July 28, 2017

C. Erica White, Executive Director
Florida State Board of Pharmacy
4052 Bald Cypress Way, Bin #C04
Tallahassee, FL 32399-3254

Dear Ms. White:

The purpose of this letter is to refer to the Florida 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 Florida BOP, Synergy Pharmacy Services, located at 31201 US HWY 19 N, Suite 2, Palm Harbor, FL 34684 (Pharmacy License: PH27691).

FDA inspected the firm from June 14, 2016, to June 21, 2016. The FDA investigator was accompanied by a Florida state investigator for one day. A redacted copy of a Form FDA 483 that documents our investigator's observations from the inspection can be found https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm511518.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 investigator reviewed a small sample of records for products compounded by Synergy Pharmacy 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. In a response to the Form FDA 483, received July 8, 2016, the firm advised FDA that it "discontinued compounding high risk sterile products and is considered to be a 503A pharmacy."

During the inspection, the FDA investigator also 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:

1. The firm did not use a sporicidal agent to disinfect the ISO 5 work areas.

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2. The firm did not perform smoke studies in the ISO 5 areas under dynamic conditions that simulated routine aseptic operations.

Synergy Pharmacy Services committed to FDA in its written responses received on July 8, 2016, and January 4, 2017, to correct the deviations in the Form FDA 483. In addition, the deviations identified appear to be readily correctable. Furthermore, in the January 4, 2017, response, Synergy Pharmacy Services stated that it ceased sterile drug production at the location FDA inspected, is in the process of moving sterile drug compounding to a new facility, and will not be compounding sterile drug products for the next 8 to 18 months.

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 Florida 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 me at (214) 253-5288.

Sincerely,

John W. Diehl -S

Digitally signed by John W. Diehl -S
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John W. Diehl
Acting Director, Compliance Branch
Office of Pharmaceutical Quality Operations, Division II