DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
U.S. Food and Drug Administration 404 BNA Drive Bldg 200 Suite 400 Nashville, TN 37217 615-366-7801 FDA-483 Responses: ORAPHARMA2_RESPONSES@FDA.HHS.GOV	03/09-13/2020;03/16/2020; 04/09/2020
	FEI NUMBER 3010536120

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Joe S. Moore, President and Owner

FIRM NAME	STREET ADDRESS
Medical Center Pharmacy, Inc	2401 N Ocoee Street
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Cleveland, TN 37311-3853	Producer of Sterile and Non-Sterile Drug Products

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OBSERVATION 1

Sources of non-microbial contamination were observed in the ISO 5 classified aseptic processing areas that are difficult to clean, particle-generating and visibly dirty.

Specifically, on 03/09/2020, we observed the following inside your firm's Laminar Air Flow Hood (LAFH) (ISO-5 classified), (b) (4), where aseptic human and veterinarian drug operations take place, including but are not limited to, intrathecal sterile drug products:

A. Visible discoloration what appears to be brown residue (approximately 3-inches in height) was observed on the HEPA screen of your firm's (b) (4) LAFH;
B. Visible discoloration that appears to be residue buildup was observed on the inside corners of the HEPA screen;
C. What appeared to be chipped paint was observed on the inside corner of the LAFH;
D. Gaps were observed on the inside of your firm's transparent acrylic plastic side wall of the LAFH where the workbench meets the wall;
E. Caulking was observed on the inside of your firm's LAFH where the workbench meets the HEPA screen. The caulking is not smooth and not easily cleanable;
F. Visible lint and residue were observed on the inside of your firm's transparent acrylic plastic side wall of the LAFH where the workbench meets the wall;

According to your firm's aseptic processing lead pharmacy technician, the status of the cleanroom (LAFH: ISO-5 classified; Buffer Room: ISO-7 classified; Anteroom: ISO-8 classified) on 03/09/2020, is clean.

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OBSERVATION 2

Disinfecting agents and cleaning wipes used in the ISO 5 classified aseptic processing areas were not sterile.

THIS IS A REPEAT OBSERVATION

Specifically,

A. Your firm uses a non-sterile bactericidal ((b) (4) or (b) (4)) cleaning solution, non-sterile (b) (4) wipes, and non-sterile (b) (4) wipes during routine (b) (4) cleanings of your classified areas where aseptic operations are performed, for example, but not limited to, the interior surfaces of ISO-5 equipment:

1. Laminar Air Flow Hood (LAFH) (ISO-5 classified), (b) (4), located in your firm's Buffer Room;

Your firm does not render these products sterile prior to use. According to your firm's aseptic processing lead pharmacy technician who conducts (b) (4) cleaning of your firm's aseptic processing areas, these non-sterile products are also used in the Buffer Room (ISO 7 classified) and anteroom (ISO 8 classified).

According to your firm's prescription log, dated April 2019 – March 2020, your firm produces, but are not limited to the following routes of administration in your LAFH (ISO 5 classified):

Route of Administration	Count of Route of Administration
Injectable (including intrathecals)	(b) (4)
Ophthalmic	(b) (4)
Inhalation	(b) (4)
Drop	(b) (4)
Irrigation	(b) (4
Grand Total	(b) (4)

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OBSERVATION 3

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

Specifically,

A. According to your firm's Certification Report, dated 16 April 2019, a viable air sample (VAS) revealed:
   1. In the (b) (4) hood (b) (4)(b) (4), taken at the center, approximately 6" from the rear:
      i. Bacterial Results and Trending: Nineteen (19) CFUs were identified as *Bacillus; Coag-Neg. Staphylococcus; Micrococcus.*
   2. In the Anteroom (ISO-7 classified) on the "counter near center of room":
      i. Fungal Results and Trending: Three (3) CFUs identified as *Exophiala*; and
      ii. Bacterial Results and Trending: Seventeen (17) CFUs identified as *Coag-Neg. Staphylococcus; Micrococcus.*

