DISTRICT ADDRESS AND PHONE NUMBER DATE(S) OF INSPECTION	STRICT ADDRESS AND PHONE NUMBER .S. Food and Drug Administration	DRUG ADMINISTRATION	N
404 BNA Drive Bldg 200 Suite 400 US400-15202(0.5/16/2020): 04/09/24 Nativile, TN 2717 15-366-7801 EDA-483 Responses: ORAPHARMA2_RESPONSES(@FDA HHS GOV 3010536120 Nake AND THUE OF BRYNDELL TO NUMER/BROW TRUED 3010536120 TO: Mr. Joe S. Moore, President and Owner 2401 N Occee Street CTV.SNAL #PCORE, COMPRY TWE BRAMARD TRUE AND T			DATE(S) OF INSPECTION
Nastwille, IN 37217 3010536120 FDA_483 Responses: ORAPHARMA2_RESPONSES@FDA.HHS.GOV 3010536120 State.abs/TMLOFBRUTERING The State Sta	J4 BNA Drive Bldg 200 Suite 400		03/09-13/2020;03/16/2020; 04/09/2020
FDA-483 Responses: ORAPHARMA2_RESPONSES@FDA.HHS.GOV Note: AND THE OF REMYRICAL TO VELOCITIES OF MALES AND THE OF REMYRICAL TO VELOCITIES OF REMYRICAL TO SUBJECT ACCENTS. 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 submit this information to FDA at the address above. OBSERVATION 1 Sources of non-microbial contamination were observed in the ISO 5 classified aseptic processing a 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), (D) (4), where aseptic human and veterinarian drug operatitake 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) observed on the HEPA screen of your firm's (b) (4)			
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TO: Mr. Joe S. Moore, President and Owner PREMANSE 2401 N Occee Street CHY, STATE, PRODECOMMENT TWE DETAILIBURGAT DESERTION Cleveland, TN 37311-3853 Producer of Sterile and Non-Sterile Drug Products 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, you may discuss the objection or submit this information to FDA at the address above. If you have ar questions, please contact FDA at the phone number and address above. OBSERVATION 1 Sources of non-microbial contamination were observed in the ISO 5 classified aseptic processing a 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 operatitake 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) 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 corner			
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	and the second firm to according to a	1 pharmacy techn	ician, the status of the cleanroom (LAFI -8 classified) on 03/09/2020, is clean.
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	SO-5 classified; Buffer Room: ISO-7 classified	r, Anteroom, 150-	

TORM ED & 483 (00/08)	PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS	PAGE 1 OF 10 PAGES
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE June P. Page, Investigator Demario L. Walls, Investigator	DATE ISSUED 04/09/2020

	NT OF HEALTH AND HUMAN SERVICES DOD AND DRUG ADMINISTRATION
DISTRICT ADDRESS AND PHONE NUMBER U.S. Food and Drug Administration 404 BNA Drive Bldg 200 Suite 400 Nashville, TN 37217 615-366-7801 <u>FDA-483 Responses</u> : ORAPHARMA2_RESPONSES@FDA.	DATE(S) OF INSPECTION 03/09-13/2020;03/16/2020; 04/09/2020 FEINUMBER 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

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 Administ	
Injectable (including intrathecals)	(b) (4
Ophthalmic	(b) (4)
Inhalation	(b) (4)
Drop	(b) (4
Irrigation	(D) (4
Grand Total	(b) (4)

FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATIONS	PAGE 2 OF 10 PAGES
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	June F. Page, Investigator	P. Page -S3 ***********************************	DATE ISSUED

