b) (6) using bare hands to don sterile clean room garments including sterile mask, sterile goggles, and sterile overalls in the ISO 7 Ante Room.

B. Sterile gowns and goggles are re-used in the same day. We observed technicians (b) (6) and (b) (6) hung goggles and overalls in the ISO 7 Ante Room when exiting the ISO 7 Clean Room facility. They re-donned the same goggles and overalls upon returning to the ISO 7 Clean Room resume aseptic compounding of sterile injectable drug products.

C. We observed exposed skin on the right cheek areas of both technicians. There was no mirror in the Ante/Gowning room to check if gowning is adequate.

D. We observed discoloration on the frame of a pair of sterile goggle and the protective lense was loose and shifted from the frame. Clean room goggles were purchased non-sterile and (b) (4) prior to use. However, your firm did not validate how many times each pair of goggles can be (b) (4)

OBSERVATION 12

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

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A. The beyond use dates (BUDs) of your sterile drug products are not determined by stability indicating assays. Your current practice is to assign BUDs by using information from literatures, (b) (4) and (b) (4) (online journal). Your sterile injectables have BUDs up to 365 days. For example: You have not performed stability testing to evaluate storage condition, sterility and potency for the labeled claim of BUD of 180 days in refrigeration for lyophilized Sermorelin drug products. On 8/17/18, all of your Sermorelin drug products including Sermorelin/Ipamorelin 18 mg/15 mg Lyophilized Powder, lot 07272018:31; expiry 1/23/19 was observed stored in the freezer, not in the refrigerator.

B. The BUD of sterile drug products exceeded the expiry of a raw material component used in production. For example: Raw material component Papaverine 70 mg/mL Stock Solution; expiry 10/4/18 was formulated into Trimix Papaverine/Phentolamine/Alprostadil 30 mg/1 mg/10 mcg Powder, lot 06062018:79; with expiry of 12/3/18.

OBSERVATION 13

Procedures designed to assure that correct labels, labeling and packaging materials are used for drug products are not written and followed.

Specifically, your labeling operation including the issuance and approval of labels, labeling activities, reconciliation, reconditioning and examination of packaged and labeled products is deficient to ensure correct labels are applied on products and to prevent mix-ups. For example:

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A. Finished product labels that were issued and approved by a pharmacist had inaccurate labeling information. The labels for LIPO-MIC W/ Methylcobalamin, lot 08132018:75/A that were printed, approved, and issued by Owner and Pharmacist JCD on 8/16/18 had inaccurate lot number "08142018:00" and production date "8/14/2018".

B. Finished product vials that were stored with released products in the refrigerator were observed with inaccurate labeling. On 8/16/18, 16 of (b) (4) vials of LIPO-MIC W/ Methylcobalamin, lot 08132018:75/A were observed to be labeled with inaccurate lot numbers and production dates.

C. Reconditioning activity was performed by a technician without first notifying a supervising pharmacist. On 8/16/18, Technician (b) (6) was observed to be removing the labels of (b) (4) product vials by peeling the labels off the vials and partially submerging the vials in a (b) (4) solution without first notifying a pharmacist.

D. Your (b) (4) system authorizes personnel with a pharmacist user role to generate and print product labels; however, your current practice allows technicians to access the pharmacist account, under "(b) (4) ", to generate and print product labels which are then applied on product containers.

E. Review of your records show that your firm does not always record batch activities and perform reconciliation of product labels at the time the activities took place. During the inspection, your Compliance Officer was observed to apply and sign off on a product label on a reconciliation form to provide to an inspector for review.

F. Your firm does not record activities relevant to the issuance, approval and reconciliation of carton labels that are apply on your drug products. Additionally, your firm does not document activities relevant to the packaging of drugs into cartons.

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G. Your firm does not document reconditioning activity. For example, your firm received (b) (4) returned vials in response to your product recall D-0426-2017 due to misbranding. Your firm replaced the product labels and subsequently distributed the recalled products; however, there is no record to show when the reconditioning activity took place, who approved and issued the new label that was applied on the products. Additionally, there is no label specimen of the new label your firm applied on the recalled product.

OBSERVATION 14

Batch production and control records do not include complete labeling control records, including specimens or copies of all labeling used for each batch of drug product produced.