   According to your firm's Sterile Log, the following products were produced on 16 April 2019, including but are not limited to:

Drug Name	Lot Number
Vitamin B Complex High Potency Injection	04162019@4
Nandrolone Decanoate 200mg/1ml	04162019@8
Anastrozole/Testosterone Cypionate Oil Injection 1mg/200mg/mL	04162019@9
Estradiol Valerate/Testosterone Cypionate 40mg/50mg Per mL	04162019@6

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B. According to your firm's Certification Report, dated October 2019, a viable air sample revealed:
   1. In the Laminar Air Flow Hood (LAFH) (ISO-5 classified), (b) (4), at the center, approximately 6" from the rear:
      i. Bacterial Results and Trending: One (1) CFUs were identified as *Bacillus.*
   2. In the Buffer Room (ISO-7 classified) on the "top shelf of shelving":
      i. Bacterial Results and Trending: Two (2) CFUs identified as *Micrococcus.*
   3. In the Anteroom (ISO-8 classified) on the "counter near center of room":
      i. Fungal Results and Trending: Four (4) CFUs identified as *Non-Sporulating; Curvulvaria; Pithomyces; Yeast*; and
      ii. Bacterial Results and Trending: Five (5) CFUs identified as *Coag-Neg. Staphylococcus; Micrococcus.*

   4/9/2020 GP
   11 Oct 2019

   According to your firm's Sterile Log, the following products were produced on ~~16 April 2019~~, including but are not limited to:

Drug Name	Lot Number
Hydromorphone - Preservative Free 5mg/mL	10112019@5

Your firm does not have a written procedure outlining cleaning requirements for VAS excursions. However, your firm's Staff Pharmacist, stated a thorough clean should be conducted followed by resampling when environmental monitoring excursions are evident.

Review of your firm's (b) (4) and (b) (4) cleaning records does not document a rigorous cleaning was conducted. For example, but are not limited to:

- On 4/16/2019, environmental monitoring for VAS was performed by a 3rd party contractor; your firm's (b) (4) cleaning records document cleaning was performed (b) (4) EM sampling with non-sterile (b) (4) 4/16-19/2019, (b) (4) was performed on 4/20/2019, and a (b) (4) clean was performed on 04/30/2019. Your firm aseptically produced (b) (4) lots from 4/16-20/2019.
- On 10/11/2019, environmental monitoring for VAS was performed by a 3rd party contractor; your firm's (b) (4) cleaning records document cleaning was performed with non-sterile (b) (4) (b) (4) EM sampling, a (b) (4) clean was performed on 10/21/2019, your firm did not provide documentation that (b) (4) was performed in October 2019. Your firm continued aseptic operations until 03/11/2020. To date, a viable air resampling has not been performed.

Your firm produces sterile drug products including, but not limited to: injectables (including intrathecals), ophthalmics, and inhalations.

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OBSERVATION 4

Your aseptic processing conditions do not offer sufficient assurance that the finished product will meet an endotoxin specification appropriate for its route of administration.

Specifically, according to your firm's pharmacist-in-charge, your firm doesn't perform any bacterial endotoxin testing for your finished intrathecal drug products. These preparations are made using non-sterile active pharmaceutical ingredients (APIs). No bacterial endotoxin testing was performed on these APIs prior to use in aseptic operations. Furthermore, your firm does not calculate the bacterial endotoxin limit. According to your firm's written procedure, 9.140: "*Bacterial Endotoxin (Pyrogen) Testing*", endotoxin testing is to be performed at least every (b) (4) and for (b) (4)

In addition, the expiration dates of your intrathecals are inconsistent, for example, but not limited to:

Date Compounded	Drug Name	Lot Number	Expiration Date on Rx Label	Days until expiry
02/17/2020	Fentanyl/Morphine/Bupivacaine/Hydromorphone Intrathecal 2500mcg/25mg/7.5mg/10mg	02172020@18	02/04/2021	~1 year
02/20/2020	Clonidine/Baclofen 200mcg/2000mcg	02202020@7	02/18/2021	~1 year
02/19/2020	Baclofen (Preservative Free) 3000mcg/mL	02192020@12	02/20/2020	1 day

Your firm has not performed any stability studies to support these expiration dates.

