DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration
Atlanta District Office
60 Eighth Street NE
Atlanta, GA 30309

May 21, 2015

Lee Ann F. Bundrick
Administrator
South Carolina Board of Pharmacy
Kingstree Bldg, 110 Centerview Dr.
Columbia, SC 29210

Dear Ms. Bundrick:

The purpose of this letter is to refer to the South Carolina 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 South Carolina State BOP, Medi-Home Infusion Pharmacy, a Division of Medical Services of America, Inc., located at 2 Palmetto Wood Parkway, Irmo, SC 29063 (Licensed Pharmacy # 15201).

FDA inspected the firm from September 8, 2014, to September 17, 2014. The South Carolina BOP was informed of the inspection, and the FDA investigator was accompanied by South Carolina 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/downloads/aboutfda/centersoffices/officeofglobalregulatoryoperationsandpolicy/ora/oraelectronicreadingroom/ucm432645.pdf.

During the inspection, the FDA investigator reviewed a small sample of records for products compounded by Medi-Home Infusion Pharmacy 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 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:

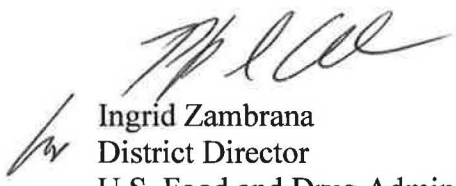
1. The firm's ISO-5 hood used to produce sterile chemotherapy injectable drugs had numerous cracks along the entire length of each side. These cracks are difficult to clean and disinfect.
2. The firm did not conduct any surface environmental monitoring of the ISO-5 chemotherapy hood.
3. The firm failed to demonstrate through appropriate studies that the ISO-5 chemotherapy and IV hoods are able to provide adequate protection of the area in which products intended or expected to be sterile are processed.

Medi-Home Infusion Pharmacy committed to FDA in its response to the Form FDA 483, received October 7, 2014, to correct some deviations in the Form FDA 483. In addition, the deviations identified appear to be readily correctible.

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 South Carolina 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 Marie F. Mathews, Compliance Officer, at (404) 253-1289, or by email at marie.mathews@fda.hhs.gov.

Sincerely,



Ingrid Zambrana
District Director
U.S. Food and Drug Administration
Atlanta District Office