U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations III
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Detroit, MI 48207
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October 31, 2019

UPS NEXT DAY
SIGNATURE REQUIRED

Dr. Yashwant Amin
Director of Drug Compliance
Division of Professional Regulation
100 W Randolph St
Suite 9-300
Chicago, IL 60601

Dear Dr. Amin:

The purpose of this letter is to refer to the Illinois Department of Financial and Professional Regulation, Division of Professional Regulation, Illinois 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 Illinois BOP, Orsini Pharmaceutical Services, Inc. dba Orsini Healthcare, located at 1107 Nicholas Blvd. Elk Grove Village, IL 60007-2516 (Pharmacy and license #054020692).

FDA inspected the firm from July 17, 2018, to July 25, 2018. Illinois BOP was informed of the inspection, but did not accompany the FDA investigator during the inspection. A copy of a Form FDA 483 that documents our investigator's observations from the inspection can be found at [https://www.fda.gov/media/116753/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 investigator reviewed a small sample of records for products compounded by Orsini Pharmaceutical Services, Inc., dba Orsini Healthcare 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, 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. Examples of deviations observed during our inspection include:

1. Cleaning procedures are deficient for the ISO-5 laminar air flow cabinets and the classified areas where sterile products are produced.

2. The firm produced beta-lactam drugs without providing adequate containment and segregation to prevent cross-contamination.

Orsini Pharmaceutical Services, Inc. dba Orsini Healthcare committed to correct the deviations in its written responses to FDA dated August 2, 2018, May 24, 2019, and July 31, 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 Illinois 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 Brian D. Garthwaite, Ph.D., Compliance Officer, at 612-758-7132.

Sincerely,

Digitally signed by Art O. Czabaniuk -S
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Date: 2019.10.31 13:14:36 -04'00'

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

cc:
Michael C. Fieri
Chief Executive Officer
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1111 Nicholas Blvd
Elk Grove Village, IL 60007-2516