District ADDRESS AND PHORE NUMBER DATEGOR INSPECTION U.S. Food and Drug Administration 03/09-13/2020;03/16/2020; 04/09/2020 Nashville, TN 37217 615-366-7801 FDA-433 Responses: ORAPHARMA2_RESPONSES@FDA.HHS.GOV 3010536120 VAME ANDITITIO OF INNIVIDUAL TO WHOM REPORT ISSUED 3010536120 TO: Mr. Joe S. Moore, President and Owner FIRMAMAR STREET ADDRESS Medical Center Pharmacy, Inc 2401 N Occee Street CITY, MATE JPHONE, CONFIG TYPE ESTABLISHMENT INSPECTED Cleveland, TN 37311-3853 Producer of Sterile and Non-Sterile Drug Products This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional 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. 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.		HEALTH AND HUM	
6153657801 3010536120 TOS_MR_ION_STRUE_INMEMORATING STRUE_STRUET MARKET 3010536120 MOMERATING STRUERS, INMERATING AND	U.S. Food and Drug Administration 404 BNA Drive Bldg 200 Suite 400	DIROUADMINISTRAL	DATE(S) OF INSPECTION 03/09-13/2020;03/16/2020; 04/09/2020
Decision Mr. Joe S. Moore, President and Owner States Annexes Medical Center Planning, Inc 24013 Mocess Reset 24013 Mocess Reset 24013 Mocess Reset Cleveland, TN 37311-13833 Producer of Sterile and Non-Sterile Drug Products Producer of Sterile and Non-Sterile Drug Products This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observation, or there implemented, or perturb 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, places contact FDA at the phore number and address above. 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 classifier area. Specifically, A. According to your firm's Certification Report, dated 16 April 2019, a viable air sample (VAS) revealed: I. In the (b) (4) hood (b) (4) hood (b) (4) (b) (4) f. Bacterial Results and Trending: Nineteen (19) CFUs were identified as Bacillus; Caag-Neg. Staphylococcus; Micrococcus. 2. In the Anteroom (ISO-7 classified) on the "counter near center of room": i. Fungal 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, includi	615-366-7801 FDA-483 Responses: ORAPHARMA2_RESPONSES@FDA.HHS.GOV		3010536120
Medical Center Planamacy, Inc. 2401 N Conce Siteset Origination Sectors Producer of Sterile and Non-Sterile Drug Produces Cleveland, TN 37311-3853 Producer of Sterile and Non-Sterile Drug Produces This document lists observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding your compliance. If you have any questions, please connate FDA at the phone number and address above. OBSERVATION 3 You did not make addequate 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:			
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EXERCISE DATE ISSUED Vitamin B Complex High Potency Injection 04162019@4 Nandrolone Decanoate 200mg/1ml 04162019@8 Anastrozole/Testosterone Cypionate Oil 04162019@9 Injection 1mg/200mg/mL 04162019@9 Estradiol Valerate/Testosterone Cypionate 04162019@9 40mg/50mg Per mL 04162019@6 SEEE REVERSE June P. Page, Investigator June P. Page -53			Lot Number
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40mg/50mg Per mL 04162019@6 DATE ISSUED SEE REVERSE June P. Page, Investigator June P. Page -53 Date Instruction 04/09/2020	Injection 1mg/200mg/mL		04162019@9
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FORM FDA 483 (09/08)

PREVIOUS EDITION OBSOLETE

INSPECTIONAL OBSERVATIONS

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	LTH AND HUMAN SERVICES IG ADMINISTRATION
U.S. Food and Drug Administration	DATE(S) OF INSPECTION 03/09-13/2020;03/16/2020; 04/09/2020
404 BNA Drive Bldg 200 Suite 400 Nashville, TN 37217	FEINUMBER
615-366-7801 FDA-483 Responses: ORAPHARMA2_RESPONSES@FDA.HHS.GOV	3010536120
TO: Mr. Joe S. Moore, President and Owner	
FIRM NAME	STREET ADDRESS
Medical Center Pharmacy, Inc CITY, STATE, ZIP CODE, COUNTRY	2401 N Ocoee Street TYPE ESTABLISHMENT INSPECTED
Cleveland, TN 37311-3853	Producer of Sterile and Non-Sterile Drug Products
This document lists observations made by the FDA representative(s) observations, and do not represent a final Agency determination reg observation, or have implemented, or plan to implement, corrective action with the FDA representative(s) during the inspection or subm questions, please contact FDA at the phone number and address abo	arding your compliance. If you have an objection regarding an action in response to an observation, you may discuss the objection or it this information to FDA at the address above. If you have any
B. According to your firm's Certification Repo	rt, dated October 2019, a viable air sample revealed:
1. In the Laminar Air Flow Hood (LAF	TH) (ISO-5 classified), (b) (4) , at the
center, approximately 6" from the re	
2. In the Buffer Room (ISO-7 classified	ng: One (1) CFUs were identified as <i>Bacillus</i> . t) on the "top shelf of shelving":
i. Bacterial Results and Trendin	ng: Two (2) CFUs identified as Micrococcus.
3. In the Anteroom (ISO-8 classified) of	on the "counter near center of room":
	: Four (4) CFUs identified as Non-Sporulating;
<i>Curvulvaria; Pithomyces; Ye</i> ii Bacterial Results and Trendi	$\frac{19}{200}$ ng: Five (5) CFUs identified as Coag-Neg.
Staphylococcus; Micrococcu	
According to your firm's Sterile Log, the fo	llowing products were produced on 16 April 2019,
including but are not limited to:	
Drug Name	Lot Number
Hydromorphone - Preservative Free	
Your firm does not have a written procedure outlini	ng cleaning requirements for VAS excursions.
However, your firm's Staff Pharmacist, stated a thor resampling when environmental monitoring excursi	ons are evident
Review of your firm's ^{(b) (4)} and (b) (4) cleaning r conducted. For example, but are not limited to:	ecords does not document a rigorous cleaning was
• On 4/16/2019 environmental monitoring for	r VAS was performed by a 3rd party contractor; your
firm's ^{(b) (4)} cleaning records document clea	ning 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 asepti-	cally 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 clea	ning was performed with non-sterile (b) (4)
(b) (4) EM sampling, a (b) (4) clean was per	formed 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 viab	but not limited to: injectables (including intrathecals),
ophthalmics, and inhalations.	
EMPLOYEE(S) SIGNATURE June P. Page	-S3 Balance III - address IIII - address III - add
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	ECTIONAL OBSERVATIONS PAGE 4 OF 10 PAGES

