DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661	3/14/2019-4/5/2019* FEI NUMBER 3011795133

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Robert Schwartz, RPh, Director of Pharmacy

FIRM NAME	STREET ADDRESS
Metro Drugs 3rd Avenue Corp	931 Lexington Ave
CITY, STATE, ZIP CODE, COUNTRY New York, NY 10065-5771	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 I OBSERVED:

OBSERVATION 1

Disinfecting agents and cleaning pads or wipes used in the ISO 5 area aseptic processing areas are not sterile.

Specifically, on 3/14/19, I observed an aseptic operator using non-sterile (b) (4) Wipes (b) (4), to disinfect the ISO 5 (b) (4) laminar flow hood and as a place mat where syringes, needles, and sterile (b) (4) were placed upon during aseptic filling.

OBSERVATION 2

Your firm released drug product in which the strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

Specifically, the following out-of-specification potency results were observed:

- T3 6mcg capsules S/R, lot #01082019@9, Liothyronine Sodium (T3) potency: 86.3%;
- T3 20mcg capsules S/R, lot #01252019@7, Liothyronine Sodium (T3) potency: 116%;
- T3 30mcg, lot #01252019@14, Liothyronine Sodium (T3) potency: 75.0%;
- Estriol/ DHEA/ Testosterone/ Pregnenolone 100mg/4mg/45mg/mg/mL, lot #02142019@1, DHEA potency: 81.3%, Estriol potency: 77.2%, and Testosterone potency: 84.5%;
- Methylcobalamin 1000mcg/mL (PF) injectable, lot #02212019@1, Methylcobalamin potency:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Rachael A Moliver, Investigator	X Rachael A Moliver Investigator Signed By: Rachael Moliver -S Date Signed: 04-05-2019 09:06:52	4/5/2019

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53.3%;

- Tri-Mix Quad (Alprostadil 10mcg/ Papaverine 12mg/ Phentolamine 1mg/ Atropine 0.15mg/mL), lot #03052019@6, Atropine Sulfate Monohydrate potency: 134.51%; and, Atropine 0.1% Stock Solution, lot #03052019@8, Atropine Sulfate Monohydrate potency: 107.38%.

No product impact assessment has been conducted and recorded, except for the Tri-Mix Quad and Atropine 0.1% Stock Solution.

OBSERVATION 3

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,

a) Your firm did not evaluate any conditions that provide a challenge to aseptic operations as part of the firm's media fill. For example, operators do leave and reenter the ISO 5 area during production; however, this was not addressed in any of the media fills.

b) One of your pharmacy technicians was not qualified by a media fill prior to preparing sterile drug products and continued to perform aseptic processing of sterile drug products despite failing a media fill performed on 1/17/19.

OBSERVATION 4

ISO-5 classified areas were not certified under dynamic conditions.

Specifically, unidirectional airflow was not verified under dynamic conditions. The most recent smoke pattern tests were performed on (b) (4) by(b) (4) on the firm's ISO 5 biological safety cabinet and ISO 5 laminar flow clean bench under static conditions.

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OBSERVATION 5

Inadequate pressure differentials between higher quality air rooms and lower quality air rooms were observed.

Specifically, pressure differential readings for (b) (4), which monitors the pressure from the ISO 7 Hazardous Prep Room to the ISO 8 Non-Hazardous Prep/Buffer Room (established negative pressure differential limit (b) (4)), were out of specification on 1/14/19 to 1/15/19, all of December 2018, and 11/1/18 to 11/27/18. Mixing of non-sterile active pharmaceutical ingredients and non-sterile commercial products is conducted in the (b) (4) hoods (b) (4) located in both the ISO 7 Hazardous Prep Room and the ISO 8 Non-Hazardous Prep/Buffer Room. No product impact assessment was conducted and recorded.

***DATES OF INSPECTION**

3/14/2019(Thu), 3/15/2019(Fri), 3/18/2019(Mon), 3/19/2019(Tue), 3/25/2019(Mon), 3/26/2019(Tue), 3/28/2019(Thu), 3/29/2019(Fri), 4/04/2019(Thu), 4/05/2019(Fri)

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