DEPARTMENT OF HEALTH & HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

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Philadelphia, PA 19106

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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

March 27, 2014

Melanie Zimmerman,
Executive Secretary
Pennsylvania State Board of Pharmacy
P.O. Box 2649
Harrisburg, PA 17105-2649

Dear Ms. Zimmerman:

The purpose of this letter is to refer to the Pennsylvania 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 Pennsylvania BOP, Home Infusions Solutions, Inc., located at 2 Walnut Grove Drive, Suite 140, Horsham, Pennsylvania.

FDA inspected the firm from May 1, 2013, to May 21, 2013, after analysis of a sample collected in response to a consumer complaint revealed out-of-specification results for ertapenem within the firm's Beyond Use Date (BUD). Pennsylvania BOP was informed of the inspection but did not accompany FDA investigators during the inspection. Attached is a redacted copy of a Form FDA 483 that documents our investigators' observations.

During the inspection, the FDA investigator reviewed a small sample of records for products compounded by Home Infusions 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. In the June 3, 2013 response to the Form FDA 483, the firm advised FDA that they "prepare each compounded preparation individually based on a healthcare provider's prescription, and [they] do not prepare any compounded preparation in anticipation of receiving such prescriptions."[1]

[1] See attached response letter dated June 3, 2013, from Brian Howard to Steven L. Carter, Philadelphia District Office, Compliance Branch Director.

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. Examples of deviations observed during our inspection include:

1. The aseptic processing of drug products at the firm is inadequate regarding separation of defined areas to prevent contamination. For example, the doorways between the warehouse, anteroom, and cleanroom are separated by plastic flap dividers that have large gaps between each flap and between the plastic dividers and the floor. Warehouse employees were observed moving from the warehouse into the anteroom without controls in place to prevent microbial contamination. The FDA investigators observed that there were no devices or instruments monitoring the pressure between rooms.

2. The firm's viable environmental monitoring program ensuring microbiological quality of the ISO 5 area is inadequate. For example, viable air samples were not taken in the ISO 5 Laminar Flow Hoods or the Biological Safety Cabinet during the qualification conducted in September 2012. Additionally, surface samples were not taken in the ISO 5 Laminar Flow Hoods, Biological Safety Cabinet, critical contact areas, or equipment located in the ISO 5 areas during the qualifications performed in September 2012 and April 2013, and the frequency of environmental monitoring was inadequate.

3. The firm failed to follow established test procedures that require documentation of environmental samples at the time of incubation. The FDA investigators observed seven employee environmental test results with no documentation of incubation times.

4. The firm failed to provide sufficient data demonstrating the chemical stability and sterility of injectable drug products. For example, there is no written testing program designed to assess the stability characteristics of drug products. The FDA investigators observe several drug products without stability data to support the excessive beyond-use dates (BUD) assigned by the firm.

Home Infusions Solutions committed to FDA in its June 3, 2013, response to the Form FDA 483 to correct some of the deviations.

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. In addition, the deviations identified appear to be readily correctable, and, the firm has agreed in writing to correct some of the deviations. Therefore, FDA believes that the corrective actions can be appropriately overseen by the State, and is referring this matter to the Pennsylvania 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 Robin M. Rivers, Compliance Officer, at 215-717-3076, or by email at robin.rivers@fda.hhs.gov.

Sincerely,

Anne Johnson for

Kirk D. Sooter
District Director
Philadelphia District Office

Attachment:

- June 3, 2013 letter
- FDA-483, dated, May 1, 2013 – May 21, 2013