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	4/29/2019-6/12/2019* FEI NUMBER 3007271263

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Vern A. Allen, CEO

FIRM NAME	STREET ADDRESS
Premier Pharmacy Labs Inc	8265 Commercial Way
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Weeki Wachee, FL 34613-4511	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

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically,

A. **Your firm failed to investigate the potential sources or causes of particles, fibers, and other defects observed during the visual inspection of finished drug products that were intended to be sterile.** A review of the particulate rejection logs from 2019 showed at least (b) (4) out of (b) (4) batches were identified with over (b) (4) units rejected due to cracks, leaks, fibers, or other defects. Examples include:

Drug Product	Lot number	Batch Size	Rejected Units	Defect Type	Units Distributed
Orphenadrine Citrate 30mg/ml 1ml sterile single dose syringe	ORP031119KMSECA	(b) (4)	(b) (4) (b) (4)	fibers black speck; foreign object	out of (b) (4) units released (b) (4) units distributed

AMENDMENT 2

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EMPLOYEE(S) SIGNATURE
Joanne E King, Investigator
Djamila Harouaka, FDA Center Employee or Employee of Other Federal Agencies

X Joanne E King Investigator Signed By 1300174867 Date Signed 07-25-2019 10 42 34

DATE ISSUED
7/25/2019

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Succinylcholine Chloride 20mg/ml sterile syringe	SUC030719SVEC	(b) (4)	(b) (4) (b) (4)	cracks; leaking black speck; foreign object	out of (b) (4) units released (b) (4) units distributed

B. **Your firm failed to thoroughly investigate sterility test failures and to identify the contaminating organism**. For example, sterility failures for the following pre-filled syringe lots:

i. MOR022718IJDSC morphine sulfate 2 mg/ml for injection 1 ml in 3 ml syringe on 3/6/2018.

ii. MOR022718IJDSD morphine sulfate 2 mg/ml for injection 1 ml in 3 ml syringe on 3/6/2018.

iii. MOR032318LMDSC morphine sulfate 2 mg/ml for injection 1 ml in 3 ml syringe on 3/29/2018.

iv. HYD032218SVDSC hydromorphone HCl 1mg/ml for injection 1 ml in 3 ml syringe on 4/5/2018.

v. MOR032618IJDSA morphine sulfate 4 mg/ml for injection 1 ml in 3 ml syringe on 4/5/2018.

As part of this investigation (CAPA 18003) you did not culture and identify the objectionable organisms from the original sample or from any additional samples. These pre-filled syringes were dosed from (b) (4) (b) (4) derived from (b) (4) master non-sterile bulk lots. CAPA 18003 did not assess sources of contamination recovered in the drug preparation environment (for example see D below) or in components such as excipients, API, bulk non-sterile, bulk sterile sub-lots, or syringes. By failing to identify the contaminating organism(s) you could not assess the origin of these sterility failures and therefore, potentially failed to implement adequate corrective and preventive actions. You determined that the pre-filled syringes and associated locking caps, not designed as extended storage container closures, were the root cause. However, your investigation into the referenced sterility failures was inadequate, therefore your root cause determination may be unfounded. This investigation went on from 3/7/2018-4/12/2018 while at least (b) (4) of drug products were released and distributed by your QCU.

AMENDMENT 2

C. **Your firm failed to investigate the root cause of potency test failures.** Your firm repeatedly reprocessed batches or modified the drug product formulations without determining the root cause of potency failures. A review of the Quality Related Event (QRE) log showed that between January 2017 and April 2019, approximately (b) (4) lots of drug products were reprocessed and/or reformulated due to out of specification test results for potency. Examples include:

Date	Product	Event	Description
05/04/17	Glycopyrrolate 0.2mg/ml lot GLY042517SVAB	in-process potency OOS **QRE 17039**	The measured potency was 108.1% which was outside the specification range (b) (4) . The formula worksheet was reviewed, and it was noted the formula is designed to deliver (b) (4) of glycopyrrolate. The previous two batches prepared were within specification. The formula was modified to deliver (b) (4) of the active ingredient and the lot was reprocessed.
07/25/17	Trimix 40mcg/30mg/2mg/ml lot PPP071217LMDS	in-process potency OOS **QRE 17066**	The measured potency of prostaglandin was 122.1% which was outside the specification range (b) (4) The formulation was designed to deliver (b) (4) of prostaglandin and (b) (4) of phentolamine. The formulation was modified to deliver (b) (4) prostaglandin and the batch was reprocessed.
01/30/19	Trimix 10mcg/30mg/1mg/ml lot PPP011019SVVA	in-process potency OOS **QRE 19012**	Prostaglandin potency was measured at 120.9% (specification (b) (4) The bulk drug was sent for destruction. No investigation was performed to determine the possible root cause.

