DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
New Orleans District
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Nashville, TN 37217

Phone: 615-366-7801
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August 2, 2016

Frank Gammill
Executive Director
Mississippi Board of Pharmacy
6360 I-55N, Suite 400
Jackson, MS 39211

Dear Mr. Gammill:

The purpose of this letter is to refer the Mississippi State Board of Pharmacy (BOP) for appropriate follow-up, of the U.S. Food and Drug Administration's (FDA) concerns about poor sterile practices observed during an FDA inspection at a pharmacy licensed by the Mississippi BOP, Bond Pharmacy dba Advanced Infusion Solutions, located at 132 Fairmont Street, Suite B, Clinton, MS 39056 (Pharmacy Permit #14064, exp. December 31, 2017).[1]

FDA inspected the firm from September 14, 2015, to October 27, 2015. FDA investigators were accompanied by Mississippi state investigators for one day. A redacted copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm472930.pdf

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by Advanced Infusion Solutions, and determined, based on this sample, that this firm appears to obtain valid prescriptions for individually-identified patients for the drug products that it compounds and dispenses.

During the inspection, the FDA investigators observed deviations from appropriate sterile practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. For example, our investigators observed an operator leaving the ISO 5 area and then returning to proceed with aseptic manipulations without sanitizing or changing their gloves. Furthermore, our investigators observed discoloration from a stainless steel cart wheel on the floor in the ISO 7.

[1] Advanced Infusion Solutions also operates a facility located at 623 Highland Colony Parkway, Suite 100, Ridgeland, MS 38157. This letter does not address the Ridgeland, MS facility.

Advanced Infusion Solutions committed to correcting the deviations in its response to the Form FDA 483, dated November 16, 2015.[2] In addition, the deviations identified appear to be readily correctable.

After review of the record, at this time FDA does not intend to take further action with regard to the findings of this inspection. This firm apparently obtains prescriptions for identified individual patients, consistent with traditional pharmacy practice, and FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to the Mississippi State BOP for follow-up to ensure appropriate corrective action is taken. Please notify us if you become aware of any adverse events or product quality concerns associated with drugs made at this facility, or if you observe any practices at this facility that concern you or that could be violations of Federal law.

We look forward to continuing to work with you on the oversight of compounding pharmacies. If you have additional questions, please contact Mark Rivero, Compliance Officer, at (504) 846-6103 or by email at Mark.Rivero@fda.hhs.gov.

Sincerely,

Ruth P. Dixon
District Director
U.S. Food and Drug Administration
New Orleans District Office

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[2] Because you are an FDA commissioned official, you can request an un-redacted copy of the Form FDA 483 or the firm's response to the Form FDA 483.