U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations III
300 River Place, Suite 5900
Detroit, MI 48207
Telephone: (313) 393-8100
Fax: (313) 393-8139
www.fda.gov

May 31, 2018

UPS NEXT DAY

Larry A. Hadley
Executive Directory
Kentucky State Board of Pharmacy
State Office Building Annex, Suite 300
125 Holmes Street
Frankfort, KY 40601

Dear Mr. Hadley:

The purpose of this letter is to refer to the Kentucky 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 Kentucky BOP, Spoonamore Drug Company, Inc., dba Louisville Pharmacy and Custom Script, located at 4014 Dutchmans Lane, Suite 11, Louisville, Kentucky 40207 (Retail Independent Pharmacy License #P06291).

FDA inspected the firm from January 17, 2017 to March 14, 2017. The FDA investigator was accompanied by Kentucky state investigators for 2 days. A copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM553041.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) 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.

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by Spoonamore Drug Company, Inc., dba Louisville Pharmacy and Custom Script 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 responses to the Form FDA 483, received on April 3, 2017, June 2, 2017, September 22, 2017 and January 23, 2018, the firm

advised FDA that it "conducts its compounding operations pursuant to Section 503A of the Federal Food, Drug and Cosmetic Act ("FDCA")."

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:

1. The firm produced products intended for intrathecal use from non-sterile active ingredients that were not controlled for endotoxin level.

2. The firm failed to perform adequate smoke studies under dynamic conditions to demonstrate unidirectional airflow within the ISO 5 area.

3. The firm used non-sterile wipes in the sterile compounding area.

Spoonamore Drug Company, Inc., dba Louisville Pharmacy and Custom Script, committed to FDA in its responses, received April 3, 2017, June 2, 2017, September 22, 2017, and January 23, 2018, 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 Kentucky 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 Tina M. Pawlowski, Compliance Officer, at (313) 393-8217, or by email at tina.pawlowski@fda.hhs.gov.

Sincerely,

Digitally signed by Art O. Czabaniuk -S
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Date: 2018.05.31 10:34:09 -04'00'

Art O. Czabaniuk
Program Division Director
Division of Pharmaceutical Quality Operations III

cc: Steven D. Williams, President and Owner
Spoonamore Drug Company, Inc. dba
Louisville Pharmacy and Custom Script
4014 Dutchmans Lane, Suite 11
Louisville, KY 40207