U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations I
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Via UPS Next Day Air Saver

November 16, 2017

Kimberly A. Leonard
Executive Secretary
New York State Board of Pharmacy
89 Washington Ave, 2nd Floor W
Albany, NY 12234-1000

Dear Ms. Leonard:

The purpose of this letter is to refer to the New York 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 New York BOP, BioScrip Infusion Services of New York, located at 1 Vermont Drive, Lake Success, New York 11042-1128 (Pharmacy License #021820).

FDA inspected the firm from September 10, 2014, to September 19, 2014. New York State BOP was informed of the inspection, but did not accompany the FDA investigator during the inspection. 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/UCM431092.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 investigator reviewed a small sample of records for products compounded by BioScrip Infusion Services of New York 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 October 10, 2014, the firm advised FDA that it "does not engage in *any* office use compounding, or compounding in anticipation of receiving prescriptions from prescribers."

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

2. The firm failed to demonstrate through appropriate studies that their hoods are able to provide adequate protection of the ISO 5 areas in which sterile products are processed. Therefore, the firm's products may be produced in an environment that poses a significant contamination risk.

BioScrip Infusion Services of New York committed to FDA in its written responses, dated October 10, 2014, 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 New York 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 Maya M. Davis, Compliance Officer, at (860) 240-4289 ex. 25, or by email at maya.davis@fda.hhs.gov.

Sincerely,

Craig W. Swanson -S

Digitally signed by Craig W. Swanson -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300092363, cn=Craig W. Swanson -S
Date: 2017.11.17 08:56:19 -05'00'

For Diana Amador-Toro
Division Director/OPQ Division 1
New Jersey District Office

CC: Ms. Ana Martinez, Pharmacy Manager
BioScrip Infusion Services of New York
1 Vermont Drive
Lake Success, NY 11042