



**August 14, 2020**

**CMS #: 319038**

**VIA ELECTRONIC MAIL**

Tanja D. Battle  
Executive Director  
Georgia State Board of Pharmacy  
2 Peachtree St. NW  
6th Floor  
Atlanta, Georgia 30303

Ms. Battle:

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, Piedmont Hospital, Inc. dba Phcy-Corp, located at 1968 Peachtree Rd. NW, Atlanta, Georgia 30309-1231 (hospital pharmacy license: #PHH003535; expires June 30, 2021).

FDA inspected the firm from January 30, 2020, to February 18, 2020. FDA investigators were accompanied by Georgia state investigators during the inspection. A copy of a Form FDA 483 that documents our investigators' observations from the inspection is currently under review for redaction and will be available at: <https://www.fda.gov/drugs/human-drug-compounding/compounding-inspections-recalls-and-other-actions>, 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 Piedmont Hospital 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.

U.S. Food & Drug Administration  
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Dallas, Texas 75204  
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Georgia State Board of Pharmacy  
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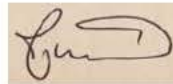
Additionally, during the inspection, the FDA investigators observed deviations from appropriate sterile practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. For example, it was observed that disinfecting agents and cleaning wipes used in the ISO 5 classified aseptic processing areas were not sterile.

Piedmont Hospital, Inc. committed to FDA in its response to a Request for Additional Information (RAI) letter, received May 12, 2020, 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 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 Jose R. Lopez, Compliance Officer, at (787) 729-8603, or by email at [JoseR.Lopez@fda.hhs.gov](mailto:JoseR.Lopez@fda.hhs.gov).

Sincerely,



Digitally signed by John W. Diehl -S4  
DN: c=US, o=U.S. Government, ou=HHS,  
ou=FDA, ou=People, cn=John W. Diehl -S4,  
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Date: 2020.08.14 12:26:38 -05'00'

John W. Diehl, M.S.  
Director, Compliance Branch  
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Cc:

Donald Wright  
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