DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	9/11/2017-9/20/2017* FEI NUMBER 3009422393

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Pamela M. Nenaber , CEO

FIRM NAME	STREET ADDRESS
Banner Pharmacy Services, LLC	7300 W Detroit St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Chandler, AZ 85226-2410	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

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

Specifically,

Your firm failed to reject batches of sterile drug product that did not meet specifications for potency and particulate matter. The following drug products failed potency or particulate matter testing and were released for distribution without adequate justification for invalidating failing test results:

Lot Number	Drug Product	Date Released	Test Failed
062817S2	Magnesium Sulfate 10g added to Lactated Ringers 250mL bag	8/14/2017	Particulate Matter
071417S1	Norepinephrine Bitartrate 8mg added to 0.9% Sodium Chloride 250mL bag	8/7/2017	Particulate Matter
071417S2	Oxytocin 30 units added to 0.9% Sodium Chloride 500mL bag	8/23/2017	Potency
071717S1	Oxytocin 30 units added to 0.9% Sodium Chloride 500mL bag	8/23/2017	Potency
072017S4	Oxytocin 30 units added to 0.9% Sodium Chloride 500mL bag	8/23/2017	Potency

OBSERVATION 2

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Results of stability testing are not used in determining expiration dates.

Specifically,

Your firm's beyond-use dates (BUD) for sterile drug products are not assigned based on adequate stability testing. We reviewed stability study lots and observed OOS results for potency at one or more time points. Your firm assigned BUD based only on the passing results and disregarded the data from failing lots. For example:

- Oxytocin 30 units in 500ml NS current BUD of 119 days was based on one (1) product lot that had potency testing data within specification at all time points. However, three (3) additional lots on stability were out of specification for potency on days 36, 45, and 113.

- Lidocaine HCL 1% buffered has a current BUD of 45 days. However, while one (1) lot is still under testing, three (3) lots on stability were out of specification for potency on days 14, 45, and 60.

- Midazolam 100 MG (1 MG/ML) in 0.9% Sodium Chloride 100 ML Cassette current BUD of 180 days was based on one (1) product lot that had potency testing data within specification at all time points. However, a second product lot on stability was out of specification for potency on day 120 of the study.

OBSERVATION 3

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

Specifically,

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A. On September 13, 2016, your firm's (b) (4) testing of your cleanroom revealed there were leaks in 1 of the (b) (4) HEPA filters in the ISO 7 non-hazardous compounding room and 1 of the (b) (4) HEPA filters in the ISO 8 anteroom (gowning area). These leaks were documented again during the March 2017 (b) (4) certification testing. The two leaking HEPA filters were replaced on August 3, 2017. Your firm continued to manufacture sterile drug products from September 13, 2016 until August 3, 2017 and did not perform an investigation to determine if the leaking HEPA filters would compromise the sterility of your drug products.

B. Your firm's March 2017 cleanroom testing revealed the ISO 7 non-hazardous compounding room and anteroom (gowning area) did not meet the compendial pressure differential criteria of +0.02" of water. For example, the Non-hazardous drug room to pass through window (to non-sterile compounding room) had a pressure reading of +0.0005" of water and the anteroom (b) (4) to prep area had a pressure reading of +0.0075" of water. Furthermore, you did not investigate the potential impact to products manufactured in the ISO 5 laminar flow hoods located in the ISO 7 non-hazardous drug room.

OBSERVATION 4

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

Specifically,

A. Your firm utilizes (b) (4) as a sporicidal cleaning disinfectant for (b) (4) cleaning of the ISO 5 laminar flow hoods, ISO 7 non-hazardous compounding room, ISO 8 anteroom (gowning room), and ISO 8 prep area. Your firm does not have scientific data to ensure the cleaning solution is effective as a sporicidal disinfectant.

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B. Your firm failed to perform cleaning in the ISO 7 non-hazardous compounding room after loss of positive pressure was observed as required per your SOP entitled, "Clean Room Downtime". The SOP states "If airflow or pressures out of range for greater than (b) (4) (b) (4))" and "Down for less than (b) (4) clean". On the following days, your firm failed to follow procedures and perform cleaning required following a loss of pressure:

Date	Total time with lost pressure	Cleaning Performed per Clean Room Downtime SOP
May 25, 2017	Up to 6 hours and 12 minutes ((b) (4)	No (Cleaning with (b) (4) (b) (4)

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May 25, 2017	Up to 23 minutes ((b) (4) (b) (4))	No cleaning performed
April 17, 2017	Up to 1 hour and 5 minutes (b) (4) (b) (4))	No cleaning performed

Approximately (b) (4) TPN drug products were produced on May 25, 2017 after the loss of pressure observed from (b) (4) . These drug products were made from approximately (b) (4) (b) (4) .

