



U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations III
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Detroit, MI 48207
Telephone: (313) 393-8100
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www.fda.gov

March 6, 2019

UPS NEXT DAY
SIGNATURE REQUIRED

Alexandra Blasi
Executive Secretary
Kansas State Board of Pharmacy
800 SW Jackson St, Suite 1414
Topeka, KS 66612

Dear Ms. Blasi:

The purpose of this letter is to notify the Kansas State Board of Pharmacy (BOP) that the U.S. Food and Drug Administration (FDA) does not intend to take further action with regard to an inspection of a pharmacy licensed by the Kansas BOP, ARJ Infusion Services, Inc., located at 7930 Marshall Drive, Lenexa, KS, 66214 (Pharmacy Permit #: 2-09948; and Distributor Permit #: 5-01870).

FDA inspected the firm from September 25, 2018, to October 1, 2018. The Kansas BOP was informed of the inspection but did not accompany FDA investigators during the inspection. No Form FDA 483 was issued to the firm.

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by ARJ Infusion Services, 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, which is consistent with traditional pharmacy practice.

After review of the records, FDA does not intend to take further action with regard to the findings of this inspection at this time and believes that the firm's pharmacy practice can be appropriately overseen by the State. 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 any additional questions, please contact Eric Mueller, Compliance Officer, at (402) 331-8536 ext. 101 or by email at: ORAPHARM3_RESPONSES@fda.hhs.gov.

Sincerely,



Digitally signed by Art O. Czabaniuk -S
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Date: 2019.03.06 12:16:16 -05'00'

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

cc: Mary L. Sackuvich
President and Owner
ARJ Infusion Services, Inc.
7930 Marshall Drive
Lenexa, KS 66214