U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations I
10 Waterview Blvd, 3rd FL
Parsippany, NJ 07054
Telephone: (973) 331-4900
FAX: (973) 331-4969
www.fda.gov

FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
OFFICE OF PHARMACEUTICAL QUALITY OPERATIONS

EMAIL DELIVERY
RETURN RECEIPT REQUESTED

December 01, 2021

Mr. David Miller
Pharmacist in Charge
Millers of Wyckoff, Inc.
678 Wyckoff Avenue
Wyckoff, NJ 07481-1430
FEI: 3004600183

Dear Mr. Miller:

From September 16, 2020, to October 9, 2020, a U.S. Food and Drug Administration (FDA) investigator inspected your facility, Millers of Wyckoff, Inc., located at 678 Wyckoff Avenue, Wyckoff, NJ 07481. During the inspection the investigator noted deficiencies in your practices for producing drug products, which put patients at risk.

FDA issued a Form FDA 483 to your firm on October 9, 2020. FDA acknowledges receipt of your facility's response, dated October 19, 2020. Based on this inspection, it appears that you produced drug products that violate the Federal Food, Drug, and Cosmetic Act (FDCA).

A. Compounded Drug Products Under the FDCA

Section 503A of the FDCA describes the conditions under which human drug products compounded by a licensed pharmacist in a State licensed pharmacy or a Federal facility, or a licensed physician, qualify for exemptions from three sections of the FDCA: compliance with current good manufacturing practice (CGMP) (section 501(a)(2)(B)); labeling with adequate directions for use (section 502(f)(1)); and FDA approval prior to marketing (section 505) [21 U.S.C. §§ 351(a)(2)(B), 352(f)(1) and 355(a)].

B. Violations of the FDCA

Adulterated Drug Products

The FDA investigators noted that drug products were prepared, packed, or held under insanitary conditions, whereby they may have become contaminated with filth or rendered injurious to health, causing your drug products to be adulterated under section 501(a)(2)(A) of the FDCA. For example, the investigators observed that:

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 are not cleaned with a process that utilizes an agent to deactivate residual APIs.

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.

It is a prohibited act under section 301(k) of the FDCA [21 U.S.C. § 331(k)] to do any act with respect to a drug, if such act is done while the drug is held for sale after shipment in interstate commerce and results in the drug being adulterated.

C. Corrective Actions

We have reviewed your firm's response to the Form FDA 483. Regarding your response related to the insanitary conditions, we cannot fully evaluate the adequacy of the following corrective action described in your response because you did not include sufficient information or supporting documentation. Specifically, in your response you state that the pharmacy dedicates utensils to HD compounding but, during the inspection, the investigator observed utensils used in the production of these potent drugs, such as, spatulas, jars and glass beakers are not dedicated. As a corrective action, you state that that you are currently using disposable spatulas, but no corrective action for requiring dedicated jar and glass beakers for potent drugs is referenced in your response.

Additionally, you state that for both dates cited in Form FDA 483, Observation 2, the pressure excursions were due to routine (b) (4) cleaning just prior to inspection, however, no documentation of these cleanings was submitted in your response. Moreover, at the time of this observation, there was no requirement to record pressure differentials at a set interval. Your response states that the correct pressure of (b) (4) would have been achieved prior to any compounding, but with no set requirement of when to record pressure differentials, you do not provide assurance as to how the correct pressure differential would have been verified prior to compounding. Your response stated that the pharmacy will proactively modify its policies in this area so that the quantitative values of pressures shall be reviewed and documented on a log at least (b) (4) (minimum frequency shall be at (b) (4) or by (b) (4) . You did not include any updated procedure or retraining of staff to ensure this new requirement would be implemented.

Please be aware that section 501(a)(2)(A) of the FDCA concerning insanitary conditions applies regardless of whether drug products you compound meet the conditions of section 503A.

FDA strongly recommends that your management undertake a comprehensive assessment of operations, including facility design, procedures, personnel, processes, maintenance, materials, and systems. In particular, this review should assess your aseptic processing operations. A third-party consultant with relevant sterile drug manufacturing expertise should assist you in conducting this comprehensive evaluation.

D. Conclusion

The violations cited in this letter are not intended to be an all-inclusive statement of violations at your facility. You are responsible for investigating and determining the causes of any violations and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations.

Within thirty (30) working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to address any violations. Please include an explanation of each step being taken to prevent the recurrence of any violations, as well as copies of related documentation. If you believe that your products are not in violation of the FDCA, include your reasoning and any supporting information for our consideration. If you cannot completely address this matter within thirty (30) working days, state the reason for the delay and the time within which you will do so.

Please send your electronic response to ORAPHARM1_Responses@fda.hhs.gov and copy Office of Pharmaceutical Quality Operations, Division I, Compliance Officer, at email:samina.khan@fda.hhs.gov. Please identify your response with FEI #3004600183.

If you have questions regarding the contents of this letter, please contact Samina Khan at samina.khan@fda.hhs.gov.

Sincerely,

Diana Amador-toro -S

Digitally signed by Diana Amador-toro -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300011579, cn=Diana Amador-toro -S
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Diana Amador-Toro
Program Division Director/District Director
Office of Pharmaceutical Quality Operations
Division I