DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax:(214) 253-5314 Industry Information: www.fda.gov/oc/industry	04/20/2015 - 05/05/2015 FEI NUMBER 3010054268

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: John R. Carson, President

FIRM NAME	STREET ADDRESS
Home Intensive Care Pharmacy, LLC	7220 Louis Pasteur Dr Suite 168
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Antonio, TX 78229-4537	Producer of Sterile Drug Products

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

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

Specifically, media fills performed by your firm with each of the operators that work in the ISO 5 area do not closely simulate actual production conditions or cover worst case or most challenging conditions. In routine production, your firm fills various size vials ((b) (4)- (b) (4)) as well as syringes and batch sizes up to (b) (4) units. The media fill your firm performs has the operator filling (b) (4) of media into (b) (4) (b) (4) vials and (b) (4) of media into (b) (4) positive control vials. For example, On 3/18/15, your firm filled an order for (b) (4) 5mL syringes of Bupicicaine/Lidocaine (lot#HIC031815-1SS) with a Beyond Use Dating (BUD) of 04/01/15. Operations to include the production of sterile syringes are not assessed in your current media fill validations.

The media fills samples are incubated in the firm's incubator ((b) (4), Model Number: (b) (4), Serial No. (b) (4), ID#(b) (4)) . The media fills are incubated at (b) (4)° - (b) (4)°C. There is no written procedure outlining the use and maintenance of the incubator. There is no record of temperature monitoring being done on the incubator.

Additionally, on 4/24/15, I observed operator (b) (6) preparing lot# C166853/C157764 of Morphine/Clonidine injectable with a compound worksheet with pre-filled results for the (b) (4) (b) (4) testing. Operator stated (b) (6) prefills the worksheet because (b) (6) knows it will pass".

AMENDMENT 1

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OBSERVATION 2

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

Specifically, your firm does not have a written procedure regarding the performance of environmental monitoring of ISO 5 classified areas used to produce sterile drug products. Monitoring of the firm's ISO 5 laminar flow hood environments and ISO 7 Cleanroom environment used to produce sterile drug products is not done during production. For example,

a) Your Policy entitled "Policy: Quality Control – Compounding" (no version or effective date associated with this policy) states "Environmental Quality of sterile compounding preparation areas shall be performed every (b) (4) ." Your firm's General Manager stated the monitoring is performed by the firm (b) (4) . Your (b) (4) log dated 4/22/15 indicated (b) (4) surface areas tested: (b) (4) . The last monitoring was conducted by your outside contractor on 1/14/15. Additionally, from 1/14/15 through 4/20/15 you have prepared approximately (b) (4) sterile drug products from non-sterile bulk.

b) Viable air monitoring of the ISO 7 cleanroom and the ISO 7 ante room and ISO 8 prep room is only performed every (b) (4) during the certification of the rooms. Your firm does not perform viable air monitoring in the ISO 5 laminar flow hoods. The last monitoring was conducted by your outside contractor on 1/14/15. Additionally, from 1/14/15 through 4/20/15, your firm has prepared sterile drug products approximately (b) (4) .

c) Your firm is not monitoring each operator working in the ISO 5 and ISO 7 clean room each day sterile drug products are prepared. Your firm is currently sampling the fingertips of all operators (b) (4) . Fingertip sampling was conducted by your firm on the following dates:

(b) (4)	(b) (4)	(b) (4)	(b) (4)

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(b) (4) (b) (4) (b) (4)

OBSERVATION 3

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

Specifically,

a) Your firm uses non-sterile wipes to clean and disinfect the ISO 5 laminar flow hoods where drug products are prepared.
b) Your firm only uses (b) (4) in the ISO 5 laminar flow hood. The firm does not use a sporicidal disinfectanct in the ISO 5 laminar flow hood and ISO 7 cleanroom where sterile drug products are prepared.
c) Your firm's operators are not spraying components and materials with sterile (b) (4) (b) (4) before moving them into the ISO 5 laminar flow hood.

