U.S. FOOD & DRUG ADMINISTRATION

March 22, 2017

Kimberly A. Leonard
Executive Director
New York State Education Department
Office of the Professions
State Board of Pharmacy
89 Washington Avenue
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, Americare Compounding, LLC, located at 319 Nassau Blvd in Garden City South, New York 11530 (Registration Number: 031410).

FDA inspected the firm from June 10, 2015, to June 22, 2015. The New York 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 http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM469397.pdf

During the inspection, the FDA investigator reviewed a small sample of records for products compounded by Americare 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, dated July 13, 2015, the firm advised FDA that it "compounds prescriptions only for individually identified patients, and it complies with local laws concerning compounding of sterile and non-sterile products."

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. Specifically, the firm's Standard Operating Procedure (SOP) states that "an appropriate BUD" (Beyond Use Date) must be assigned, but was not specific about the exact days or time periods for their in-process ingredients. In addition, the firm did not specifically indicate in their SOP "Cleaning and Maintenance of the Clean Room Facility" whether their disinfectant is used

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New York District
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within the ISO 5 hoods.

Americare committed to FDA in its response to the Form FDA 483, dated July 13, 2015, 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 actions are 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 Frank Verni, Compliance Officer, at 718-662-5702, or by email at Frank.Verni@fda.hhs.gov.

Sincerely,

Ronald M. Pace
District Director
New York District Office