DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Division of Pharmaceutical Quality Operations I 10 Waterview Blvd, 3rd Floor Parsippany, NJ 07054 ORAPharm1_responses@fda.hhs.gov Industry Information: www fda.gov/oc/industry	09/16/2020-10/09/2020 FEI NUMBER 3004600183

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. David Miller, Pharmacist in Charge

FIRM NAME	STREET ADDRESS
Millers of Wyckoff, Inc	678 Wyckoff Avenue
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Wyckoff, NJ, 07481	Producer of Sterile and Non-Sterile Drugs

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

Hazardous drugs were produced without providing adequate cleaning of utensils to prevent cross contamination.

Specifically, your firm produces potent drugs including, but not limited to Progesterone, Testosterone, or a combination of these drug products from (b) (4) Active Pharmaceutical Ingredients (APIs). Utensils used in the production of these potent drugs, such as, spatulas, jars and glass beakers are not dedicated and not cleaned with a process that utilizes an agent to deactivate residual APIs.

Your firm utilizes a store-bought brand liquid dish detergent and potable water for cleaning of theses utensils in the processing of potent APIs. The following potent drug products were observed being prepared and produced using the non-sterile hazard production room on 09/17/2020:

A.) Testosterone Topical 50mg/gm 15% Cream Rx: (b) (6) Lot# 09172020@22, BUD:10/22/2020, Date Made: 09/17/2020
B.) BIEST ((b) (4))/Progesterone 2mg/100mg, Rx: (b) (6) Lot# 09172020@15, BUD: 12/16/2020, Date Made: 09/17/2020
C.) BIEST ((b) (4))/ Progesterone 2.5mg/125mg, RX: (b) (6) Lot # 09172020@25, BUD: 12/16/2020, Date Made: 09/17/2020

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Tonia Bernard -S Digitally signed by Tonia Bernard -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Tonia Bernard -S, 0.9.2342.19200300.100.1.1=2001637553 Date: 2020.10.09 09:40:41 -04'00'	10/09/2020

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OBSERVATION 2

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

Specifically, your records of differential room pressures are inadequate, in that, you do not record the quantitative value of the pressures. Additionally, your record of differential room pressures failed to record pressure excursions for your Sterile Hazardous Room in the following instances:

Your most recent cleanroom certification report, dated: 08/14/2020, documents that the Sterile Hazardous Room (ISO 7) pressure was recorded at (negative)- 0.064" w.c. According to your specification, the acceptance range for differential pressure of this room is between (b) (4) In this instance, the reported differential pressure reading was out of specification. However, you continued to use this room as well as, adjacent cleanrooms for production of sterile drug products.

In addition, on 09/25/2020, I observed that the Magnahelic equipment used to monitor the pressure differential reading for the Hazardous Room was (negative) -0.11" w.c, which was not within specifications.

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*DATES OF INSPECTION

09/16/2020,09/17/2020,09/18/2020,09/21/2020,09/24/2020,09/25/2020,09/30/2020,10/02/2020,10/09/2020

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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."