DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1
Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically,

On 11 Apr 16, during aseptic processing of Phenylephrine HCL Injectable, lot 04112016@2, and IC Rescue Solution lot 04082016@13, brown stains were observed on the surface of the HEPA filter located in the ISO 5 classified Laminar flow hood.

On 13 Apr 16, rusty conditions were observed on the metal support structure beneath the ISO 5 Laminar flow hood in the IV room.

OBSERVATION 2
Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically,

Cleaning records dated between 01 Jan 16 and 31 Mar 16 do not demonstrate use of sporicidal disinfectant in the ISO 5 Laminar flow hoods in the IV room, or in the ISO 7 areas. The only product used to disinfect the ISO 5 hoods, is sterile.

OBSERVATION 3
Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.

Specifically,

A. Your firm did not validate the sterilization to demonstrate the process was adequate for 100% of 100% glycerin injectable. Validation records did not show sterilization was achieved with however, glycerine 100% injectable, lot numbers 03242016@31 and 03282016@33 were sterilized on 29 Mar 16 and 04 Apr 16, respectively and dispensed.

B. Your firm did not adequately validate the depyrogenation process to demonstrate the process was adequate for depyrogenating the in-process glassware. Your validation report did not include the in the validation process.

C. Your firm did not perform media fills to simulate the most challenging production conditions. Media fill records dated between 17 Jun 15 and 05 Jan 16 showed that media fills with however, prostaglandin 500 mcg/ml lot 02042016@40, lot 12142015@41, and lot 10262015@17 (120 ml) exceeded the media fill volume.

OBSERVATION 4

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

Specifically,

A. Environmental monitoring for viable and non-viable particulates is not performed each day sterile drug products are produced. For example.

1) Your firm performs

AMENDMENT 1
2) Your firm's personnel monitoring (fingertips) are monitored.
3) Viable and nonviable air monitoring is not documented.

B. Records were not available to demonstrate Magnehelic gauges used to measure pressure differentials between the following areas were calibrated:
1) Between the
2) Between the
3) Between the
In addition, the pressure differential between the is not documented.

OBSERVATION 5
There is no written testing program designed to assess the stability characteristics of drug products.

For example,

A. Sterility, endotoxin, and potency were not tested throughout the six (6) months shelf life for Testosterone Cypionate (Sesame) 200mg/ml injectable, lot number 01062016@18 and Methylcobalamin 25mg/ml (PF) injection solution, lot number 02182016@22.

B. Sterility and endotoxin were not tested throughout the six (6) months shelf life for Prostaglandin (UD) 500mcg/ml injectable, lot number 02042016@40.

C. Sterility method suitability was not assessed for Testosterone Cypionate (Sesame) 200mg/ml injectable.
OBSERVATION 6
Protective apparel is not worn as necessary to protect drug products from contamination.
Specifically.
During aseptic processing of Phenylephrine HCL Injectable, lot 04112016@2, and IC Rescue Solution lot 104082016@13 on 11Apr16, a technician was observed with exposed skin around the eyes and eyebrows.

*DATES OF INSPECTION
4/11/2016(Mon), 4/12/2016(Tue), 4/13/2016(Wed), 4/14/2016(Thu), 4/15/2016(Fri), 4/18/2016(Mon)

X Linda F Murphy
Linda F Murphy
Investigator
Signed by Linda F Murphy