DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse, Rm 900 2nd & Chestnut St Philadelphia, PA 19106 (215) 597-4390 Fax:(215) 597-0875 Industry Information: www.fda.gov/oc/industry	05/01/2013 - 05/21/2013* FEI NUMBER 3009803574

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: David M. Tomasello, Chief Operating Officer

FIRM NAME	STREET ADDRESS
Home Infusions Solutions, Inc.	2 Walnut Grove Dr Suite 140
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Horsham, PA 19044-2219	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

Buildings used in the manufacture, processing, packing, or holding of a drug product do not have the suitable size, construction, and location to facilitate cleaning, maintenance, and proper operations.

Specifically,
1. Plastic flap dividers with large gaps between each flap are utilized to separate the warehouse area from the anteroom. Plastic flap dividers with large gaps are also utilized to separate the anteroom from the clean room which houses all ISO 5 Laminar Flow Hoods and the biological safety cabinet. 2 Buckets used for cleaning were observed directly next to, and adjacent to both sides of the plastic flap divider. This plastic flap divider is used to separate the anteroom from the clean room that houses all ISO 5 Laminar Flow Hoods (LFH) and the Biological Safety Cabinet.

2. There is no designated area for personnel responsible for processing sterile injectable drugs to gown into masks, shoe covers, caps, gloves and gowns prior to entering the clean room where the ISO 5 Laminar Flow Hoods are located.

3. Warehouse employees were observed moving from the warehouse area into the anteroom which is adjacent to the clean room in an uncontrolled manner. Warehouse personnel were observed coming in contact with components that were staged to enter the clean room, where the ISO 5 Laminar Flow Hoods are located.

OBSERVATION 2

The control systems necessary to prevent contamination or mix-ups are deficient.

Specifically,
1. (b) (4) is used for cleaning and disinfecting the core sterile injectable

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	Anita R. Michael, Investigator	05/21/2013

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processing areas. No cleaning studies were performed to assure the suitability and effectiveness of the (b) (4) used for spore, fungi and bacterial removal. Also, no recovery studies or challenges were performed to assure (b) (4) is effective. (b) (4) is used for cleaning and disinfecting the clean room, ISO 5 Laminar Flow Hoods and Biological Safety Cabinet.

2. No viable air samples for fungi or bacteria were taken during the (b) (4) qualification conducted in September 2012 for any of the ISO 5 Laminar Flow Hoods (LFHs P2, P6, and P7) or the Biological Safety Cabinet (P4). Additionally, during (b) (4) qualifications performed in September 2012 and April 2013 no surface samples for bacteria or fungi were obtained for the critical areas inside the ISO 5 Laminar Flow Hoods (LFHs P2, P6 and P7), Biological Safety Cabinet (P4), critical contact areas, or equipment located in the ISO 5 areas.

3. Per SOP 3106.0 for finger tip testing the (b) (4) are required to be tested using (b) (4). The SOP requires that (b) (4). For the following fingertip samples no time the samples were incubated was documented:
JJ-1499637
IRB-1499637
BF-1499637
CM-1499637
DS-1499637
SP-1499637
DP-1499637

Additionally, the manufacture instructions require that the (b) (4) Also, there are no records available describing what type of bacteria, yeast mold and fungi , (b) (4) can support.

OBSERVATION 3

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

Specifically,
1. Per SOP 3106.0 (titled Process Simulation Testing) as part of the media fill tests, process simulating

testing must be completed to assure employees processing sterile injectable drugs are trained and qualified to perform aseptic processing. (b) (4) media was used during the media fill tests. Per the SOP 3106.0 the (b) (4) For the following media fill tests, the time each sample was incubated was not documented for all tests listed below. Also, test dates were missing (arrows used) and sample numbers were missing for all samples listed below. Additionally, media lots numbers were not documented as listed below:

Media Test BF L/TSB
Media Test RN L/TSB
Media Test SP L/TSB
Media Test DS L/TSB
Media Test TH L/TSB
Media Test DP L/TSB
Media Test IRB L/TSB
Media Test CB L/TSB no media lot number documented
Media Test JJ L/TSB no media lot number documenetd
Media Test CM L/TSB no media lot number documented

Additionally, the manufacture instructions require that the (b) (4) . There is no data to support the shortened incubation times listed in the SOP 3106.0. Also, there are no records available describing what type of bacteria, yeast, mold and fungi (b) (4) can support.

