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

July 11, 2019

UPS NEXT DAY
SIGNATURE REQUIRED

Jesse Cushman
Office Administrator
Nebraska Department of Health and Human Services
Division of Public Health, Licensure Unit
PO Box 94986
Lincoln, NE 68509-4986

Dear Mr. Cushman:

The purpose of this letter is to refer to the Nebraska Department of Health and Human Services, Division of Public Health (DHHS DPH) 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 Nebraska DHHS DPH, Kohll's Compounding (formerly known as Essential Pharmacy Compounding), located at 620 N. 114th Street, Omaha, NE 68154-1571 (Community Pharmacy License #2858).

FDA inspected the firm from July 10, 2017, to July 27, 2017. The Nebraska DHHS DPH 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/107172/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 Essential Pharmacy Compounding 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 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. Non-sterile disinfectants were used in the ISO 5 aseptic processing area.

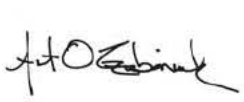
2. An operator was observed cleaning her hands with a sterile wipe and then used the same wipe to clean the ISO 5 aseptic processing area.

The firm committed to FDA in its responses dated August 15, 2017, and September 20, 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 Nebraska DHHS DPH 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 questions about this letter, 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: 2019.07.11 12:50:33 -04'00'

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

cc: Jennifer Rickner
Pharmacist in Charge
Kohll's Compounding
620 N. 114th Street
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