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U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations III
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September 11, 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, Illinois 60601

Dear Dr. Amin:

The purpose of this letter is to refer to the 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, Kalman Health & Wellness, Inc. dba Essential Wellness Pharmacy 2, located at 4625 N University Street, Peoria, IL 61614-5828 (pharmacy license #054018933).

FDA inspected the firm from June 19, 2018, to June 27, 2018. Illinois 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/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM624874.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 investigators reviewed a small sample of records for products compounded by Kalman Health & Wellness, Inc. dba Essential Wellness Pharmacy 2 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.

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During the inspection, the FDA investigators observed deviations from appropriate 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 used household dish soap and dishwater to clean and sanitize compounding equipment, such as, spatulas and graduated cylinders. It was noted that the firm was compounding beta-lactam products, such as amoxicillin and cephalexin, and hazardous drugs including cyclosporine and azathioprine. The firm did not take special cleaning precautions when compounding these products.
2. The firm was observed using water to produce human drug products. The firm did not have a certificate of analysis or test results to demonstrate that the water met or exceeded pharmaceutical grade requirements.

Kalman Health & Wellness, Inc. dba Essential Wellness Pharmacy 2 committed to FDA in its response to the Form FDA 483, received September 25, 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 Illinois 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 Pawlowski, Compliance Officer, at (313) 393-8217, or by email at ORAPHARM3_RESPONSES@fda.hhs.gov.

Sincerely,

Nicholas F. Lyons -S

Digitally signed by Nicholas F. Lyons -S
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Date: 2019.09.11 16:22:25 -05'00'

Nicholas F. Lyons
Director of Compliance
Division of Pharmaceutical Quality Operations III

For

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