DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404) 253-1161 Fax:(404) 253-1202 Industry Information: www.fda.gov/oc/industry	09/08/2014 - 09/17/2014* FEI NUMBER 3010951596

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Christina M. Jeffcoat, Executive Director

FIRM NAME	STREET ADDRESS
Medi-Home Infusion Pharmacy	2 Palmetto Wood Parkway
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Irmo, SC 29063	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 I OBSERVED:

OBSERVATION 1

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

Specifically,

A. The firm did not conduct any surface sampling in the IV hood or chemo hood during certification. Surface sampling in the IV hood is routinely conducted (b) (4) and there is no routine surface sampling conducted in the chemo hood. Additionally, the instruction sheet for documenting the contact sampling states to collect the sample (b) (4)

B (b) (4) used for surface sampling of the IV hood are incubated (b) (4) and not in a temperature controlled incubator.

C. The unidirectional flow of air in the ISO 5 air flow hoods (IV hood and Chemo hood) have not been confirmed through visual mechanisms (such as smoke studies) under dynamic conditions to ensure adequacy for use.

D. The firm has no written procedures describing the environmental monitoring program for the clean room areas including the ISO 5 laminar flow hoods or personnel monitoring.

OBSERVATION 2

Buildings used in the processing of a drug product are not maintained in a good state of repair.

Specifically, the flooring material in the clean room (directly in front of the ISO 5 IV hood) was deteriorated/missing with visible loose debris/paint and particles present. SOP MED-28, "Clean Room and Ante Room", requires that the surface of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the clean area shall be smooth, impervious, free from cracks and crevices, and nonshedding, thereby promoting cleavability and minimizing spaces in which microorganisms and

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other contaminants may accumulate.

OBSERVATION 3

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically, there was no investigation of the fungal growth found on the IV room doorway (inside the cleanroom) during certification of this area on May 5, 2014 and no documentation of the subsequent cleaning performed. Additionally, there was no resampling or recertification of this area to assure fungus was no longer present.

OBSERVATION 4

Equipment and utensils are not maintained at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically, the (b) (4) (ISO 5 chemo hood used to produce sterile chemotherapeutic injectable drugs) was noted to have numerous cracks along the entire length of each side. These cracks were located on the interior side of the (b) (4) and could prevent adequate cleaning/sanitization of this surface. SOP MED-28, "Clean Room and Ante Room", requires that the surface of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the clean area shall be smooth, impervious, free from cracks and crevices, and nonshedding, thereby promoting cleavability and minimizing spaces in which microorganisms and other contaminants may accumulate.

OBSERVATION 6

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and written.

Specifically,

A. On 9/9/14 I observed an operator (b) (6) sanitizing supplies/drug containers (to be used in the processing of sterile injectable drugs) with (b) (4) in the anteroom without wearing gloves, gown, head cover, or mask.

B. The firm only conducts glove fingertip sampling (b) (4) . Additionally, the instruction sheet for glove fingertip sampling states the sampling is to be done (b) (4)

C. The firm's media fills are inadequate in that the only documentation provided was an instruction sheet entitled, "Medi Home Infusion RL-2 Aseptic Technique Validation Instructions" which does not describe the requirements for media fills or the acceptance criteria. These instructions only describe the steps for transfer of (b) (4)

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OBSERVATION 6

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

Specifically, SOP MED-21, "Certification of Clean Room and/or Airflow Hood" does not require air sample testing for viable particulates, surface sampling, HEPA filter recertification, or dynamic smoke studies and there is no acceptance criteria specified.

OBSERVATION 7

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

Specifically, personnel responsible for processing sterile injectable drugs within the ISO 5 Laminar Flow Hoods (IV hood and Chemo hood) were not gowned in sterile gowning. For example the mask, shoe covers, caps and gowns were not sterile. Additionally, personnel put on shoe covers in the general pharmacy area directly outside the anteroom.

OBSERVATION 8

There is a lack of written procedures describing in sufficient detail the methods, equipment and materials to be used for sanitation.

Specifically, the firm's procedure MED-29, "Cleaning of Clean Room and Ante Room", does not specify the types/concentrations of cleaning and sanitizing agents to be used in these areas or the contact times.

*** DATES OF INSPECTION:**
09/08/2014(Mon), 09/09/2014(Tue), 09/10/2014(Wed), 09/11/2014(Thu), 09/17/2014(Wed)

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