October 31, 2017

VIA UPS EXPRESS

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

Dear 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, Partners In Care, Inc., located at 2551 Limestone Parkway, Suite 2, Gainesville, Georgia 30501 (Active Georgia Retail Pharmacy License PHRE007828, exp. 6/30/19.

FDA inspected the firm from February 21, 2017, to March 7, 2017. 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, https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm550762.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, 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 Partners In Care, Inc., 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

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:

> Non-sterile wipes are used to clean drug components prior to placing them in the ISO 5 Laminar Flow Hood. In addition, the wipes used to clean the ISO 5 Laminar Flow Hood are also not sterile.

In the response to the Form FDA 483, received on March 21, 2017, the firm advised FDA that starting March 7, 2017 they "will no longer use non-sterile wipes to clean and disinfect the room and equipment." Additionally, the firm stated that sterile wipes have been purchased "specifically for cleaning and disinfecting the drug components prior to placing them in the ISO 5 Laminar Flow Hood," as well as "to clean and disinfect the ISO 5 Flow Hood to produce aseptic conditions." Thus, Partners In Care, Inc., appears to have corrected the deviations in the Form FDA 483, which were readily correctible, and provided documentation in support of those corrective actions.

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 human or animal 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 me at (214) 253-5288, or by email at john.diehl@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: 2017.10.31 10:42:21 -05'00'

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

CC:

Chalres A. Fulmer, Owner
Partners In Care, Inc.
2551 Limestone Parkway, Suite 2
Gainesville, GA 30501