DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612 (949) 608-2900 Fax:(949) 608-4417 Industry Information: www.fda.gov/oc/industry	06/29/2015 - 07/08/2015* FEI NUMBER 3011630209

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: William A. Stuart, RPh, President

FIRM NAME	STREET ADDRESS
Hartley Medical Center Pharmacy, Incorporated	113 W Victoria St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Long Beach, CA 90805-2162	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 WE OBSERVED:

OBSERVATION 1

Clothing of personnel engaged in the processing of drug products is not appropriate for the duties they perform.

Specifically,

a. No goggles are worn during the preparation of sterile drug products which allows exposed skin around the neck and eyes.
b. Non-sterile gowning materials (scrub pants, scrub jacket, bouffant, and face mask) are worn in the aseptic area during preparation of sterile products.
c. The firm allows the clean room pants and jackets to be re-used throughout the day.

OBSERVATION 2

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

Specifically, personnel monitoring and surface sampling in the LAF hoods is not performed each day that final drug products are prepared.

OBSERVATION 3

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

Specifically,

a. No sporicidal agent is used in the cleanroom.
b. (b) (4) Germicidal Solution used to clean the aseptic area are not rendered sterile prior to use.
c. The firm uses non sterile (b) (4) to clean the surfaces of the LAF hoods where drug products are prepared.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Caryn M. Mcnab, Investigator Caryn M. McNab Jennifer M. Gogley, Microbiologist Jennifer M Gogley Drew M. Love, Consumer Safety Officer	07/08/2015

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OBSERVATION 4

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

Specifically, the firm's media fills do not simulate the batch process in which up to (b) (4) The current media fills only simulate the preparation of a patient specific drug product in which (b) (4)

OBSERVATION 5

Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.

Specifically,

A. There is no endotoxin testing of the final drug product in the pre-filled syringe or of the (b) (4) at the time of dispensing to assure that the endotoxin level of the drug product delivered to the patient remains within the established specification (b) (4). Drug (b) (4) such as preservative free Fentanyl Citrate, Clonidine, and Baclofen for intrathecal use are (b) (4) (b) (4) (b) (4) are tested for (b) (4) at the time of (b) (4) ; however the firm (b) (4).

B. Suitability testing for the sterility test method, necessary to demonstrate that the product does not interfere with the test, has not been performed by the contract testing laboratory which conducts the release test. For example:
   i. Clonidine HCL 2mg/ml lot number CL7106AB was prepared on 5/11/15. Sterility testing was performed by a contract lab however no suitability testing per USP <71> has been performed for this formulation.
   ii. Fentanyl Citrate 25mg/ml lot number FE8154 was prepared on 5/22/15. Sterility testing was performed by a contract lab however no suitability testing per USP <71> has been performed for this formulation.
   iii. Morphine Sulfate 50mg/ml lot number MS2226 was prepared on 6/2/15. Sterility testing was performed by a contract lab however no suitability testing per USP <71> has been performed for this formulation.

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OBSERVATION 6

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug product containers, closures, and in-process materials conform to appropriate standards of identity, strength, quality and purity.

Specifically, the firm has not performed suitability testing for the sterility test methods used during in-process testing of drug (b) (4) that are intended to demonstrate the solutions remain sterile at (b) (4) (b) (4) (b) (4) (b) (4) (b) (4). In addition, the sterility test conducted at the (b) (4) (b) (4) does not include fluid thioglycollate media, instead only (b) (4) is used.

*** DATES OF INSPECTION:**
06/29/2015(Mon), 06/30/2015(Tue), 07/01/2015(Wed), 07/08/2015(Wed)

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