DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE Suite 210 Bothell, WA 98021 (425)302-0340 Fax:(425)302-0404	11/9/2021-12/17/2021* FEI NUMBER 3012465222

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Robert A. Myers, Operations Manager

FIRM NAME	STREET ADDRESS
Compound Preferred LLC	1125 Hollipark Dr.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Idaho Falls, ID 83401	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

You did not make adequate product evaluation and take remedial action where actionable microbial contamination was found to be present in the ISO 5 classified aseptic processing area during aseptic production.

Your investigations are inadequate in that corrective actions do not address the root cause in non-conformances. Specifically,

A) Viable count excursions:
   1) The Quality Unit opened non-conformances (NC) for each of the thirteen (13) personnel monitoring excursions observed between 08/02/2019 to 11/08/2021 in the ISO 5 and ISO 7 classified areas. However, an adequate root cause, and corrective and preventive action to address the nine (9) non-conformances related to the detection of spore forming microorganisms was not determined. Instead, as a corrective action, the Quality Unit decided to relax the Action Limit for fingertip glove sampling and increase the Action Limit from (b) (4) CFU to (b) (4) CFUs. In addition, SOP 08-004, "Environmental Monitoring and Personnel Monitoring", Revision 12, Effective Date: 10/15/2021 was implemented to reflect this change.

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	Kenneth O Gee, Investigator Sangeeta M Khurana, Investigator	X Kenneth O Gee Investigator Signed By 2001873861 Date Signed 12-17-2021 15:45:33	12/17/2021

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#	NC#	NC Date	Product	Lot#	Organism	Location	CFU
1	02	10/02/2021	Procaine 2%	(b) (4)	B. megaterium, B. aryabhattai	Fingertip	1
2	07	10/28/2021	Avastin		Not isolated and identified	Gown	32
3	09	11/13/2021	Avastin		B. mycoides	Fingertip	1
4	10**	11/16/2021	PEG/DEX		Paenibacillus lactis	Left Settle Plate	TNT*
5	14	12/28/2021	Methylcobalamin, Procaine 1%, Dexpanthenol		B. mycoides	Fingertip	1
6	19	02/22/2021	(b) (4)		Paenibacillus jilunlii	Fingertip	1
7	20**	02/26/2021	Procaine 2%, Dexpanthenol		Cytobacillus oceanisediminis	Fingertip	TNT*
8	28	04/23/2021, 04/26/2021, 04/29/2021	Avastin (b) (4) (b) (4)		Not isolated and identified	Gown	1, 1, 2
9	37	07/01/2021	Avastin (136)		B. subtilis	Fingertip	1
10	40	07/29/2021	Avastin (163)		B. altitudinis, B. pumilus	Fingertip	1
11	47	08/21/2021	Dexpanthenol, Procaine 1%		B. idriensis, Paenibacillus timonensis, Corynebacterium singulare	Fingertip, Gown, Hood	1, 1, 1
12	50**	09/18/2021, 09/21/2021	MIC B-Complex		Micrococcus luteus	(b) (4)	18

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13	51	09/27/2021	Procaine 1% (50, (100)	(b) (4)	Plates discarded. Excursions recorded on 8/20 and 08/24/21, neither reported to QA	Fingertip	1, 1

*TNT is too numerous to count
** Product lots associated with NC 10, 20, and 50 were not compounded for distribution

2) On 10/28/2020, during the sterile production of Avastin Lot (b) (4), 32 colonies were recovered on a (b) (4) plate taken from a gown during Personnel Monitoring. The Quality Unit failed to isolate and identify the colonies and released the product for distribution. The Quality Unit initiated NC-07 and decided to continue the monitoring the gown excursions for three months to determine the alert levels for future excursions. However, the firm had already established an action level of (b) (4) CFU for the gowns in SOP 08-004, "Environmental Monitoring and Personnel Monitoring" Rev. 4, Approved 10/06/2020.

Later, the Quality Unit added an alert level of (b) (4) CFU for the gowns in SOP 08-004, "Environmental Monitoring and Personnel Monitoring" Rev. 7, Approved 01/29/2021. The action level was established as (b) (4) CFU or (b) (4) alert level of (b) (4) (b) (4).