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On April 17, 2017, three drug products were made in the morning:

- Lidocaine HCl 1% Buffered 0.2 mL J-Tip Syringe – Lot #041717S3
- Vancomycin HCl 1.25 gram added to 0.9% Sodium Chloride 500 mL bag – Lot #041717S2
- Norepinephrine Bitartrate 8 mg added to 0.9% Sodium Chloride 250mL bag – Lot #041717S1

OBSERVATION 5

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

Specifically,

A. On 9/11/2017, we observed Technicians (b) (6), (b) (7)(C), performing aseptic processing of Lidocaine HCl, Oxytocin, and Vancomycin sterile drug products. We observed all (b) (4) technicians entering and leaving the ISO 5 Laminar Flow Hood (LFH) multiple times without sanitizing their gloved hands during the production of these sterile drug products.

B. We also observed all (b) (4) technicians introducing items such as 0.9% Sodium Chloride 500mL bags and J-Tip Syringes into the ISO 5 LFH without sanitizing the items or their outer packaging. In addition, your firm removes sterile items including Sodium Chloride 500mL bags and (b) (4) medication cassette reservoirs from their outer packaging in the ISO 8 prep room.

C. Not all of your technicians are qualified to perform aseptic drug production as only 2 out of a total of (b) (4) echnicians have performed media fills that simulated the most complex or high

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volume compounding processes under normal operating conditions.

D. Your cassette media fill performed on 6/9/2015 was not representative of your firm's production for the three products distributed in cassettes. One technician completed both stages of the cassette media fill process, but during routine production, two separate technicians complete the processes independently.

E. Your firm stores sterile personnel media fill samples on a shelf in the ISO 8 Prep Room, Room (b) (4) These samples are to be incubated at (b) (4) °C for (b) (4) . Temperature monitoring records reviewed for room (b) (4) revealed the temperature was consistently below (b) (4) °C while three different media fill sample sets were stored in this room for the (b) (4) incubation. The Facility Operations Senior Manager confirmed the temperature for the room was set to (b) (4) °F ((b) (4) °C) and regularly fluctuated below the set point.

F. Our review of the media fill records revealed pharmacists and technicians do not always complete the (b) (4) sterile media fill qualification in a timely manner. Pharmacist (b) (6) whose media fill qualification was due by 7/2/2016, was not completed until 12/16/16. Pharmacist (b) (6) and Technician (b) (6) were due for Sterile Personnel Media Fill qualification on 1/28/2016 and 9/1/2016, respectively. They completed qualifications more than three months past these due dates, on 5/9/2016 and 12/14/2016, respectively.

OBSERVATION 6

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

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A. Your firm's gowning practices are inadequate to prevent contamination of sterile gowning materials. On 9/12/2017, we observed (b) (4) technicians in the anteroom gowning at the same time. The technicians were observed walking in the ISO 8 anteroom/gowning area with non-sterile shoe covers, donning sterile shoe covers, and then walking in the same area. We observed one technician who had donned a sterile gown bump into another technician who was in his scrubs. The technician did not re-gown. These technicians were gowning in order to perform (b) (4) cleaning operations for the ISO 7 non-hazardous compounding area. In addition, your firm does not have an occupancy limit for the gowning anteroom.

B. Your firm stores laundered scrubs in the restrooms/changing rooms in front of the bathroom stalls. On 9/18/2017, we observed the door to the scrub storage unit in the men's restroom was opened. These scrubs are worn by technicians underneath their sterile gowns while performing aseptic operations.

C. Your firm's technicians wear non-sterile goggles while performing aseptic compounding of sterile drug products. We observed technicians re-use goggles by sanitizing them with sterile (b) (4) and non-sterile dry wipes. Your firm does not have data to ensure the sanitization process is adequate.

OBSERVATION 7

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

Specifically,

A. Your firm does not perform non-viable particulate air monitoring in the ISO-classified areas

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during aseptic processing of sterile drug products. Non-viable air sampling is only conducted during (b) (4) certification of your cleanroom.

B. Your firm does not routinely monitor all ISO-classified areas in your facility. For example, the ISO 8 Prep Room (b) (4) is not sampled for viable air or viable surface. Also, non-viable air sampling for ISO 8 Prep Room (b) (4) is only performed during the (b) (4) certification. We observed sterile items, such as 0.9% sodium chloride injection USP 500 ml IV bags and (b) (4) medication cassette reservoirs were removed from their outer packaging in Prep Room (b) (4) and placed in a non-sterile plastic tote. These items were later transferred to the ISO 5 LFH for production without any further sanitization of these items.

