DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Dr., Suite 205 Lenexa, KS 66214 (913) 495-5100	5/16/2017 - 5/25/2017* FEI NUMBER 3013452490

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Andrew P. Copeland, Vice President and General Manager

FIRM NAME	STREET ADDRESS
ARJ Infusion Services, Inc.	7930 Marshall Dr.
CITY, STATE, ZIP CODE, COUNTRY Lenexa, KS 66214	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drugs

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

From February 15th through May 18th your firm has produced approximately (b) (4) sterile drugs and non-sterile drugs. These drugs include but are not limited to Normal Saline/Sodium Chloride 0.9% solution, Methylpredisolone Sodium Succinate and Tysabri for IV injection. The following observations are associated with your practices used to produce these sterile drugs.

OBSERVATION 1

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

A. You have not performed your media fill during worst case processing conditions of your sterile processed drugs.

B. Your main pharmacy technician has not performed a media fill at your current address.

C. You have not performed dynamic smoke studies in your laminar air flow hood.

D. Air pressures are not monitored during sterile drug production or at any other time to ensure adequate or (b) (4) are maintained in your anteroom, (b) (4) room and laminar air flow hood.

I observed sterile processing of Normal Saline/Sodium Chloride 0.9% (identified by raw material lot (b) (4) and (b) (4)) conducted by your Pharmacy Technician in your laminar air flow hood on 5/16/2017 and 5/17/2017.

SEE REVERSE OF THIS PAGE	Robert J Ham, Investigator	X	5/25/2017

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Dr., Suite 205 Lenexa, KS 66214 (913) 495-5100	5/16/2017 - 5/25/2017* FEI NUMBER 3013452490

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Andrew P. Copeland, Vice President and General Manager	
FIRM NAME ARJ Infusion Services, Inc.	STREET ADDRESS 7930 Marshall Dr.
CITY, STATE, ZIP CODE, COUNTRY Lenexa, KS 66214	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drugs

OBSERVATION 2

Equipment used in the processing, sterile drug products is not of appropriate design to facilitate operations for its intended use and cleaning and maintenance.

Specifically,

A. I observed your laminar air flow hood with an area of rust with (b) (4) applied over it consisting of approximately 1/4" x 1'.

B. I observed your laminar air flow hood with a crack along its overhead paneling ((b) (4)) consisting of approximately 1 linear foot.

OBSERVATION 3

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically,

I observed sterile processing of Normal Saline/Sodium Chloride 0.9% (identified by raw material lot (b) (4) and (b) (4)) conducted by your Pharmacy Technician in your laminar air flow hood on 5/16/2017 and 5/17/2017. During sterile processing, I observed the following inadequate aseptic techniques employed:

- your Pharmacy Technician's beard cover left exposed skin and hair
- inadequate/infrequent use of (b) (4) upon entry/re-entry into the laminar air flow hood
- cleaning of the laminar air flow hood was not performed per your procedure(s)
- components were not adequately cleaned before placement into the laminar air flow hood
- written cleaning procedures and records do not verify the use of sporicidal cleaning agents used to clean the laminar air flow hood.

SEE REVERSE OF THIS PAGE	Robert J Ham, Investigator	X [signature]	5/25/2017