ImprimisRx Pharmacy LLC 8/3/17

Division of Pharmaceutical
Quality Operations I
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USPS CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
17-PHI-10

August 3, 2017

Tari E. Shapiro, Pharmacist-In-Charge
ImprimisRx PA, Inc., dba ImprimisRx
780 Primos Avenue, Unit E
Folcroft, PA 19032-2000

Dear Ms. Shapiro,

From June 28, 2016, to August 1, 2016, U.S. Food and Drug Administration (FDA) investigators inspected your facility, ImprimisRx PA, Inc., dba ImprimisRx, located at 780 Primos Avenue, Unit E, Folcroft, PA 19032-2000. During the inspection, the investigators noted serious deficiencies in your practices for producing drug products, which put patients at risk.

FDA issued a Form FDA 483 to your firm on August 1, 2016. FDA acknowledges receipt of your facility's responses, dated August 22, 2016, and November 11, 2016. FDA also acknowledges the statement in your November response letter indicating that effective November 10, 2016, your facility "no longer compounds formulations with powdered penicillin and/or related beta-lactam APIs." 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, the investigators observed the following insanitary conditions:

1. Your firm's cleaning and disinfecting procedures for work surfaces and utensils used for beta-lactam products are inadequate. Specifically, your firm uses **(b)(4)** to clean the non-dedicated Y-tubing used to compound beta-lactam products along with other products. **(b)(4)** alone might not be effective in deactivating beta-lactam and preventing cross contamination.

2. Your firm's controls to prevent cross contamination of beta lactam drugs with other products during production are insufficient. Specifically, multiple batches of different drug products, including beta-lactam drugs, were present together in the same production areas, increasing the risk of cross-contamination or mix-ups.

During the inspection, FDA investigators collected samples of two lots of a product compounded at your pharmacy. Under section 501(a)(1) of the FDCA [21 U.S.C. § 351(a)(1)], a drug is adulterated if it consists in whole or in part of any filthy, putrid, or decomposed substance. FDA analysis indicated that fibrous material consistent with wood was present in the sample taken from one of those lots of your product.

Under section 301(a) of the FDCA [21 U.S.C. § 331(a)], the introduction or delivery for introduction into interstate commerce of any drug that is adulterated is a prohibited act.

B. Corrective Actions

We have reviewed your firm's responses to the Form FDA 483. To address the insanitary conditions noted in the Form FDA 483, your firm committed to stop producing formulations with powdered penicillin and/or related beta-lactam ingredients, effective on November 10, 2016. Your action adequately addresses our concerns and such commitment will be verified during a follow up inspection.

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 [21 U.S.C. §353a].

Should you compound and distribute drug products that do not meet the conditions of section 503A, the compounding and distribution of such drugs would be subject to the new drug approval requirement, the requirement to label drug products with adequate directions for use, and the drug CGMP regulations.

FDA strongly recommends that your management undertake a comprehensive assessment of operations, including facility design, procedures, personnel, processes, maintenance, materials, and systems.

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 the violations. Please include an explanation of each step being taken to prevent the recurrence of the 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 fifteen (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 the Warning Letter Number above 17-PHI-10. Please address your reply to:

Yvette I. Johnson
Compliance Officer
Philadelphia District Office
US Customs House, Room 900
200 Chestnut Street
Philadelphia, PA 19106

If you have questions regarding the contents of this letter, please contact Yvette Johnson by phone at 215-717-3077 or by email at Yvette.Johnson@fda.hhs.gov.

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