Baptist Health Medical Towers Pharmacy and Infusion Services 9/12/17

U.S. FOOD & DRUG ADMINISTRATION

Office of Pharmaceutical Quality Operations, Division II
4040 N. Central Expressway, Suite 300
Dallas, Texas 75204

September 12, 2017

CMS Case # 527394

WARNING LETTER

VIA UPS EXPRESS

Steven D. Weeks, Executive VP / COO
Baptist Health Medical Towers Pharmacy and Infusion Services
9601 Baptist Health Drive, Suite 109
Little Rock, Arkansas 72205-6323

Mr. Weeks:

From April 11, 2016 to April 28, 2016, a U.S. Food and Drug Administration (FDA) investigator inspected your facility, Baptist Health Medical Towers Pharmacy and Infusion Services, located at 9601 Baptist Health Drive, Suite 109, Little Rock, Arkansas 72205-6323. During the inspection, the investigator noted serious deficiencies in your practices for producing sterile drug products, which put patients at risk. In addition, on February 28, 2017, an employee from FDA joined representatives from the Arkansas State Board of Pharmacy ("the Board") to conduct an investigation of your facility.

FDA issued a Form FDA 483 to your firm on April 28, 2016. FDA has reviewed your facility's response, dated May 13, 2016. FDA also acknowledges your firm's voluntary recall, initiated on April 18, 2016, of all products within expiry that were intended to be sterile produced from April 6, 2016 to April 15, 2016, due to lack of sterility assurance. Additionally, FDA acknowledges the consent agreement, dated April 20, 2016, between your firm and the Board, to suspend all sterile compounding until the Board restored this privilege on March 2, 2017 after a USP 797 inspection by the Board. Based on this inspection, it appears that you produced drug products that violate the Federal Food, Drug, and Cosmetic Act (FDCA).

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 [21 U.S.C. § 351(a)(2)(A)]. For example:

- At the time of the 2016 inspection, our investigator observed two unidentified black spots on one of the HEPA filters in your ISO 7 buffer room, a white unidentified substance on the metal diffusers within one of your ISO 5 hoods, and unidentified rust-colored spots on the HEPA filters inside two of your ISO 5 hoods.
- Our investigator observed poor aseptic practices at your firm, including a technician touching the outer surfaces of sterile gloves with his bare hands while donning them.
- Technicians were observed not disinfecting their sterile gloves or materials prior to introducing them from the ISO 7 area into the ISO 5 area.
- Your firm used non-sterile disinfectants as part of your disinfection program for the aseptic processing areas.

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.

Corrective Actions

We have reviewed your firm's response to the Form FDA 483. We acknowledge your April 18, 2016, voluntary recall of all products within expiry that were intended to be sterile produced from April 6, 2016 to April 15, 2016, due to lack of sterility assurance. We also acknowledge your consent agreement to suspend all sterile compounding until the Board restored this privilege on March 2, 2017.

During the February 28, 2017, investigation, it was observed that your firm was not operational for the production of sterile drugs. While several corrective actions were acknowledged, these would still need to be verified during the next inspection and your aseptic processing techniques would need to be observed. In addition, FDA strongly recommends that your management continues to undertake a comprehensive assessment of operations, including facility design, procedures, personnel, processes, maintenance materials (e.g., including procedures for compounding with drug products, taking expiry into account), 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.

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

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.

Now that you have resumed sterile operations, 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, or you may inform us that you do not intend to resume production of sterile drugs. Now that you have resumed production of sterile drugs in the future, 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 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 fifteen (15) days prior to resuming production of any sterile drugs in the future. Your written notification should refer to the Warning Letter Number above (**CMS Case # 527394**).

Please address your reply to John W. Diehl, Acting Director, Compliance Branch, at the FDA address provided. In addition, please submit a signed copy of your response to john.w.diehl@fda.hhs.gov.

If you have questions regarding the contents of this letter, you may contact Mr. Diehl at (214) 253-5288.

Sincerely,
/S/
Monica R. Maxwell
Acting Program Division Director
Office of Pharmaceutical Quality Operations, Division II