D. **Your firm failed to thoroughly investigate environmental monitoring failures**. Your firm failed to identify the potential sources or root causes of recurrent contamination events and did

not extend the investigations to determine whether other batches (for example see B above) of drug product intended to be sterile might have been impacted. For example, per CAPA 18004 (05/23/2018), Burkholderia species were recovered from multiple settle plates (passive air) and one fingertip sample collected in ISO 5 Laminar Air Flow (LAF) hoods between 03/22/18 and 05/29/18 during production of non-sterile bulk lots or sterile sub lots of drug products intended to be sterile.

Date	Drug Product	Lot number	LAF Hood	CFU Recovered	Species ID
03/22/18	Chlorpromazine 25mg/ml	Non-sterile bulk lot (b) (4)	(b) (4)	1 CFU (settle plate)	Burkholderia contaminans
04/10/18	Ephedrine Sulfate 5mg/ml	Non-sterile bulk lot (b) (4)		1 CFU (settle plate)	Burkholderia contaminans
05/14/18	Potassium Chloride 2mEq/ml	Non-sterile bulk lot (b) (4)		5 CFU (settle plate)	Burkholderia cepacia
05/15/18	Morphine Sulfate 2mg/ml	Sterile sub lots (b) (4) and (b) (4)		2 CFU (settle plate)	Burkholderia contaminans
05/23/18	Ephedrine Sulfate 5mg/ml	Non-sterile bulk lot (b) (4)		1 CFU (settle plate)	Gram negative rod; no further ID
05/29/18	Potassium Chloride 2mEq/ml	Non-sterile bulk lot (b) (4)		1 CFU (fingertip sample)	Burkholderia cepacia

Your investigation established that the contamination was not localized to a specific laminar flow hood, operator, or product. However, the investigation was not extended to a review of potential contamination in the cleanrooms or from other sources. The investigation was not

extended to determine whether other batches of drug products intended to be sterile may have been impacted.

* Out of the (b) (4) vials of Potassium Chloride lot (b) (4) that were released, (b) (4) vials were distributed to a customer on 05/11/2019~~8~~.

E. **Your firm failed to thoroughly investigate complaints**. Your pharmacist received a call-in complaint on 1/6/2017 from a clinic/client after using glycerin 72 % in 20 ml vials for injection. The complaint was concerning 4 cases of minor hematuria (blood in urine) after procedures using glycerin 72 % in 20 ml vials for injection prepared by your firm over the course of 4 months. You identified that two lots of glycerin 72 % in 20 ml single dose vials (SDV) for injection were sent to this customer at two separate locations. Specifically, the customer was sent (b)(4) vials of GLY083016MMAB and (b)(4) vials of GLY121416LJKT for a sub-total of (b)(4) vials to each location. This totals (b) (4) vials of glycerin 72 % in 20 ml vials for injection. The referenced report was assigned the quality related event (QRE) number 17003 and was logged as a complaint in your firm's log. There was no documentation related to an investigation into the lots used by each patient. No complaint samples were collected and no retain samples were documented as examined. Each patient was also not identified as a separate complaint and investigated independently. An evaluation was not made or documented to establish if hematuria reactions were unexpected adverse events or if the primary focus of your investigation was on the aspects of the formulation and not injury to the patients. The complaint was closed on 2/24/2017 by your quality control unit.

This is a repeat observation from the 2014 and 2016 inspections.

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OBSERVATION 2

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

Specifically,

(1) HEPA filters in ISO 5 hoods used to prepare drug products purported to be sterile appeared to be visibly stained. On 05/01/2019, I (JEK) observed the preparation of the drug product bulk orphenadrine citrate 30 mg/ml lot (b) (4) and the sterile sub-lots (b) (4) and (b) (4) in Hood (b) (4) in cleanroom (b) (4) (CR (b) (4) The HEPA filter in (b) (4) appeared to have stains and discoloration. I (JEK) also observed what appeared to be stains on the HEPA filter in Hood (b) (4) in cleanroom (b) (4)

(2) During production of orphenadrine citrate 30mg/ml bulk lot (b) (4) and sub-lots (b) (4) and (b) (4) I (JEK) observed open air vents between CR (b) (4) and the unclassified sterile preparation area. I (JEK) also observed open vents in ISO 7 cleanrooms (b) (4) and (b) (4) hat opened to unclassified areas. These vents were not appropriate for their intended use.