However, on 05/04/2021, the Quality Unit opened NC# 28 when the alert level exceeded (b) (4) times on the personnel gowns (1 CFU, 1 CFU and 2 CFUs recovered on 04/23, 04/26 and 04/29/2021 respectively). These excursions were observed during the production of Avastin (Lot (b) (4) and (b) (4)), (b) (4) (Lot (b) (4)) and (b) (4) (Lot (b) (4)). The Quality Unit failed a second time to isolate or identify the colonies and released the compounded drugs for distribution.

3) On two occasions, 08/26/2021 and 08/30/2021, your compounding technician observed

growth on (b) (4) plates collected during the production of two lots of Procaine 1%, Lots (b) (4) and (b) (4) respectively. (b) (6) recorded the growth in the EM and PM Log and then discarded the plates. The Quality Unit was not notified, no non-conformance was raised, and no microbial growth was available for conducting the identity testing. These lots were released for distribution. The Quality Unit reviewed the log on 09/27/2021, observed the positive growths, and started the non-conformance, NC-51. However, as a corrective and preventive action, the Quality Unit did not update SOP 08-004, "Environmental Monitoring and Personnel Monitoring", to state that a second person concurrently verifies the microbial growth results.

B) Non-viable count excursions:

1) A review of all environmental non-conformances observed between 08/02/2019 to 11/08/2021 by the firm showed there were eight (8) non-viable particulate excursions in the ISO 5 and 7 classified areas as shown in the table below:

NC#	Date	Drug Product	Lot#	Location
11	11/18/2021	Avastin	(b) (4)	ISO 5
12	11/24/2021	Avastin, Dexamethasone, Vancomycin, Ceftazidime		ISO 7
13	12/02/2021	(b) (4), Avastin		ISO 5
18	02/23/2021	Avastin		ISO 5
30	05/27/2021	Avastin		ISO 5
33	06/09/2021, 06/10/2021	(b) (4) and Avastin		ISO 5
39	07/16/2021	Avastin		ISO 5

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Non-viable particulate count samples are taken from (b) (4) different locations, (b) (4) (b) (4) of the ISO 5 classified hood. The Quality Unit opened non-conformances for each of the eight (8) non-viable particulate count excursions observed between 08/02/2019 to 11/08/2021 in the ISO 5/ISO 7 classified areas. However, an adequate root cause, and corrective and preventive action to address the above eight (8) non-conformances was not determined. The Quality Unit decided if the non-viable particulate count exceeded the required specifications at a single location the non-viable particulate count taken from (b) (4) sample locations would be (b) (4). In addition, SOP 08-004, "Environmental Monitoring and Personnel Monitoring", Revision 12, Effective Date: 10/15/2021 was changed to reflect (b) (4) of non-viable particulate count results.

2) In addition to the above eight (8) non-viable particulate excursions, the firm's records revealed two (2) more non-viable particulate excursions observed during the weeks of 06/28/2021 to 07/02/2021 and 08/16/2021 to 08/20/2021. However, the Quality Unit did not open any non-conformance, conduct any investigations, or determine the root cause for the above two excursions.

This is a repeat observation from the FDA inspections conducted in August of 2019.

OBSERVATION 2

Laboratory controls do not include the establishment of scientifically sound and appropriate standards designed to assure that drug product containers conform to appropriate standards of identity, strength, quality and purity.

Specifically, your firm does not the follow manufacturer's test instructions while performing the Endotoxin, (b) (4) test for your compounded drug products.

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For example, on 11/17/2021 we observed Endotoxin testing being conducted for Procaine (1%) HCl 10mg/mL Injection Solution 30mL MDV, Lot (b) (4), produced on 11/16/2021. During the endotoxin test we observed that your firm failed to:

A. Perform the Endotoxin Control Series (b) (4) Your firm only performs (b) (4) and does not perform (b) (4) per the manufacturer's instructions.