OBSERVATION 5

Your aseptic processing conditions do not offer sufficient assurance that the finished product is sterile.

Specifically, the air pressure gauge used to perform (b) (4) (b) (4) of all (b) (4) have not been calibrated since 2015.

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OBSERVATION 6

Media fills are not conducted to simulate aseptic production operations that represent the most-challenging and stressful conditions

THIS IS A REPEAT OBSERVATION

Specifically, on 03/16/2020, your pharmacist-in-charge stated the largest batch size produced at your firm under aseptic operations is (b) (4) . However, the media fill (aseptic processing simulation) records performed by your firm's personnel, who engage in aseptic operations, only represent 25% of your firm's largest batch size.

In addition, your pharmacist-in-charge stated the most-challenging aseptic operation performed at your facility is for inhalation nebulizers. However, the media fills performed are for (b) (4) products.

OBSERVATION 7

You had inadequate HEPA filter coverage and airflow over the area to which sterile product was exposed.

Specifically,

A. ISO 5 Classified Areas:
   1. LAFH: A loose light fixture with exposed wiring was observed on the ceiling of your firm's LAFH.

B. ISO 7 Classified Areas:
   1. HEPA filters were not sealed around each perimeter of the support frame:
      i. HEPA filter frames: Missing caulk was observed around the perimeter of the HEPA filter frames that seal the HEPA filters to the ceiling, located in your firm's buffer room (ISO-7 classified):
         1. Located directly above your firm's LAFH (ISO-5 classified);
         2. Located approximately 6 feet from your firm's LAFH (ISO-5 classified); and
         3. Located approximately 10 feet from your firm's LAFH (ISO-5 classified).

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2. Light fixture: Missing caulk was observed around your firm's light fixture
3. Ceiling: A crack observed in the sheetrock located on your firm' ceiling directly above the ISO 5 hood.

C. ISO 8 Classified Areas:

1. HEPA filter frames: A loose bolt and missing caulk were observed around the perimeter of the HEPA filter frames that seal the HEPA filters to the ceiling, located in your firm's anteroom (ISO-8 classified);
2. Light fixture: missing gasket/caulking was observed around the perimeter of your light fixture; and
3. (b) (4) : lacks established controls - according to your pharmacist-in-charge, beakers (containing drug components used in aseptic operations) are (b) (4) anteroom (ISO 8 classified) to the buffer room (ISO 7 classified) (b) (4) (b) (4) (b) (4) In addition, your pharmacist-in-charge admitted the beakers are not always covered or sanitized when (b) (4) (b) (4)

OBSERVATION 8

Equipment and Materials or supplies were not disinfected prior to entering the aseptic processing areas.

Specifically,

A. On 03/16/2020, your pharmacist in charge admitted the glassware (e.g. beakers), containing drug products used in aseptic operations are uncovered and are not disinfected or sanitized when placed in your firm's unclassified (b) (4) . This (b) (4) anteroom (ISO 8 classified) to your firm's buffer room (ISO 7 classified). According to your firm's PIC, this same beaker remains uncovered in the (b) (4) (located in the anteroom – ISO 8 classified), (b) (4) (b) (4) (unclassified), staging tray (located in the buffer room – ISO 7 classified), and in the LAFH (ISO 5 classified).

B. Your lead pharmacy technician, who conducts cleaning on a routine basis, admitted the trash bins are removed from the buffer room (ISO 7 classified) and placed into the anteroom (ISO 8 classified) when the floors are cleaned. However, the trash bins are not disinfected or sanitized when entering an area of higher classification.

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OBSERVATION 9

The area adjacent to the ISO 5 classified aseptic processing areas had difficult to clean, particle-generating and visibly dirty equipment or surface.

