



U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations III
300 River Place, Suite 5900
Detroit, MI 48207
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March 6, 2019

UPS NEXT DAY
SIGNATURE REQUIRED

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

Dear Ms. Sackuvich:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility, ARJ Infusion Services, Inc., located at 7930 Marshall Drive, Lenexa, KS, 66214, from September 25, 2018, to October 1, 2018, by the U.S. Food and Drug Administration (FDA). In addition, we are enclosing the letter sent to the Kansas State Board of Pharmacy for follow up.

When the Agency considers an inspection to be “closed” under 21 C.F.R. 20.64(d)(3), it will release a copy of the EIR to the inspected establishment.

The Agency continually works to make its regulatory process and activities more transparent for regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the Freedom of Information Act (FOIA) and 21 C.F.R. Part 20. This, however, does not preclude you from requesting and possibly obtaining any additional information under FOIA.

If you have any questions regarding this letter, please contact Eric Mueller, Compliance Officer, at (402) 331-8536 ext. 101 or by email at: ORAPHARM3_RESPONSES@fda.hhs.gov.

Sincerely,

**Nicholas F.
Lyons -S**

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

Digitally signed by Nicholas F. Lyons -S
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People,
0.9.2342.19200300.100.1.1=1300120033,
cn=Nicholas F. Lyons -S
Date: 2019.03.06 10:25:12 -06'00'

Enclosure: EIR and State Referral Letter

cc: FMD cover letter only

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