U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations III
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May 1, 2019

UPS NEXT DAY
SIGNATURE REQUIRED

Steven W. Schierholt, Esq.
Executive Director
Ohio State Board of Pharmacy
77 South High Street, 17th Floor
Columbus, OH 43215-6126

Dear Mr. Schierholt:

The purpose of this letter is to refer to the Ohio 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 Ohio BOP, Buderer Drug Company, Inc. located at 26611 Dixie Hwy Ste 119, Perrysburg, OH 43551-1765 (Multi-Disciplinary Pharmacy, License #021198400).

FDA inspected the firm from July 17, 2017 – July 24, 2017. Ohio 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 http://osar.fda.gov/document/documentum?objectId=090026f780bcb656, 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 Buderer Drug Company, 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. Additionally, in response to a telephone conference with the FDA on August 1, 2018, the firm advised FDA that all compounded drug products produced using bulk drug substances will comply with the FDA's Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and

Cosmetic Act:
(https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469120.pdf).

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. Tiny white particulates were seen in retained sample vials from all batches of Sodium Tetradecyl Sulfate, Straight Chain 3% 30ml Vascular Injection MDV.

2. The technician producing sterile drug products introduced the sleeves of their gowns into the ISO 5 area, however these were non-sterile and re-used throughout the day.

3. A gap in the doors on both sides of the pass-through between the ISO 7 cleanroom and the unclassified prep-area allowed palpable airflow exchange between the areas.

Buderer Drug Company, Inc. committed to FDA in its Form FDA 483 responses dated August 2, 2017 and October 28, 2017, 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 Ohio 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 Pawlowski, Compliance Officer, at (313) 393-8217 or by email at ORAPHARM3_RESPONSES@fda.hhs.gov.

Sincerely,

Digitally signed by Art O. Czabaniuk -S
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Date: 2019.05.01 13:30:27 -04'00'

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