Specifically,

A. Your firm does not always include a label specimen in your batch records for the label applied on primary drug containers. For example, you did not have a label specimen for the following drugs:

1. Sermorelin/GHRP-2/GHRP-6 Mannitol 9 mg/9 mg/9 mg 300 mg, lot 06252018:30

2. Trimix Papaverine/Phentolamine/Alprostadil 30 mg/1 mg/10 mcg Lyophilized Power, lot 06122018:31.

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B. Your firm did not retain label specimens for the labels applied on the secondary drug containers.

This is a repeat observation.

OBSERVATION 15

The labels of your outsourcing facility's drug products are deficient.

Specifically,

A. The statement, "This is a compounded drug" is not on all of your drug product labels. Examples of drug product labels that do not contain this statement are:

1. Testosterone Cypionate 200 mg/mL 30mL Injectable, lot 08062018:67A.
2. Testosterone Cypionate/Proprinate 200 mg/10mg/1mL 30mL 200 mg/10mg/1mL Injectable, lot 02272018:63/A.
3. Phenol 7% and Glycerin Aqueous Solution 10 mL 1432-10 7% Injectable, lot 08082018:86.
4. Human Chorionic Gonadotropin/0.3 gm Mannitol Lyophilized Powder, lot 08062018:96.
5. Sermorelin/Ipamorelin 18 mg/15 mg Powder, lot 03272018:75.
6. Tri-Mix XL 150 mg/10 mg/100 mcg Lyophilized Powder, lot 06122018:06.

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This is a repeat observation.

B. The quantity or volume is not on all of your drug product labels. Examples of drug product labels that do not contain the quantity or volume are:

1. Human Chorionic Gonadotropin/0.3 gm Mannitol Lyophilized Powder, lot 08062018:96.
2. Sermorelin/Ipamorelin 18 mg/15 mg Powder, lot 03272018:75.
3. Tri-Mix XL 150 mg/10 mg/100 mcg Lyophilized Powder, lot 06122018:06.
4. Lipo-Mic with Methylcobalmin Injectable, lot 08132018:75/A, lot 08132018:75/A.

OBSERVATION 16

Your outsourcing facility did not submit a report to FDA identifying the drugs compounded during the previous six month period.

Specifically,

Your firm did not submit a report in June 2018 that identify drug products compounded from January 2018 to June 2018. Some of the sterile compounded drugs produced between January 2018 and June 2018 were:

- APOMORPHINE 12MG TROCHE 12MG TROCHE
- BACTERIOSTATIC WATER FOR INJECTION 10 ML 10 ML INJECTABLE
- B-COMPLEX B-1, B-6, B-3, B-12, B-5 INJECTABLE

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- BI-MIX PAPAVERINE / PHENTOLAMINE (LYO) 150 MG/5 MG POWDER
- CAFFEINE AND SODIUM BENZOATE INJECTION 125 MG/125 MG/ML INJECTABLE
- EPINEPHERINE 1 MG/1ML 3 ML 1MG/ML INJECTABLE
- HCG LYOPHOLIZED 5000 IU INJECTABLE
- LIPO MIC-12 COMPOUND INJECTABLE
- METHYLCOBALAMIN INJECTABLE in 1 MG/ML 10 ML 1 MG and 1 MG/ML 30 ML 1 MG
- PHENOL 5% AND GLYCERIN AQUEOUS SOLUTION 10 ML 1431-10 5% INJECTABLE
- SERMORELIN / IPAMORELIN 18 MG/ 15 MG POWDER
- SILDENAFIL / APOMORPHINE TROCHE 150 MG/12 MG TROCHE
- TESTOSTERONE 200 MG/ML GRAPESEED OIL 30 ML 200 MG/ML INJECTABLE
- THYROID 15 MG CAPSULE PINK/AQUA BLUE 15 MG CAPSULE
- TRIMIX BM3 PAPAVERINE 60 MG/PHENTOLAMINE 4 MG INJECTABLE

This is a repeat observation.

***DATES OF INSPECTION**

8/13/2018(Mon), 8/14/2018(Tue), 8/15/2018(Wed), 8/16/2018(Thu), 8/17/2018(Fri), 8/20/2018(Mon), 8/21/2018(Tue), 8/23/2018(Thu), 8/24/2018(Fri), 8/28/2018(Tue)

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