U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
OPQO DIVISION OF PHARMACEUTICAL QUALITY OPS 3

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UPS NEXT DAY

Dr. Yashwant Amin
Director of Drug Compliance
Division of Professional Regulation
100 W Randolph St. Suite 9-300
Chicago, Illinois 60601

Dear Dr. Amin:

The purpose of this letter is to refer to the Illinois State Board of Pharmacy (BOP) for appropriate follow up, 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 Illinois BOP, Heartland Home Infusions, Inc. dba HHI Infusion Services, located at 901 McClintock Drive Suite 106, Burr Ridge, IL 60527-0871 (Pharmacy License #054011903).

FDA inspected the firm from July 6, 2017, to July 27, 2017. The FDA investigator was accompanied by Illinois state investigators for one day. A copy of a Form FDA 483 that documents our investigator's observations from the inspection can be found at https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM575007.pdf, with any nonpublic information redacted. Because we consider this inspection to be "closed" under 21 CFR 20.64(d)(3), you may request a copy of the Establishment Inspection Report (EIR) that FDA will provide to the firm, which contains additional information about our inspection. If you are a Commissioned Official or if your state agency has entered into a 21 CFR 20.88 information sharing agreement, you may be able to receive a copy of the Form FDA 483 or the EIR that includes certain nonpublic information. Alternatively, you may also choose to request a copy of the EIR directly from the firm.

During the inspection, the FDA investigator reviewed a small sample of records for products compounded by HHI Infusion Services 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 distributes.

During the inspection, the FDA investigator observed deviations from appropriate sterile practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Examples of deviations observed during our inspection include:

1. The firm failed to use a sporicidal agent in the cleanrooms and in the ISO 5 aseptic processing areas.
2. The firm produced beta-lactam and non beta-lactam drug products in the same hood with out adequate controls to prevent cross contamination.
3. Non-microbial contamination was observed in the production area.

HHI Infusion Services committed to FDA in its written responses dated August 3, 2017 and October 23, 2017, to correct the deviations. The firm also provided documentation in support of those corrective actions and the deviations identified appear to be readily correctable.

After review of the record, FDA does not intend to take further action at this time with regard to the findings of this inspection. This firm apparently obtains prescriptions for identified individual patients before distributing its compounded drugs, as required by section 503A(a) of the Federal Food, Drug and Cosmetic Act, and FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to the Illinois 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 Russell Riley, Compliance Officer at 312-596-4219 or by email at Russell.Riley@fda.hhs.gov.

Sincerely,

Nicholas F. Lyons
Compliance Director
Division of Pharmaceutical Quality Operations III

for
Art O. Czabaniuk
Program Division Director
Division of Pharmaceutical Quality Operations III