June 15, 2017

Kimberly A. Leonard
Executive Secretary
New York State Board of Pharmacy
89 Washington Ave, 2nd Floor West
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, RegionCare, Inc., located at 200 Community Drive, Great Neck, NY 11021-5504 (Pharmacy License #021785; Expires 7/31/19).

FDA inspected the firm from May 18, 2016 to June 10, 2016. The New York State BOP was informed of the inspection, but did not accompany the FDA investigator during the inspection. A redacted copy of a Form FDA 483 that documents our investigator's observations from the inspection can be found at https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm507448.pdf.

During the inspection, the FDA investigator reviewed a small sample of records for products compounded by RegionCare, 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. In the response to the Form FDA 483, received June 30, 2016, the firm advised FDA that it "operates as a state-licensed pharmacy for the purpose of compounding and dispensing home infusion therapies for patients within the state of New York on the basis of patient-specific prescriptions' and that it "ceased providing non-patient-specific compounding services and deregistered as an outsourcing facility with the FDA as of October 6, 2015."

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. For example, the firm did not perform smoke studies under dynamic conditions that simulated routine aseptic operations.

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RegionCare, Inc. committed to FDA in its responses to the Form FDA 483, received June 30, 2016, and November 29, 2016 to correct the deviations in the Form FDA 483. In addition, the deviations identified appear to be readily correctable.

After review of the record, at this time FDA does not intend to take further action with regard to the findings of this inspection. This firm apparently obtains prescriptions for identified individual patients 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 CDR Frank Verni, Compliance Officer at (718) 662-5702, or by email at frank.verni@fda.hhs.gov.

Sincerely,

Craig W. Swanson -S

Digitally signed by Craig W. Swanson -S
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Diana Amador-Toro
District Director
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