(3) Smoke studies performed in February 2019 were deficient in that the camera angle or the amount of visible smoke made it difficult to visualize the air flow patterns videotaped under dynamic conditions. For example, insufficient smoke was introduced over the vials being filled in biosafety cabinet (b) (4) (BSC (b) (4) Insufficient smoke was introduced into (b) (4) to permit visualization of the airflow patterns while dosing syringes. **This is a repeat observation from the 2016 inspection.** Furthermore, the February 2019 smoke studies demonstrated that air arced upward as it flowed out of hoods (b) (4) and (b) (4) The irregular delivery of smoke into the ISO 5 area in CR (b) (4) makes it difficult to ascertain the airflow pattern.

(4) The most recent certification of the cleanrooms on 02/14/19-02/15/19 was performed at rest. Certification of the ISO 5 zone in cleanroom (b) (4) was also performed at rest.

AMENDMENT 2

(5) The ISO 5 zone in cleanroom (b) (4) (CR (b) (4) is not fully covered by HEPA filters in the ceiling. The ISO 5 zone is separated from the ISO 7 CR (b) (4) by (b) (4) (b) (4) (b) (4) the stainless-steel table on which the (b) (4) filling machine ((b) (4)) rests. An operator must enter the ISO 5 zone to set up the filling machine (install stopper hopper, filling needle, tubing set), to load trays of sterile vials for filling, to perform interventions during filling, and to remove trays of filled and stoppered vials. Sterile vials are opened in the ISO 5 area.

(6) On 05/20/2019, I (DH) observed (b) (4) classified and unclassified areas: (a) (b) (4) the ISO 7 cleanroom (b) (4) and the unclassified buffer room containing the sink and dishwasher used to clean glassware. This (b) (4) is used to bring items into the cleanroom; (b) (b) (4) the ISO 7 cleanroom (b) (4) (CR (b) (4) and the unclassified sterile prep area is used for finished drug products exiting CR (b) (4) This cleanroom is used to enter the hazardous chemical preparation room, which is maintained at negative pressure relative to CR (b) (4) (c) (b) (4) the ISO 7 cleanroom (b) (4) CR (b) (4) and unclassified visual inspection area. This (b) (4) is marked "Do Not Use" and is blocked by shelving in the unclassified room. All (b) (4) do not have HEPA filtered air supplies.

(7) A damper was installed in the door between the ISO 8 anteroom and unclassified buffer room containing the sink. The damper consists of a hole approximately 15cm in diameter with a flap.

(8) In-house test with a (b) (4) performed in November 2018 demonstrated stagnant air near the ceiling of the ISO 8 anteroom (gowning room). Between 01/05/2018 and 04/29/2019, fungal and spore-forming microbes were isolated from active air samples collected in the anteroom including Aspergillus astroafricanus, Aspergillus fumigatus, Alicyclobacillus acidoterrestris, and Geobacillus toebii. As part of a corrective action, vents and door sweeps were added to the bottom of the door between the anteroom and unclassified buffer room. In January 2019 a fan was installed to increase airflow through the HEPA filter in the anteroom ceiling, but the anteroom and HEPA filter were not recertified until 02/14/2019.

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OBSERVATION 3

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

Specifically,

(1) Vials filled with drug products that are intended to be sterile and stoppered on the (b) (4) machine are moved from the ISO 5 area into the ISO 7 clean room (CR(b) (4) for capping and crimping. The stoppering arm on the (b) (4) machine broke on 11/26/2018 and was not repaired until 01/24/2019. Batches filled on the (b) (4) during this time were (b) (4) stoppered. There are no controls in place to ensure (b) (4) applied stoppers are fully seated before the vials are transferred to the ISO 7 cleanroom. Caps are (b) (4) applied to filled stoppered vials (b) (4) The caps are crimped using a non-sterile tool. Examples of product lots filled on the (b) (4) between 12/2018 and 01/2019 include:

Lot SOD121118SVVA sodium bicarbonate 8.4 % for injection
Lot SOD121218~~SV~~**IJ**VA sodium bicarbonate 8.4 % for injection
Lot SOD121318SVVA sodium bicarbonate 8.4 % for injection

(2) Media fill batch records do not include documentation of all interventions performed. Therefore, there is no assurance that your media fill is representative of your filling operations. For example, on 11/06/2018, media fill lot (b) (4) included (b) (4) stoppering of vials filled on the (b) (4) The media fill protocol/report did not contain documentation of all interventions performed and did not specify whether (b) (4) stoppering was performed using (b) (4)

OBSERVATION 4

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The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,

(1) Batches were released and distributed to patients without review and approval by the QCU. Examples of 503A batches approved and released with pharmacist signature. This includes batches released without endotoxin and sterility testing.
(2) Vendor Qualification of suppliers is deficient. SOP for vendor qualification does not include a complete supplier qualification program and there is no requirement to verify evidence obtained in the questionnaire.
(3) Your Quality Unit failed to establish a specification for air velocity for air passing through HEPA filters in the Laminar Airflow Hoods and in the cleanrooms. All smoke studies have not been received or evaluated that were performed in 2/2019. These were also not evaluated at the time performed.

OBSERVATION 5

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

Specifically, on 2/28/2019, your prepared the sterile drug product 550 ml in ON-Q pump bupivacaine 0.125% (125 mg/ml) preservative free for injection with the beyond use date of 3/9/2019 lot BUP022819NREC to fill the prescriptions (b) (6) for one pump and (b) (6) also for one pump to be used as a pain block for shoulder arthroscopy. There were no tests performed for sterility and endotoxins and no visual check for particles. These sterile prepared drugs were distributed to patients for use on 2/28/2019. In addition to not performing this testing viable particle environmental monitoring performed at the time of this batch preparation in the clean room (b) (4) (b) (4) ISO 5 hood recovered a colony of mold later identified as *Engyodontium album* by your contract test lab.

OBSERVATION 6

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

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Specifically,

(1) Your firm does not continuously monitor differential pressure between classified rooms or between classified and unclassified areas. On 05/24/2019 a magnahelic gauge was installed to permit measurement of the differential pressure between the ISO 7 cleanroom (b) (4) (CR (b) (4) and the ISO 8 anteroom (gowning room). There is no gauge to monitor differential pre ure between the ISO 5 zone and the ISO 7 cleanroom (b) (4) There is no alarm system to alert operators if the differential pressure cascade is out of specification.

(2) Non-viable particle counts in the ISO 7 cleanrooms are measured (b) (4)

OBSERVATION 7

Aseptic processing areas are deficient in that floors, walls and ceilings are not smooth and/or hard surfaces that are easily cleanable.

Specifically,

(1) A wall in the hazardous chemical preparation room adjacent to biosafety cabinet (b) (4) BSC (b) (4) appears to be constructed of cinder block.

(2) The door between the hazardous chemical preparation room and cleanroom (b) (4) is constructed of wood and painted with epoxy paint.

(3) The door between the unclassified buffer room and ISO 8 anteroom (gowning room) is constructed of wood and painted with epoxy paint.

(4) On 05/01/2019, I (JEK) observed that the ceiling tiles in cleanroom (b) (4) (CR (b) (4) were not flush and were not caulked.

AMENDMENT 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Joanne E King, Investigator Djamila Harouaka, FDA Center Employee or Employee of Other Federal Agencies	X Joanne E King Investigator Signed By 1300174867 Date Signed 07-25-2019 10 42 34	7/25/2019

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OBSERVATION 8

Aseptic processing areas are deficient regarding temperature and humidity controls.

Specifically, according to the logs used to record temperature, percent relative humidity and differential pressure, the specification for relative humidity in the cleanrooms is ≤(b) (4) Such a high level of humidity is not suitable for cleanroom environments.

Sodium Bicarbonate 8.4% lot SOD032819SVEC was filled on the (b) (4) on 03/28/2019 in cleanroom (b) (4) The batch record showed that the humidity level at the start of filling was 65%. A review of the pressure, temperature, and humidity log showed that on 05/13/2019, the relative humidity measured in cleanroom (b) (4) was 68%.

