DATE April 26, 2022

VIA ELECTRONIC MAIL

Eric Lacefield, MBA
Executive Director
Georgia State Board of Pharmacy
2 Peachtree Street, NW, 6th Floor
Atlanta, GA 30303
elacefield@dch.ga.gov

Dear Mr. Lacefield:

The purpose of this letter is to refer to the Georgia 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 Georgia BOP, BioScrip Infusion Services, located at 17th Street Suite 107 Augusta, GA 30901-1305, (pharmacy license #PHRE010676).

FDA inspected the firm from August 2, 2021, to August 9, 2021. Georgia BOP was informed of the inspection but did not accompany FDA investigators during the inspection. A copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at FDA's FOIA Electronic Reading Room, 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 investigators reviewed a small sample of records for products compounded by BioScrip 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.

1. Additionally, 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: Disinfecting agents and cleaning pads or wipes used in the ISO 5 area (aseptic processing areas) are not

sterile. The equipment and cleaning practices used at your firm pose a risk to the sterility of the drug products produced. Specifically, the sterile wipes pack kept in the ISO 7 area has resealable closure and is not completely sealed. The remaining unused wipes were left in the pack in the ISO 7 environment and then used for sanitizing components and product going into the ISO 5 area.

2. The firm lacks smoke studies performed under dynamic conditions that mimic aseptic processing conditions. Specifically, multiple personnel were observed producing sterile drugs in the same hood simultaneously. However, the firm's smoke study video demonstrated that only one technician performed manipulations and interventions in one hood at a time.

BioScrip Infusion Services committed to FDA in its response to the Form FDA 483, received September 14, 2021 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 Georgia 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 Mark W. Rivero Compliance Officer, at (504) 846-6103 or by email at mark.rivero@fda.hhs.gov.

Sincerely,

Caroline H. Le -S3

Digitally signed by Caroline H. Le -S3
Date: 2022.04.26 12:20:32 -06'00'

Caroline Le, Pharm.D.
Acting Director, Compliance Branch
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