DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900 Fax:(973)331-4969 ORAPHARM1_RESPONSES@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	05/17/2022-06/17/2022
	FEI NUMBER 3010924627

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Teresa Malanda, RPh, Pharmacist-In-Charge, Owner

FIRM NAME	STREET ADDRESS
Mandell's Clinical Pharmacy	7 Cedar Grove Ln
CITY, STATE, ZIP CODE, COUNTRY Somerset, NJ 08873-1331	TYPE ESTABLISHMENT INSPECTED 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, 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
Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

Specifically, the media fill performed by your firm to support aseptic filling practices in the ISO 5 Biological cabinet (BSC) located in the ISO 7 room does not represent the most challenging conditions. The media fill run simulates the processing of Progesterone Ethyl Oleate 100mg/ml, Progesterone Ethyl Oleate 50mg/ml, and progesterone olive oil 50mg/ml, which are (b) (4). This does not represent the most challenging scenario, in that there are other production processes that require (b) (4) (b) (4). Below are examples of (b) (4) products:

- Micro Dose Leuprolide Acetate 50mcg/0.2ml
- Leuprolide Trigger Prefilled syringes

(***Repeat Observation***)

OBSERVATION 2
Personnel were observed putting on gowning apparel in a way that may cause the gowning apparel to become contaminated.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Adetutu M Gidado, Investigator Daniel J Min, Investigator Sayyem H Akbar, Investigator X Adetutu Gidado -S Digitally signed by Adetutu Gidado -S Date: 2022.06.17 14:19:51 -04'00' Adetutu Gidado Investigator	06/17/2022

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Teresa Malanda, RPh, Pharmacist-In-Charge, Owner

FIRM NAME	STREET ADDRESS
Mandell's Clinical Pharmacy	7 Cedar Grove Ln
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Somerset, NJ 08873-1331	Producer of sterile and non-sterile drug products

Specifically, On 06/01/2022 during aseptic processing of the sterile drug, Micro Dose Leuprolide Acetate 50mcg/0.2ml, Lot #220601A, BUD 08/29/2022, quantity (b) (4) units in the ISO 5 Biosafety cabinet,

1. The pharmacist producing sterile drugs was observed stepping on the sterile gown while gowning, resting on the wall of the anteroom, squeezing in between the cart and the metal shelves, and touching the surfaces of materials in the anteroom before entering the sterile production room.

2. The skin on the leg of the pharmacist was observed exposed during aseptic processing.

OBSERVATION 3

No assurance that sterile drug products were processed and stored under ISO 5 quality air.

Specifically, on 06/01/2022, while visually observing your pharmacist's aseptic processing of the sterile drug, Micro Dose Leuprolide Acetate 50mcg/0.2ml, Lot #220601A, BUD 08/29/2022, quantity (b) (4) units in the ISO 5 Biosafety cabinet, the pharmacist's hands was observed resting on the return vent.

OBSERVATION 4

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

Specifically, your firm's current airflow studies (smoke studies) of the ISO 5 Biosafety cabinet were not performed under conditions showing aseptic operations that are representative of your current production practices nor did they emulate all critical unit operations and interventions used during production of your sterile drug products.

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	Adetutu M Gidado, Investigator Daniel J Min, Investigator Sayyem H Akbar, Investigator X Adetutu Gidado -S Digitally signed by Adetutu Gidado -S Date: 2022.06.17 14:29:42 -04'00' Adetutu Gidado Investigator	06/17/2022

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Teresa Malanda, RPh, Pharmacist-In-Charge, Owner

FIRM NAME	STREET ADDRESS
Mandell's Clinical Pharmacy	7 Cedar Grove Ln
CITY, STATE, ZIP CODE, COUNTRY Somerset, NJ 08873-1331	TYPE ESTABLISHMENT INSPECTED Producer of sterile and non-sterile drug products

***DATES OF INSPECTION**
5/17/2022(Tue), 5/19/2022(Thu), 5/26/2022(Thu), 6/01/2022(Wed), 6/03/2022(Fri), 6/10/2022(Fri), 6/17/2022(Fri)

X Daniel J. Min -S Digitally signed by Daniel J. Min -S Date: 2022.06.17 14:21:11 -04'00'

Daniel Min

X Sayyem H. Akbar -S Digitally signed by Sayyem H. Akbar -S Date: 2022.06.17 14:22:09 -04'00'

Sayyem Akbar

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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."