U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

September 13, 2017

VIA UPS EXPRESS

Lee Ann Bundrick, Administrator
South Carolina Board of Pharmacy
Synergy Business Park, Kingstree Building
110 Centerview Drive
Columbia, SC 29210

Dear Ms. Bundrick:

The purpose of this letter is to refer to the South Carolina 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 South Carolina BOP, InfuScience, a subsidiary of Bioscrip, located at 462 Wando Park Blvd, Suite A, Mount Pleasant, SC 29464-7906 (Pharmacy License #021820).

FDA inspected the firm from May 12, 2015, to May 15, 2015. FDA investigators were accompanied by South Carolina state investigators for one day. A copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm448054.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. 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 investigators reviewed a small sample of records for products compounded by InfuScience, a subsidiary of Bioscrip, 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. In a response to the Form FDA 483, dated June 5, 2015, the firm advised FDA that it "only fills prescriptions for individually identified patients pursuant to a valid prescription from a prescriber, as required by Section 503A of the Federal Food, Drug, and Cosmetic Act."

U.S. Food & Drug Administration
Office of Pharmaceutical Quality Operations, Division II
4040 N. Central Expressway, Suite 300
Dallas, Texas 75204
www.fda.gov

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 firm used non-sterile wipes and a non-sterile disinfectant to clean and disinfect the ISO 5 hoods.

2. The firm did not use a sporicidal agent to disinfect the ISO 5 work areas.

3. The investigators observed disinfectant bottles hanging from the side of trash cans as well as operators repeatedly touching the trash can liner in order to reach the disinfectants.

InfuScience, a subsidiary of Bioscrip, committed to FDA in its written responses, dated June 5, 2015, and May 31, 2017, to correct the deviations in the Form FDA 483 and provided documentation in support of those corrective actions. In addition, 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 South Carolina 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 Rebecca Asente, Compliance Officer, at (504) 846 - 6104, or by email at rebecca.asente@fda.hhs.gov.

Sincerely,

John W. Diehl -S

Digitally signed by John W. Diehl -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=John W. Diehl -S, 0.9.2342.19200300.100.1.1=2000099727
Date: 2017.09.12 16:22:47 -05'00'

John W. Diehl
Acting Director, Compliance Branch
Office of Pharmaceutical Quality Operations, Division II

Cc: Chirag A. Patel, General Manager
InfuScience a subsidiary of Bioscrip
462 Wando Park Blvd, Suite A
Mount Pleasant, SC 29464-7906