C. Sampling of operator gowns is not performed after daily operations but is instead performed once every (b) (4) per operator prior to production activities on that day.

D. Your firm's viable surface action level limits are inadequate. For example, your firm uses (b) (4) software default setting for the ISO 7 and ISO 8 viable surface action level limits. The software default action limit is (b) (4) cfu/plate for the ISO 7 floors and (b) (4) cfu/plate for the ISO 7 walls. Your Director of Pharmacy stated you follow USP <797> guideline to establish action limits; however the USP <797> recommended action level for ISO 7 surface sample is > 5 cfu per plate.

E. Your firm lacks written justifications and descriptions for how each environmental monitoring location was selected. Additionally, your firm lacks adequate justification for not utilizing passive air sampling in the ISO 5 LFH where sterile drug products are compounded.

F. Your firm does not perform growth promotion for each lot of ready-prepared (b) (4) (b) (4) used for viable surface monitoring. Additionally, there is no growth promotion of agar media used by your vendor for the viable active air sampling of your firm's ISO-

classified areas. Without growth promotion, your firm lacks assurance that the media can reliably recover microorganisms from the cleanroom environment.

G. Your firm incubates (b) (4) media plates at (b) (4) °C for (b) (4) after viable surface sampling. Your firm was unable to provide documentation ensuring that the single temperature incubation can adequately recover yeast and mold species that prefer ambient incubation conditions.

H. On 9/11/2017, we observed viable active air samples collected on 9/8/2017, 9/9/2017, and 9/10/2017 were stored in a refrigerator pending shipment to the contract laboratory for incubation. Your firm was unable to provide documentation to demonstrate storage at refrigeration temperatures and delayed incubation will not adversely affect the recovery of microorganisms from the agar media.

OBSERVATION 8

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,

A. Your firm's environmental monitoring excursion investigations are inadequate. For example, your firm does not identify a probable root cause and does not assess product impact. Additionally, your investigations lack information stating when the investigations were open, closed, and who performed the investigations. Also, not all investigations have been reviewed and approved. Examples of investigations include but are not limited to:

a. On 5/26/2016, ISO 5 (b) (4)-Hood (b) (4) viable active air was sampled and one (1) cfu was reported. On 6/13/2016, the contract testing lab notified your firm that speciation determined the colony to be Gram negative non-enteric bacteria and your firm's CAPA stated, "As per USP <797>, the gram negatives, yeast and mold are considered highly pathogenic and can be fatal to patients, especially immune compromised patients, receiving CSP's". (b) (4) product lots had been compounded in Hood (b) (4) from 5/26/2016 to 6/13/2016.

b. On 6/11/2016, ISO 5 (b) (4)-Hood (b) (4) viable surface was sampled and six (6) cfu's were reported. On 8/17/2016, the contract testing lab notified your firm that speciation determined the colony to be yeast and your firm's CAPA stated, "As per USP <797>, the gram negatives, yeast and mold are considered highly pathogenic and can be fatal to patients, especially immune compromised patients, receiving CSP's". Approximately (b) (4) product lots had been compounded in Hood (b) (4) from 6/11/2016 to 8/17/2016.

c. On 8/30/2016, ISO 5 (b) (4)-Hood (b) (4) viable active air was sampled and one (1) cfu was reported. On 9/20/2016, the contract testing lab notified your firm that speciation determined the colony to be Gram negative non-enteric bacteria and your firm's CAPA stated, "As per USP <797>, the gram negatives, yeast and mold are considered highly pathogenic and can be fatal to patients, especially immune compromised patients, receiving CSP's". (b) (4) product lots had been compounded in Hood (b) (4) from 8/30/2016 to 9/20/2016.

B. Your firm has not established a procedure to investigate technician's sterile glove fingertip sampling failures. Your firm neither performs root cause investigations nor assesses product impact due to these failures. The following examples of fingertip sampling failures were not

investigated:

- On 2/18/2016, Technician (b) (6) glove fingertip sampling exceeded action level limits following the aseptic production of Magnesium Sulfate 10 Gm Lot #021816S3. Bacteria species *Streptococcus ferus* and *Staphylococcus hominis* were isolated and identified.
- On 6/13/2016, Technician (b) (6) glove fingertip sampling exceeded action level limit following the aseptic production of Cefazolin Sodium 2 Gm Lot #061316S3. Bacteria species *Staphylococcus epidermidis* was isolated and identified.
- On 7/27/2016, Technician (b) (6) glove fingertip sampling exceeded action level limit following the aseptic production of Oxytocin 30 Units Lot #072716S4. Bacteria species *Staphylococcus pasteuri* was isolated and identified.