OBSERVATION 9

Equipment and utensils are not cleaned, maintained and sanitized at appropriate intervals to prevent malfunctions and contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

A. On 5/1/2019, during the processing of the bulk in-process non-sterile orphenadrine citrate 30 mg/ml for injection lot (b) (4) in cleanroom (b) (4) I (JEK) observed that the bulk drug substance orphenadrine citrate USP lot (b) (4) was mixed with sterile water for injection using in-house reusable depyrogenated glassware (b) (4) beakers) and reusable stir bars. I (JEK) observed the use of a (b) (4) (b) (4) that was directly placed into the (b) (4) beaker containing the in process orphenadrine citrate for pH adjustments. This (b) (4) was not dedicated to this product and may be used with other bulk non-sterile substances. I (JEK) also observed the use of a squeeze bottle that was not cleaned, sterilized, or depyrogenated that was used to rinse off the (b) (4) (b) (4) prior to placing it into the (b) (4) beaker containing the in process orphenadrine citrate bulk non-sterile drug. Both the (b) (4) and the reusable squeeze bottle are potential sources of cross-contamination.

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B. You are using a strainer and a food grade silicone mat to assist in the amber vial rinses with water for irrigation and water for injection prior to depyrogenation in accordance with *SOP 531 Washing, Depyrogenating, and Sterilization of Glass Vials, Stoppers, and Caps*. This strainer is not cleaned and was not considered a possible vector for the high number of rejected drug products for white particles, black particles, hairs, and fibers that your QCU is trending.

OBSERVATION 10

Laboratory controls do not include the establishment of scientifically sound and appropriate sampling plans and test procedures designed to assure that in-process materials and drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically, bioburden tests performed by your contract test lab used (b) (4) as the sample size drawn from a (b) (4) bulk non-sterile in process batch of morphine sulphate 2 mg/ml lot (b) (4) to test for bioburden in accordance with <USP 61> as listed on the COA and the contract test lab *SOP 451.1 Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests*. The sample size required by these test methods are (b) (4) or (b) (4)

A sterile (b) (4) sub-lot (of the bulk non-sterile morphine sulphate 2 mg/ml lot (b) (4) listed above) of morphine sulphate 2 mg/ml lot MOR032318LMDSC was used to dose (b) (4) syringes on 3/27/2018 and a sample of (b) (4) syringes containing (b) (4) each tested positive for microbes using your contract test labs (b) (4) sterility test method *SOP 420.2 Use of* (b) (4) *for Sterility Testing of Drug Samples* which requires a sample size in accordance with (b) (4) (b) (4)

OBSERVATION 11

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

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Specifically,

(1) According to procedure 340.7 entitled Cleaning, Use, and Maintenance of the (b) (4) Vial Filling System, effective 03/11/2019, section 7.3.2 and 7.4.5, the (b) (4) used to fill drug products intended to be sterile into vials is not cleaned using a sporicidal agent.

(2) The (b) (4) separating the ISO 5 area from the ISO 7 cleanroom (b) (4) (CR (b) (4) are cleaned with (b) (4) (sporicidal agent) and (b) (4)

(3) Multipacks of sterile wipes are opened in the ISO 7 room, completely unwrapped, and placed in a PETG (polyethylene terephthalate glycol) open plastic container in the ISO 7 cleanrooms. These wipes are used to clean the interior of the ISO 5 LAF hoods and the ISO 5 biosafety cabinet. **This is a repeat observation from the 2014 inspection**.

OBSERVATION 12

Results of stability testing are not used in determining appropriate storage conditions and expiration dates.

Specifically,

A. **Your firm failed to complete stability studies to support the BUD for drug products intended to be sterile.** For example, stability studies have not been completed for the following drug products which are labeled to be stored at room temperature:

Product	BUD
Chlorpromazine HCl 25mg/ml 1ml in a 5ml single dose vial	180 days

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Ephedrine Sulfate 10mg/ml preservative free 5ml in a 6ml syringe	60 days
Morphine Sulfate 4mg/ml preservative free 1ml in 3ml syringe	90 days
Orphenadrine Citrate 30mg/ml 1ml sterile single dose syringe	180 days
Succinylcholine Chloride 20mg/ml 10ml single dose syringe	150 days

This is a repeat observation from the 2016 inspection.

