Colonia Care Pharmacy 10/12/17

Division of Pharmaceutical
Quality Operations I
10 Waterview Blvd, 3rd FL
Parsippany, NJ 07054
Telephone: (973) 331-4900
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WARNING LETTER
WL # 537790

October 12, 2017

VIA UPS Next Day Air

Svetislav Milic, R.Ph., Owner
Colonia Care Pharmacy
515 Inman Avenue, Suite A
Colonia, New Jersey, 07067-1114

Dear Mr. Milic:

From March 3, 2016, to April 15, 2016, a U.S. Food and Drug Administration (FDA) investigator inspected your facility, Colonia Care Pharmacy, located at 515 Inman Avenue, Suite A, Colonia, New Jersey, 07067-1114. During the inspection, the investigator noted serious deficiencies in your practices for producing sterile drug products, which put patients at risk.

FDA issued a Form FDA 483 to your firm on April 15, 2016. FDA acknowledges receipt of your facility's responses, dated May 5, 2016, and July 25, 2016. FDA acknowledges your action on July 28, 2016, to voluntarily recall all lots of compounded injectable drug products produced from sterile-filtered stock solutions and cease production of drug products produced from sterile-filtered stock solutions.

Based on this inspection, it appears that you produced drug products that violate the FDCA.

A. Violations of the FDCA

Adulterated Drug Products

The FDA investigator noted that drug products intended or expected to be sterile 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 investigator noted that your production records indicate that you have produced drugs purported to be sterile using stock solutions that were sterile filtered into **(b)(4)** stored in an unclassified area, and then filled into finished drug product vials without a further sterilization step. The investigators also observed that your "**(b)(4)**, where aseptic processing of drug products occurs, was located in an unclassified room. Our investigators found that your firm failed to demonstrate through appropriate studies that your **(b)(4)** is able to provide adequate protection of the ISO 5 area in which sterile products are processed. Therefore, your products may be produced in an environment that poses a significant contamination risk**.**

B. Corrective Actions

We acknowledge your response to the Form FDA 483 inspectional observations, dated May 5, 2016. We acknowledge your recall on July 28, 2016, of all lots of injectable drug products within expiry which were produced from sterile-filtered stock solutions. In addition, we acknowledge that you ceased production of these drug products due to concerns of sterility assurance.

Regarding the insanitary condition observations in the Form FDA 483, we are unable to fully evaluate some of your corrective actions due to lack of adequate supporting documentation. Specifically, your response states that "smoke testing under dynamic conditions has been and will continue to be performed during each and every certification." Your response did not include, however, any documentation to support this statement, or a description of how dynamic conditions are simulated during performance of smoke studies.

In addition, we remain concerned that the current location of your ISO 5 "**(b)(4)**," where aseptic processing occurs, does not mitigate the risk associated with potential contamination of sterile drug products.

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 if you decide to resume production of drugs produced from sterile- filtered stock solutions, your management first 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.

C. 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 the violations identified above 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.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction.

Within fifteen (15) working days of receipt of this letter, please notify this office in writing if you have taken any specific steps to correct the violations cited in this letter. Please include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you do not believe that the products discussed above violated the FDCA, include your reasoning and any supporting information for our consideration. In addition to taking appropriate corrective actions, you should notify this office 15 days prior to resuming production of drug products produced from sterile-filtered stock solution in the future.

Your written notification should refer to the Warning Letter # 537790. Please address your reply to:

CDR Liatte Krueger
Compliance Officer/OPQ Division 1
New Jersey District Office
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

If you have questions regarding the contents of this letter, please contact CDR Liatte Krueger at (973) 331-4933.

Sincerely,
/S/
Diana Amador Toro
Division Director/OPQ Division 1
New Jersey District Office