FOOD AND DR	LTH AND HUMAN SERVICES UG ADMINISTRATION
U.S. Food and Drug Administration 404 BNA Drive Bldg 200 Suite 400 Nashville, TN 37217 615-366-7801 EDA-483 Responses: ORAPHARMA2_RESPONSES@FDA.HHS.GOV	DATE(S) OF INSPECTION 03/09-13/2020;03/16/2020; 04/09/2020 ITEL NUMBER 3010536120
TO: Mr. Joe S. Moore, President and Owner	
FIRM NAME	STREET ADDRESS
Medical Center Pharmacy, Inc	2401 N Ocoee Street
CHY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Cleveland, TN 37311-3853	Producer of Sterile and Non-Sterile Drug Products

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 Drug Name Compounded		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	~l 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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DEPAR	RTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION
DISTRICT ADDRESS AND PHONE NUMBER U.S. Food and Drug Administration 404 BNA Drive Bldg 200 Suite 400 Nashville, TN 37217 615-366-7801 FDA-483 Responses: ORAPHARMA2_RESPONSES@	DATE(S) OF INSPECTION 03/09-13/2020;03/16/2020; 04/09/2020 PELNUMBER 3010536120
TO: Mr. Joe S. Moore, President and Owr	1 12
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

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);
 - 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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	FOOD AND DR	ALTH AND HUMAN SERVICES	
DISTRICT ADDRESS AND PHONE NUMBER U.S. Food and Drug Administration		DATE(S) OF INSPECTION	
404 BNA Drive Bldg 200 Suite 400 Nashville, TN 37217		03/09-13/2020;03/16/2020; 04 FELNUMBER	4/09/2020
615-366-7801		3010536120	
FDA-483 Responses: OR NAME AND TITLE OF INDIVIDUAL	APHARMA2_RESPONSES@FDA.HHS.GOV		
	loore, President and Owner		
FIRM NAME		STREET ADDRESS	
Medical Center Pharmac CITY, STATE, ZIP CODE, COUNTRY		2401 N Ocoee Street TYPE ESTABLISEMENT INSPECTED	
Cleveland, TN 37311-38	53	Producer of Sterile and Non-Sterile Drug Products	
observations, and do n observation, or have in action with the FDA ra	ot represent a final Agency determination re nplemented, or plan to implement, corrective	s) during the inspection of your facility. They are inspect garding your compliance. If you have an objection regar- e action in response to an observation, you may discuss the nit this information to FDA at the address above. If you ove.	ding an he objection o
2. Lis	t fixture: Missing caulk was obs	served around your firm's light fixture	
3. Ce	iling: A crack observed in the she	etrock located on your firm' ceiling direct	ly above th
	D 5 hood.		- - 1997
C. ISO 8 Cla			
		d missing caulk were observed around the	
		HEPA filters to the ceiling, located in you	r firm's
	eroom (ISO-8 classified);		12
		ng was observed around the perimeter of y	our light
Complete State	ture; and	1 10 1 1 1 1 1 1	4
3. (b)		controls - according to your pharmacist-in	-charge,
		ts used in aseptic operations) are (b) (4) $(120, 7, 2)$	b) (1)
		uffer room (ISO 7 classified) (b) (4) (1) -charge admitted the beakers are not alwa	b) (4)
	itized when (b) (4)	(b) (4)	lys covered
Sai			
OBSERVATION			
Equipment and M	aterials or supplies were not disir	nfected prior to entering the aseptic process	
			sing areas.
Specifically,			sing areas.
	2020 your pharmacist in charge	admitted the alassware (a.g. haskers) cont	
A. On 03/16/		admitted the glassware (e.g. beakers), cont	aining dru
A. On 03/16/ products u	sed in aseptic operations are unco	overed and are not disinfected or sanitized	aining dru
A. On 03/16/ products u in your fir	sed in aseptic operations are uncom's unclassified(b) (4)	overed and are not disinfected or sanitized . This(b)(4) anto	aining dru l when plac eroom (IS)
A. On 03/16/ products u in your fir classified)	used in aseptic operations are unco m's unclassified(b) (4) to your firm's buffer room (ISO	. This (b) (4) anto 7 classified). According to your firm's PIC	aining dru l when plac eroom (ISC C, this sam
A. On 03/16/ products u in your fir classified) beaker rer	ised in aseptic operations are uncom's unclassified (b) (4) to your firm's buffer room (ISO nains uncovered in the (b) (4) (loca	. This (b) (4) anto 7 classified). According to your firm's PIC ated in the anteroom – ISO 8 classified), (b	aining dru l when plac eroom (ISC C, this sam) (4)
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FDA-483 Responses: ORAPHARMA2_RESPONSES@FDA.HHS.GOV				
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			

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:
 - 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.
 - 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.
 - 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).
 - 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).
 - 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:
 - 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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Cleveland, TN 37311-3	853	Producer of Sterile and Non-Sterile Drug Products			
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OBSERVATIO	N 11				
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