B. **Your firm reprocessed drug products if these products were not expected to maintain acceptable potency levels through the end of the established beyond use date (BUD).** For example, on 11/09/2018, Cyanocobalamin (Vitamin B-12) 1000mcg/ml solution lot CYA110918NRVA was initially formulated with (b) (4) of cyanocobalamin in 33000ml (b) (4) and benzyl alcohol) and had a measured potency of 97.2%. The potency specification is (b) (4) for cyanocobalamin 1000mcg/ml and the established BUD is 180 days. For lot CYA110918NRVA, the BUD was short-dated to 150 days based on the expiration date of the benzyl alcohol.

Lot CYA110918NRVA was reprocessed with an additional (b) (4) of cyanocobalamin in an attempt to obtain a target potency of 100%. The reprocessed lot was named CYA110918NRVAR. According to the Quality Manager (RM), products with test results near the lower end of the specification range may not maintain acceptable potency levels throughout the BUD. The products are reformulated to increase the potency at release to maximize the chance that the product will maintain a potency that meets the established specification through the end of the BUD.

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.

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Specifically, your firm has not completed product-specific process validation for drug products including Bupivacaine 0.125%, Succinylcholine Chloride 20mg/ml in 5ml or 10ml single dose syringes, and Cyanocobalamin (Vitamin B-12) 1000mcg/ml, and Potassium Chloride 2mEq/ml. There is no assurance that these products are being prepared using a process that consistently delivers products meeting established specifications.

OBSERVATION 14

You produced highly potent drugs without providing adequate containment, segregation, cleaning of work surfaces, cleaning of utensils and cleaning of personnel to prevent cross-contamination.

Specifically, highly potent non-sterile drug products containing hormones including testosterone, estradiol, estriol, and progesterone are prepared in the same (b) (4) hood where non-potent non-sterile drug products are produced. The (b) (4) hood is cleaned with sterile (b) (4) batches.

OBSERVATION 15

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

1. The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A). Specifically, the following information is not found on your some of your drug product labels:

   a) the dosage form information is not found on some of your drug product labels.

   Examples of your drug product labels that do not contain this information:

   Isoproterenol HCL in D5W, 200mcg/50mL
   Succinylcholine Chloride 20mg/ml

AMENDMENT 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Joanne E King, Investigator Djamila Harouaka, FDA Center Employee or Employee of Other Federal Agencies	X Joanne E King Investigator Signed By 1300174867 Date Signed 07-25-2019 10 42 34	7/25/2019

b) The National Drug Code number, if available;

Examples of your drug product labels that do not contain this information:

Estriol 1 mg/ml vaginal cream
Estradiol 0.3 mg capsules
Topiramate 25 mg capsules
Ursodiol 100 mg/ml suspension
Gabapentin 100 mg/ml suspension

2. The containers of your outsourcing facility's drug products does not include information required by section 503B(a)(10)(B). Specifically, your containers do not include the following information:

a) Route of administration.

Examples of drug product containers that do not contain this information: Isoproterenol HCL in D5W, 200mcg/50mL
Phenylephrine 0.1 mg/ml HCL in 0.9% NaCl PF
Naloxone 10 mg/ml in 50 ml
Succinylcholine Chloride 20mg/ml

OBSERVATION 16

AMENDMENT 2

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	4/29/2019-6/12/2019*
	FEI NUMBER 3007271263

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Vern A. Allen, CEO

FIRM NAME	STREET ADDRESS
Premier Pharmacy Labs Inc	8265 Commercial Way
CITY, STATE, ZIP CODE, COUNTRY Weeki Wachee, FL 34613-4511	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

1. You compound drugs that are essentially a copy of one or more approved drugs within the meaning of sections 503B(a)(5) and 503B(d)(2). Specifically, you compound drug products that: a) are identical or nearly identical to an approved drug that is not on the drug shortage list in effect under section 506E at the time of compounding, distribution, and dispensing; and/ or b) are not identical or nearly identical to an approved drug, but contain a bulk drug substance that is also a component of an approved drug, and for which there is no change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.

   Examples of compounded drug products that are essentially a copy of one or more approved drugs include:

   Neostigmine Methlysulfate Inj. 1mg/ml
   Succinylcholine Chloride 20mg/ml

***DATES OF INSPECTION**
4/29/2019(Mon), 4/30/2019(Tue), 5/01/2019(Wed), 5/02/2019(Thu), 5/03/2019(Fri), 5/20/2019(Mon), 5/21/2019(Tue), 5/22/2019(Wed), 5/23/2019(Thu), 5/24/2019(Fri), 5/29/2019(Wed), 6/12/2019(Wed)

AMENDMENT 2

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