DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

FORM FDA 483 (80/08)
PREVIOUS EDITION OBSOLETE
INSPECTIONAL OBSERVATIONS

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DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1:
Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not followed.

Specifically,

On 05/23/2017, we observed three out of (b) (4) of that day's production technicians resting their elbows on the front areas of multiple laminar airflow hoods while producing sterile drug products.

This behavior was observed during the production of:

1. Ropivacaine HCL PF 0.2%, 2mg/ml, Lot #10003990, NS 200 mL in 250 mL, Cassette (400 mg), in clean room (b) (4) inside laminar airflow hood #3, serial (b) (4) produced by technician one.

2. Fentanyl Citrate, PF 2mcg/mL/ Bupivacaine HCL PF 0.125% in 0.9% Sodium Chloride, 250 mL, Lot #10003982, in clean room (b) (4) inside laminar airflow hood #3, serial (b) (4) produced by technician two.

3. Magnesium Sulfate PF added to 5% Dextrose, 50 mL, Lot #10004066, in clean room (b) (4) inside biosafety cabinet #2, serial (b) (4) produced by technician three.

*DATES OF INSPECTION
5/23/2017(Tue), 5/24/2017(Wed), 5/25/2017(Thu), 5/26/2017(Fri), 5/30/2017(Tue), 5/31/2017(Wed), 6/01/2017(Thu), 6/02/2017(Fri)
**Inspectional Observations**

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**Employee(s) Signature**
Jason R Caballero, Investigator
Shatina R Alridge, Investigator

**Date Issued**
6/2/2017

**Form FDA 483 (09/08)**

**Previous Edition Obsolete**

**Inspectional Observations**

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Stephen J. Rhoades, Director of Quality

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5/23/2017 - 6/2/2017

FEI Number: 3012053582

Outsourcing Facility