A. Buffer Room (ISO-7 classified) Area:

1. On 03/09/2020, what appeared to be signs of rust and chipped paint was observed on your firm's LAFH (ISO-5 classified) support frame, located approximately 1-inch from where aseptic operations are performed.
2. On 03/09/2020, what appeared to be visible signs of dust build-up was observed on your firm's LAFH (ISO-5 classified) support frame, located approximately 1-inch from where aseptic operations are performed.
3. ***THIS IS A REPEAT OBSERVATION*** On 03/09/2020, a chair was observed to not be suitable as a cleanroom chair. What appeared to be signs of rust was observed on the back support and legs of the chair, and what appeared to be paint chippings were observed on the upper back portion of the chair.
4. On 03/09/2020, what appeared to be signs of rust was observed on the storage rack where cleaning supplies and drug components are stored.
    i. For example, but are not limited to, non-sterile (b) (4) wipes used during routine cleaning of your firm's LAFH (ISO-5 classified) is open and exposed to the ISO-7 area. These non-sterile wipes were observed to be approximately 6 inches from what appears to be signs of rust located on your firm's storage rack.
5. On 03/09/2020, what appeared to be brown residue was observed on the leg of your firm's staging tray, where drug components are placed prior to entering the LAFH (ISO-5 classified).
6. On 03/09/2020, missing caulk, creating a gap, was observed where the floor meets the wall. This area is located approximately 5 feet from the LAFH (ISO 5 classified).
7. On 03/09/2020, a crack was observed on the ceiling of the buffer room, located approximately 3 feet above the LAFH (ISO-5 classified).

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B. Anteroom (ISO-8 classified) Area:

1. On 03/09/2020, what appears to be signs of rust, chipped paint, cracks, and brown residue was observed on the inside of your firm's (b) (4) Hood (b) (4) According to your pharmacist-in-charge, who oversees aseptic operations, and your lead pharmacy technician, who performs aseptic operations on a routine basis, the (b) (4) is used to (b) (4) (b) (4) used in aseptic operations. According to your lead pharmacy technician, the status of the (b) (4) on 03/09/2020, is clean.
2. On 03/09/2020, what appears to be rust was observed around your firm's light fixture. In addition, missing caulk was observed around the perimeter of the same light fixture that seals the fixture to the ceiling.
3. On 03/09/2020, what appears to be a crack alongside the countertop, exposing particle board, located immediately adjacent to the door that leads into the firm's Buffer room (ISO 7 classified) was observed. Particle board was also observed on the underside of the countertop where the sink is located. In addition, missing caulk and a yellowish-brown residue was observed on the same countertop.

OBSERVATION 10

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

Specifically, your firm produces hazardous and non-hazardous, sterile and non-sterile, drug products without adequate segregation. On 03/09/2020, we observed what appears to be white powder residue in your firm's (b) (4) hood (b) (4) According to your firm's lead pharmacy technician, who engages in aseptic operations on a routine basis, the status of the (b) (4) is clean. All (b) (4) drugs (hazardous and non-hazardous) are (b) (4) in this non-dedicated (b) (4) Your firm does not have a separate processing schedule when producing hazardous drug products from non-hazardous drug products. For example, but are not limited to, on 1/23/2020, your firm used fluorouracil API (b) (4) (b) (4) a hazardous drug product, to produce a non-sterile cream. However, your firm also engaged in aseptic operations before and after this fluorouracil lot was produced.

Furthermore, your firm does not have appropriate cleaning solutions or appropriate controls in place after handling hazardous drug products.

In addition, your technicians do not change gowns between lots; gowns are reused per shift.

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OBSERVATION 11

Parameters for sterilization are not lethal to resistant microorganisms.

Specifically, your firm uses (b) (4) using the (b) (4), s/n (b) (4), for depyrogenation of glassware used in the production of sterile drug products. Your firm has not performed an endotoxin challenge for the glassware (b) (4)