C. Since January 15, 2017, your firm has observed and rejected (b) (4) total parenteral nutrition (TPN) bags containing particulate matter. Your firm failed to perform investigations for any of these failures to determine the potential source and root cause of the particulate matter.

OBSERVATION 9

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

Specifically,

Your firm produces non-sterile oral Vancomycin HCL 250 mg/10 ml and GI cocktail oral suspension 30 ml (20 ml Maalox plus equiv + 10 ml 2% Lidocaine) for office use. Your firm has not established

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acceptable levels of microorganisms and has not tested these finished drug products for acceptable levels and the presence of objectionable microorganisms per compendial requirements.

OBSERVATION 10

Test procedures relative to appropriate laboratory testing for pyrogens are not written and followed.

Specifically, your firm's endotoxin testing is deficient in that only five (5) out of a total of fifteen (15) sterile compounded drug products have complete endotoxin method validations per compendial requirements.

OBSERVATION 11

Determinations of conformance to appropriate written specifications for acceptance are deficient for drug products.

Specifically,

Your firm does not perform 100% visual inspection of all sterile drug products. Your firm's technicians/pharmacists perform cursory batch inspection followed by detailed visual inspections on (b) (4) in that batch. Visual inspections are performed without the use of contrasting backgrounds and a calibrated light source. Your firm has no documented training or qualification for technicians and pharmacists who perform visual inspection.

OBSERVATION 12

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

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Specifically,

A. The following information is not found on your TPN drug product labels:

1. The statement, "This is a compounded drug."
2. The name, address, and phone number of the applicable facility.
3. The lot or batch number.
4. The established name of the drug.
5. The date that the drug was compounded.
6. The storage and handling instructions.
7. The statement, "Not for resale."
8. The statement, "Office Use Only."
9. The active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient.

B. The following information is not found on some or all of your other drug product labels.

1. The established name of the drug.
2. The statement, "Office Use Only."
3. The active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient.

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Examples of drug product labels that do not contain this information include, but are not limited to:

- GI Cocktail Oral Suspension (20 mL Maalox Plus Equiv + 10 mL 2% Lidocaine Viscous)
- Oral Flavored Vancomycin
- Norepinephrine Bitartrate 8 mg and 16 mg added to 0.9% Sodium Chloride
- Ephedrine Sulfate 50 mg/10 mL Sryinge in 0.9% Sodium Chloride
- Succinylcholine Chloride 200 mg/10 mL Syringe
- Lidocaine 1% Buffered 0.2 mL
- Midazolam CASSETTE 100 mg (1 mg/mL) in 0.9% Sodium Chloride 100 mL
- Ropivacaine (PF) 0.2% (2mg/mL) 100 mL CASSETTE
- Diltiazem HCL 125 mg added to 0.9% Sodium Chloride 100 mL BAG
- Fentanyl Citrate 1000mcg 100 mL CASSETTE in 0.9% Sodium Chloride
- Fentanyl Citrate 1100mcg 55 mL ~~CASSETTE~~ **Syringe** in 0.9% Sodium Chloride
- Hydromorphone HCL 10 mg 50 mL Syringe in 0.9% Sodium Chloride
- Vancomycin HCL 1.5 gram and 1.25 gram added to 0.9% Sodium Chloride 500 mL BAG
- Oxytocin 30 Units added to 0.9% Sodium Chloride 500 ml BAG

C. The following information is not found on the container for the drug products you produce:

1. Information to facilitate adverse event reporting: www.fda.gov/medwatch and 1–800–FDA–1088.

OBSERVATION 13

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Your outsourcing facility has not submitted a report to FDA identifying a product compounded during the previous six months as required by section 503B(b)(2)(A).

Specifically, your compounded Total Parenteral Nutrition drug products were not identified on your most recent product report to FDA.

***DATES OF INSPECTION**

9/11/2017(Mon),9/12/2017(Tue),9/13/2017(Wed),9/14/2017(Thu),9/15/2017(Fri),9/18/2017(Mon),9/19/2017(Tue),9/20/2017(Wed)

X Eileen A Liu
Microbiologist
Signed By: 2000427259
Date Signed: 9/20/2017

X Nicholas L Hunt
Investigator
Signed By: Nicholas L. Hunt -S
Date Signed: 9/20/2017

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