B. (b) (4) for testing.

C. You have not performed any endotoxin (b) (4) to rule out the potential of (b) (4) by your compounded products.

D. Your firm has not calculated the (b) (4) for any of your compounded products. Per the manufacturer's instructions, the (b) (4) method should be validated at a (b) (4)

E. Ensure each compounded product has (b) (4) performing the Endotoxin test. Per the manufacturer's instructions the (b) (4) reaction requires (b) (4). On 11/17/2021, your firm tested the (b) (4) for Procaine (1%) Lot (b) (4), and the (b) (4).

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In addition, your Finished Product Testing and Release log from 04/29/2021 to 10/18/2021 shows 19 of the compounded products had a (b) (4). The (b) (4) recorded was (b) (4) for Procaine 1% Lot (b) (4) manufactured on 08/02/2021. A review of your Full Production List from 08/02/2019 to 10/19/2021 shows you have produced approximately (b) (4) lots of sterile compounded products.

OBSERVATION 3

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

Specifically,

A) A review of your firm's personnel and environmental monitoring non-conformances observed between 08/02/2019 to 11/08/2021 show there were thirteen (13) viable growth excursions in the ISO 5 and 7 classified areas. Nine (9) viable growth excursions out of these thirteen (13) were caused due to the detection of spore forming microorganisms. The Quality Unit failed to take adequate actions to address the presence of spore forming organisms in the classified areas and continued the practice of using a sporicidal agent (b) (4), per your firm's SOP 05-001, "Cleanroom Suite Cleaning and Sanitizing" Rev. 3, Effective Date: 7/21/2021.

B) On 11/16/2021 during the production of Procaine 1%, Lot (b) (4), we observed the bottom of (b) (4) used to move components and items into the clean room were not disinfected with either (b) (4) or a sporicidal agent. These (b) (4) were placed on a work bench alongside a cardboard box while collecting supplies for aseptic processing. Your SOP 09-002, "Sterile Product Preparation", Rev. 6, Effective Date; 05/17/2021, also does not adequately specify the steps to disinfect the (b) (4).

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C) During the inspection, your firm's management stated that they follow the manufacturer's recommended contact times to ensure adequate disinfection of the classified areas. However, Attachment A Cleanroom Cleaning Log from your SOP 05-001, "Cleanroom Suite Cleaning and Sanitizing" Rev. 3, Effective Date: 7/21/2021 does not specify the contact times for the disinfectant / sporicidal agents, and there is no place to record the contact times on Attachment A Cleanroom Cleaning Log.

This is a repeat observation from the FDA inspections conducted in March of 2017 and August of 2019.

OBSERVATION 4

The flow of components, drug product containers, closures and in-process materials through the building is not designed to prevent contamination.

Specifically,

A) On 11/16/2021, we observed a compounding technician getting ready for sterile drug compounding operations. (b) (6) first removed (b) (6) street clothing and donned a clean pair of surgical scrubs, a clean pair of socks and rubber clogs and a clean pair of non-sterile gloves. Then instead of going directly to the ISO 5 / ISO 7 classified areas (b) (6) began collecting supplies needed for sterile drug compounding such as sterilized gowns, face hoods and (b) (4) particle counter head. The supplies were stored in (b) (4) in an unclassified storage area. We observed (b) (6) clean surgical scrubs come in direct contact with the (b) (4). Wearing the same surgical scrubs, the compounding technician then entered the ISO 8 classified gowning area and started donning the sterile gown over the surgical scrubs to prepare for aseptic operations.

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B) On 11/16/2021, while preparing for sterile drug compounding operations, the compounding technician repeatedly moved back and forth between the ISO 8 gowning room, ISO 7 clean room and ISO 8 (b) (4) room. The movement between ISO 8 gowning room, and the ISO 7 clean room was more than seven times during cleaning and environmental monitoring operations. The movement between the ISO 7 clean room and ISO 8 (b) (4) room was at least two times.