OBSERVATION 4

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

Specifically, your firm does not exercise proper gowning technique to ensure safety and sterility of the sterile drug product. General gowning attire for entry in the ISO5/ISO7 classified areas consists of the following: Scrubs donned outside the facility, non-sterile lint-free lab coat, a non-sterile single hairnet, a non-sterile ear-loop face mask and dedicated shoes worn in ISO5/ISO7 areas. The general gowning requirements leave exposed skin around the eyes, forehead and neck of the person preparing the drug product. For example,

a) On 4/23/15, I observed operator ((b) (6)) preparing a syringe of Vancomycin Lot #HIC042215-1SS with a tear in the front of (b) (6) hairnet directly above (b) (6) forehead in the ISO 5 area.

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b) On 4/24/15, a pharmacy technician (b) (6) from your firm was performing aseptic filling Lot # C164432/C157764 of Bupivicaine/Clonidine Injectable inside the ISO 5 laminar air-flow hood wearing scrubs donned outside the facility, non-sterile lint-free lab coat, a non-sterile single hairnet, a non-sterile ear-loop face mask, and dedicated shoes.

c) On 4/24/15, I observed operator (b) (6) preparing Lot# C166853/C157764 of Morphine/Clonidine injectable with arms resting on the work bench area of laminar flow hood # (b)(4) inside the ISO 5 area wearing a non-sterile, lint-free lab coat.

OBSERVATION 5

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

Specifically, your firm does not have a stability program in place to support and determine the Beyond Use Dates (BUD) placed on your drug products.

Your firm has no documentation to justify the following BUDs placed on these preservative-free injectable drug products prepared by your firm. For example:

Intrathecal Drug Product	Prepared Date	Discard After Date	Stability Data	BUD (days)
Baclofen (Lot# C152180 #3)	03/02/2015	05/01/2015	None	60
Hydromorphone(Lot# C160900)/ Clonidine (Lot # C157764)	02/18/2015	03/20/2015	None	30
Fentanyl (Lot# C165713)/ Baclofen (Lot# C152180 #3)	03/17/2015	04/16/2015	None	30
Morphine (Lot# C156990)	03/18/2015	04/17/2015	None	30

OBSERVATION 6

Routine calibration and checking of equipment is not performed according to a written program designed to assure proper performance.

Specifically, your firm does not calibrate the pressure gauges used to monitor the measurement of the

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pressure differential between the ISO 7 cleanroom and the ISO 7 ante room, between the ISO 7 ante room and ISO 8 prep room and between the ISO 8 prep room and the unclassified general pharmacy.

OBSERVATION 7

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

Specifically, between 4/2/13 through 4/15/15, your firm has released over (b)(4) lots of sterile finished products using a non-validated testing method to detect aerobic bacteria, anaerobic bacteria and fungi (mold and yeasts) performed by a contract laboratory. The contract laboratory COA for sterility states "Does not meet all the requirements for sampling and/or method suitability specified in USP<71>." For example, the following tested lots have been released:

Intrathecal Drug Product	Unit Size	Prepared Date	Dispensed Date
Baclofen 500mcg/mL(0.5mg/mL) (Lot# C152180 #3)	40mL	1/23/15	1/23/15
Morphine 0.37mg/mL (Lot # C156990) / Baclofen 2000mcg/mL (Lot# C15280 #3)	40mL	1/23/15	1/23/15

OBSERVATION 8

Written records of investigations into the failure of a batch or any of its components to meet specifications do not always include the conclusions and follow-up.

Specifically, on 4/2/13, your firm received out of specification potency/purity results of 88.73% (test range (b)(4)%(b)(4)%) for Fentanyl 50mcg/mL, lot# HIC031313-5DC. On 3/14/13, your firm dispensed (b)(4) - 5mL syringes of Fentanyl 50mcg/mL, lot # HIC031313-5DC, with a BUD of 6/12/13. Furthermore, your firm did not perform any investigation into the lot failure.

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."