U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
OPQO DIVISION OF PHARMACEUTICAL QUALITY OPS 3

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September 12, 2019

UPS NEXT DAY
SIGNATURE REQUIRED

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

Dear Mr. Schierholt:

The purpose of this letter is to refer to the State of Ohio 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 State of Ohio BOP, RC Compounding Services, LLC, located at 3030 Center Road, Poland, OH 44514 (license# SP.021678950-03).

FDA inspected the firm from February 12, 2018, to February 16, 2018. The State of 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 https://www.fda.gov/media/111618/download, 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 RC Compounding Services, LLC 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.

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. Personnel placed equipment/supplies in an area that blocked the movement of first pass air around an open unit, either before or after it was filled with sterile product.

2. Disinfecting agents and cleaning wipes used in the ISO 5 classified aseptic processing areas were not sterile.

3. Non-sterilized and non-depyrogenated equipment was used in sterile drug production.

4. The facility design allowed the influx of poor quality air into a higher classified area.

5. The firm produced hazardous drugs without providing adequate containment, cleaning of work surfaces, and cleaning of personnel to prevent cross-contamination.

RC Compounding Services, LLC committed to correct the deviations in its written responses to FDA dated March 9, 2018, October 11, 2018, March 20, 2019, April 10, 2019, and May 9, 2019, 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 State of 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 human or animal 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 Brian D. Garthwaite, Ph.D., Compliance Officer, at 612-758-7132.

Sincerely,

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

cc:
Raymond R. Carlson
Owner/Pharmacist
RC Compounding Services, LLC
3030 Center Road
Poland, OH 44514