C) On 11/16/2021, during the production of Procaine 1%, Lot (b) (4), the compounding pharmacist used (b) (4) to transfer the compounded drug product from an unclassified Weigh/Prep, Room 3 into the ISO 7 clean room for further processing in the ISO 5 classified hood. In addition, while the filling operations were on-going, a compounding technician opened the (b) (4) multiple times. This (b) (4) leads to an unclassified Product Release Room 7. (b) (4) was opened to transfer plastic tubing, a needle holder, four (4) trays of filled and capped glass vials of Procaine 1%, Lot (b) (4) for crimping to an unclassified room and was not cleaned prior to the start of sterile compounding operations.

OBSERVATION 5

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

Specifically, since the previous FDA inspection conducted in August of 2019, your firm has not performed any dynamic smoke studies that fully simulate sterile drug production activities in your ISO 5 hoods located in the ISO 7 clean room.

During the current inspection, we reviewed the most recent smoke studies performed in March of 2021 at your firm. The smoke studies were conducted only under static conditions. No dynamic studies were performed that showed:

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A) The entire filling process, including the priming of the pump used to fill the vials with the compounded drug product.

B) The practice of (b) (4) operators working together in your ISO 5 classified hood during filling and capping operations.

The ISO 5 classified hood is used for (b) (4) operations at your facility, including the aseptic filling of Procaine (1%) HCl 10mg/mL Injection Solution 30mL MDV, (b) (4) on 11/16/2021. In addition, your Full Production List from 08/02/2019 to 10/19/2021 shows you have produced approximately (b) (4) lots of sterile compounded products.

This is a repeat observation from the FDA inspection conducted in March of 2017.

OBSERVATION 6

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

Specifically,

A) On 11/16/2021, (b) (4), which directly connects the ISO 7 clean room with the unclassified Product Release Room 7, was not cleaned and disinfected prior to the start of filling operations for Procaine 1%, Lot (b) (4) in the ISO 5 classified hood, located in the ISO 7 clean room. Your SOP 05- 001 "Cleanroom Suite Cleaning and Sanitizing", Effective Date, 07/21/2021, Rev. 3, Section 3.2.5, states (b) (4); however, the SOP does not specify when the (b) (4) should be cleaned (before or after the sterile drug production).

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B) On 11/12/2021, during our walkthrough of your facility we observed (b) (4) vials of "Methylcobalamin 5mg/mL, Injection Solution, Lot: (b) (4) , 30 mL MDV, Exp Date:01/10/2020, Prep Date:10/12/2021" stored on the top shelf of Refrigerator ((b) (4)) in the Product Release Room 7. Your firm's management stated Refrigerator ((b) (4)) was empty, unmonitored, and out of service. However, the refrigerator was not marked with any signage indicating it was out of service, and your Quality Unit failed to explain why the product was still stored in an unmonitored refrigerator. In addition, your firm has no procedure regarding the handling of out of service equipment. There is also no procedure or log which documents the inventory or storage location of your compounded products.

OBSERVATION 7

Routine calibration of automatic and mechanical equipment is not performed according to a written program designed to assure proper performance.

Specifically, on 11/16/2021 after aseptic filling operations of Procaine (1%) HCl 10mg/mL Injection Solution 30mL MDV, Lot (b) (4) , your firm used an uncalibrated (b) (4) to conduct the (b) (4) testing for confirming the (b) (4) .

According to your firm's management an uncalibrated (b) (4) was used from 08/02/2019 to 08/12/2021, and an uncalibrated (b) (4) was used from 08/13/2021 to 11/19/2021 for (b) (4) testing. In addition, the firm's management also stated there are no written procedures to assure routine calibration of the (b) (4) .

There is no assurance that while using these uncalibrated (b) (4) the readings obtained during the (b) (4) testing are accurate for (b) (4) lots of sterile compounded products produced since 08/02/2019.

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***DATES OF INSPECTION**
11/09/2021(Tue), 11/10/2021(Wed), 11/11/2021(Thu), 11/12/2021(Fri), 11/15/2021(Mon), 11/16/2021(Tue), 11/17/2021(Wed), 11/19/2021(Fri), 12/17/2021(Fri)

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Investigator
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Date Signed: 12-17-2021 15:46:46

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."