Bond Pharmacy, Inc. dba Advanced Infusion Solutions 3/1/17

New Orleans District
404 BNA Drive
Building 200 - Suite 500
Nashville, TN 37217
Telephone: (615) 366-7801
FAX: (615) 366-7802

March 1, 2017

Warning Letter No. 2017-NOL-06

UNITED PARCEL SERVICE
Delivery Signature Requested

Charles R. Bell, President and COO
Bond Pharmacy, Inc.
dba Advanced Infusion Solutions
623 Highland Colony Parkway, Suite 100
Ridgeland, Mississippi 39157-6077

Dear Mr. Bell:

From September 15 to October 27, 2015, U.S. Food and Drug Administration (FDA) investigators conducted an inspection of your facility, Bond Pharmacy, Inc., dba Advanced Infusion Solutions, located at 623 Highland Colony Parkway, Suite 100, Ridgeland, Mississippi. This inspection was conducted after receipt of an FDA MedWatch report concerning baclofen 500mcg/mL, bupivacaine 5mg/mL, and hydromorphone25 mg/mL injection, prepared by your firm, that was used to refill an intrathecal pain pump. During the inspection, the FDA investigators observed serious deficiencies in your practices for producing sterile drug products, which put patients at risk.

FDA issued a Form FDA 483, Investigational Observation (Form FDA 483) to your firm on October 27, 2015. FDA acknowledges receipt of your firm's response to the Form FDA 483 dated November 16, 2015. Based on this inspection, it appears you are producing drugs 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 been contaminated with filth, or rendered injurious to health, causing your products to be adulterated under Section 501(a)(2)(A) of the FDCA [21 United States Code (USC) 351(a)(2)(A)]. For example, the FDA investigators observed poor aseptic practices, including an operator not disinfecting or changing their gloves prior to introducing them into the ISO 5 area from the ISO 7 area and after touching non-sterile material. Multiple operators with non-sterile gowning and exposed facial skin were observed leaning into the ISO 5 work area. Investigators noted that your firm exposed stock solutions, intended to be sterile, to lower than ISO 5 quality air. Specifically, they observed the storage of said solutions in an unclassified area for further use after the container closure system had been punctured multiple times, and therefore compromised, throughout the assigned expiry period. Investigators collected a sample of unused wipes, intended for use in disinfecting the aseptic processing areas, from within your cleanroom for testing. Testing results of the sample identified microbial contamination, including spore-forming bacteria.

It is a prohibited Act under Section 301(k) of the FDCA 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

We have reviewed your firm's response to the Form FDA 483. Although several of your proposed corrective actions appear adequate, others are deficient. For example, in your response to our observation regarding stock solutions that are punctured multiple times during processing over several days and are stored in an unclassified area, you stated that your compounding procedures do not trigger the USP <797> requirements for endotoxin testing. You also stated your firm follows procedures and protocols that minimize the introduction and generation of endotoxin during aseptic processing and perform endotoxin testing of each stock solution before releasing the stock solution for use. However, your response did not address the practice of storing stock solutions, intended to be sterile, for further use in unclassified air with a compromised container-closure throughout the expiry period.

FDA strongly recommends that your management immediately undertake a comprehensive assessment of your operations, including facility design, procedures, personnel, processes, materials, and systems. In particular, this review should assess your aseptic processing operations. A third party consultant with relevant sterile drug processing expertise could be useful 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 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 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 the corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your written notification should be addressed to:

Mark Rivero, Compliance Officer
U.S. Food and Drug Administration
New Orleans District
404 BNA Drive
Building 200, Suite 500
Nashville, TN 37217-2597

If you have questions regarding any issues in this letter, please contact Mark Rivero, Compliance Officer via email at Mark.Rivero@fda.hhs.gov or by phone at (504) 846-6103.

Sincerely,
/S/
Ruth P. Dixon
District Director
New Orleans District

cc: Sheldon Bradshaw, Partner
Hutton & William, LLP
2200 Pennsylvania Avenue, NW
Washington, DC 20037- 1701