2. A computer screen was observed inside the ISO 5 Laminar Flow Hood (LFH P2) adjacent to where sterile injectable drugs are processed. This screen was located in front of the HEPA filter that provides unidirectional air flow into the core ISO 5 LFH P2. There are no cleaning studies or procedures addressing how the computer screen would be sanitized, disinfected and routinely cleaned.

3. A radio was located within the clean room that houses the (b ISO 5 Laminar Flow Hoods and (b Bio Safety Cabinet. This radio was located near the ISO 5 Laminar Flow Hood (LFH P7).

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OBSERVATION 4

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

Specifically,

1. Currently, the assigned before use date (BUD) is 7 days at refrigerated conditions for Invanz (Ertapenem), 1 GM/ml, primary packaged in the Eclipse pump. For Invanz there are no stability samples tested to support the 7 day BUD.

2. Records reviewed from 02/2012 through 09/2012 the assigned before use date (BUD) was 28 days at refrigerated conditions for Vancomycin1 GM/ml, primary packaged in the Eclipse pump. For Vancomycin there are no stability samples tested to support the 28 day BUD.

3. For records reviewed for the month of 02/2012 the assigned before use date (BUD) was 28 days for Morphine at multiple concentrations. For Morphine there are no stability samples tested to support the 28 day BUD.

4. For records reviewed for the month of 02/2012 the assigned before use date (BUD) was 28 days for Hydromorphone at multiple concentrations. For Hydromorphone there are no stability samples tested to support the 28 day BUD.

OBSERVATION 5

Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically, personnel responsible for processing sterile injectable drugs within the ISO 5 Laminar Flow Hoods were not gowned in sterile gowning. For example the mask, shoe covers, caps and gowns were not sterile.

*** DATES OF INSPECTION:**
05/01/2013(Wed), 05/02/2013(Thu), 05/03/2013(Fri), 05/06/2013(Mon), 05/07/2013(Tue), 05/08/2013(Wed), 05/09/2013(Thu), 05/21/2013(Tue)

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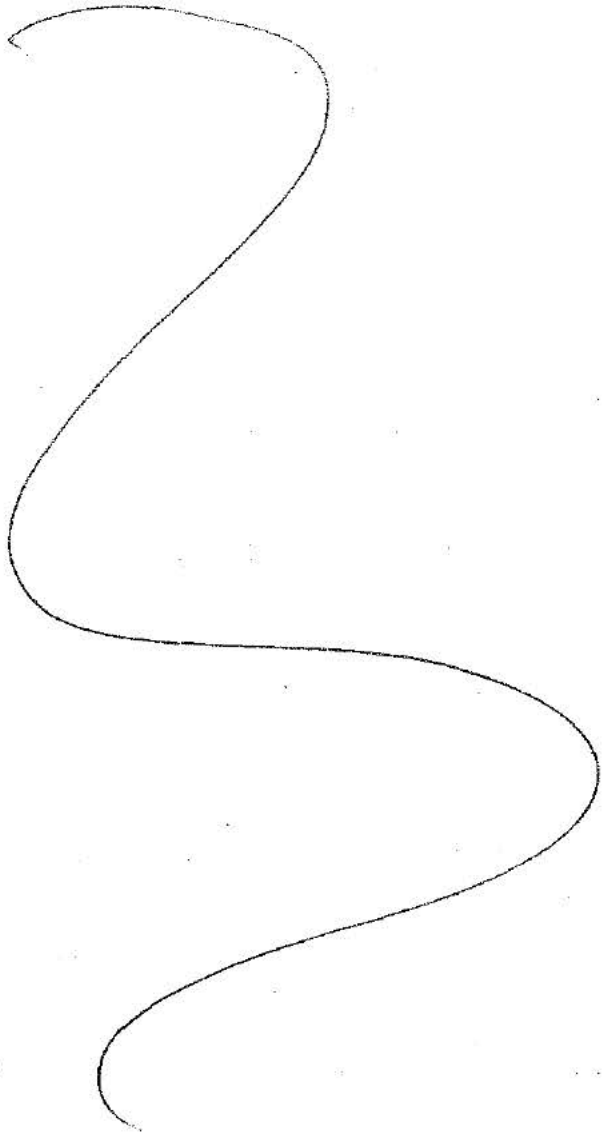

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