Magellan Rx Pharmacy, LLC 9/11/17

U.S. FOOD & DRUG ADMINISTRATION

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 # 536134

September 11, 2017

VIA UPS OVERNIGHT
Mr. Hans G. Go, R.Ph.
Director of Pharmacy Operations
Magellan Rx Pharmacy, LLC
31-75 23rd St, Suite 410
Astoria, NY 11106-4134

Dear Mr. Go:

From December 6, 2016, to December 22, 2016, U.S. Food and Drug Administration (FDA) investigators inspected your facility, Magellan Rx Pharmacy, LLC, located at 31-75 23rd Street, Suite 410, Astoria, NY 11106. During the inspection, the investigators 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 December 22, 2016. FDA acknowledges receipt of your facility's responses, dated January 13, 2017, and March 30, 2017. Based on this inspection, it appears that you produced drug products that violate the Federal Food, Drug, and Cosmetic Act (FDCA).

A. Violations of the FDCA

Adulterated Drug Products

The FDA investigators 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:

1. Your facility design is deficient for sterile drug production. For example, your ISO 7 cleanroom had a lower pressure differential than the adjacent unclassified anteroom, thereby allowing the influx of lower quality air into the ISO 7 cleanroom. In addition, the investigators observed holes in ceiling tiles in the ISO 7 cleanroom as well as a sink that is approximately 12 feet away from the ISO 5 **(b)(4)** within the ISO 7 cleanroom. The investigators also noted that the ISO 7 cleanroom contained dust-collecting ledges, such as windowsills.

2. Your cleaning and disinfection program is inadequate. For example, your firm used non-sterile wipes and a non-sterile disinfectant in aseptic processing areas, failed to disinfect the ISO 5 work area prior to performing aseptic operations, and failed to disinfect items when transferring them from the unclassified anteroom into the ISO 7 cleanroom as well as from the ISO 7 cleanroom into the ISO 5 work area. Furthermore, FDA investigators collected environmental samples of multiple locations in your facility. Our results indicated the presence of microbial contamination, including various fungi and spore-forming bacteria, at multiple locations in your ISO 7 cleanroom.

3. Our investigator observed poor aseptic practices. For example, personnel donned sterile gloves in the unclassified anteroom, used a non-sterile **(b)(4)** in the ISO 5 work area, and wore jewelry in the ISO 7 cleanroom that was not covered by gowning.

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.

B. Corrective Actions

In your firm's responses to the Form FDA 483, you described certain corrective actions you took to address the observations. However, we are unable to fully evaluate the following corrective actions due to a lack of adequate supporting documentation. For example:

1. We acknowledge your commitment to contract with a qualified consultant to assess the facility design issues. However, you did not provide any supporting documentation and you did not include any interim controls while corrective actions are being implemented.

2. Your revised standard operating procedure (SOP) entitled "**(b)(4)**" (Policy Number: **(b)(4)**) states that supplies and equipment will be wiped with **(b)(4)** the cleanroom. However, it is not clear if items will be further disinfected prior to transfer from the ISO 7 cleanroom into the ISO 5 areas. Disinfection should occur at each transition from areas of lower quality air to areas of higher quality air.

For more information on compounding, please see FDA's website, at https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm.

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 processing 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 of the specific steps that you have taken to correct violations. 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 are in violation of the FDCA, include your reasoning and any supporting information for our consideration. If you cannot complete corrective action within 15 working days, state the reason for the delay and the time within which you will complete the correction.

Your written notification should refer to Warning Letter # 536134. Please address your reply to:

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 Liatte Krueger via email at liatte.krueger@fda.hhs.gov or by phone at (973) 331-4933.

Sincerely,
/S/
Diana Amador-Toro
Division Director/OPQ Division 1

New Jersey District Office