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	7/20/2015-8/6/2015* FEI NUMBER 3011536648

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dr. Joshua D. Vinson , Pharmacy Manager

FIRM NAME	STREET ADDRESS
Walgreens Home Care, Inc. dba Walgreens Infusion Services	14220 Northbrook Dr Ste 100B
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Antonio, TX 78232-5045	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

Buildings used in the manufacture, processing, packing or holding of drug products are not maintained in a clean and sanitary condition and free of infestation by rodents, birds insects, and other vermin .

Specifically,

1. On 07/20/2015, during our physical walkthrough of the facility, the pharmacy manager was made aware of and used a non-sterile wipe to clean up what appeared to be an approximately four inch by two inch liquid filth solution from the floor of the ISO 7 classified area directly under your firm's Laminar Airflow Unit (b) (4) while your pharmacy technician was preparing the sterile drug solution, Dextrose 5% NS 1000mL, NDC #: 00338-0089-04, Lot # C974196, Expiration Date: 10-2016.

2. On 07/20/2015, during our physical walkthrough of the facility, there were what appeared to be hundreds of dead insects throughout the warehouse area utilized to store your firm's various drug products. One specific drug product within close proximity to the insects was your firm's drug product Trophamine 10% Amino Acid Injection, 500mL, NDC 0264-9341-55, expiration date 11/16, Product # (b) (4) . The warehouse area is directly adjacent to the packing pharmacy area. This is in direct contradiction to your firm's SOP, OP-Ad-80, Effective: 08/21/2013, titled "General Cleaning and Pest Control" which states, "…take action immediately at the first sight of a pest control problem (e.g. dead insects). Control and eliminate pests with the following actions: Remove all signs of pest infestation by thoroughly sweeping and/or mopping the infected area…"

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jason R Caballero, Investigator Lisa R Jennings, Investigator LisaRJennings	X Jason R Caballero Jason R Caballero Investigator Signed by: Jason R. Caballero -S	8/6/2015

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OBSERVATION 2
Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically,

1. On 07/20/2015, during our physical walkthrough of the facility, the non-sterile face mask utilized by your pharmacy technician working under your firm's Laminar Airflow Unit (b) (4) (b) (4) failed to cover (b) (4) entire face. This employee, while aseptically manipulating the sterile drug solution, Dextrose 5% NS 1000mL, NDC #: 00338-0089-04, Lot # C974196, Expiration Date: 10-2016, had exposed body areas such as neck, forehead, eyes, ears, and cheeks.

2. Your firm does not require, nor does it provide, sterile gowns, sterile hair nets, sterile facial masks, or any kind of sterile protective eye wear to employees.

OBSERVATION 3
Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not followed .

Specifically,

On 07/20/2015, during our walkthrough of your facility, we observed your pharmacy technician exhibiting poor aseptic technique while preparing sterile drug products in your firm's Laminar Airflow Unit (b) (4) . Your firm's pharmacy technician was observed leaning forward into the ISO 5 classified environment and with (b) (4) elbows covering the ventilation grid inside, inhibiting the unidirectional airflow, while aseptically manipulating the sterile drug solution, Dextrose 5% NS 1000mL, NDC #: 00338-0089-04, Lot # C974196, Expiration Date: 10-2016. This is in direct contradiction to your firm's SOP, P-132, Effective : 01/29/2015 and Revised 02/24/2015, "Aseptic

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Technique Procedures" which states, "...objects shall not be placed on the front intake and near exhaust grilles/vents so first air is not obstructed..."

OBSERVATION 4

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

Specifically,

1. Your firm does not perform viable or non-viable environmental monitoring of the ISO 5 area every day your firm prepares sterile drug products. According to SOP P-165, Environmental Monitoring, Effective 1/9/2009, Revised 2/27/2015; your "Policy" section states, "Viable air sampling shall be conducted every (b) (4) by the (b) (4) by Walgreens infusion using (b) (4) at (b) (4) ", and "Surface sampling shall be conducted (b) (4) ".

2. Your firm performs (b) (4) EM sampling (b) (4) . According to SOP P-165, Environmental Monitoring; your "Environmental Monitoring", 2.a. Surface Sampling section states, "This test is used to evaluate the presence of microbes, including bacteria, yeast and fungi, on critical work surfaces in order to evaluate effectiveness of cleaning procedures".

3. Your firm does not monitor each operator working in the ISO 5 area and ISO 7 clean room each day drug products are prepared. Currently, your firm samples the gloved fingertips of operators (b) (4) per your firm's SOP P-164, "Personnel Training and Evaluation in Aseptic Manipulation Skills", Effective 2/6/2015 and Revised 5/27/2015.

4. Your firm does not utilize positive or negative controls for (b) (4) plates used in environmental sampling.

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OBSERVATION 5

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

Specifically,

Your firm does not perform stability testing on sterile drug products, such as Dextrose 5% and 0.9% Sodium Chloride 3000mL, to determine Beyond Use Dates (BUDs) and storage conditions of the products. Your firm labels this product with a refrigerated BUD of 8 days.

OBSERVATION 6

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

Specifically,

Your firm does not monitor pressure differentials during production of sterile drug products. In addition, there is no ongoing pressure differential monitoring between ISO 7 (clean room), ISO 8 (ante room) and an unclassified area to determine if a loss of positive pressure occurs during production. Your firm does not include ongoing pressure differential monitoring in your firm's SOP P-190, Temperature, Pressure and Humidity Monitoring and Documentation, Effective 2/1/2008, Revised 7/20/2015. SOP P-190 states under Pressure Monitoring, "The pressures in all the sterile compounding areas shall be monitored (b) (4) ..."

***DATES OF INSPECTION**

7/20/2015(Mon),7/21/2015(Tue),7/22/2015(Wed),7/23/2015(Thu),7/24/2015(Fri),7/27/2015(Mon),7/28/2015(Tue),7/29/2015(Wed),7/30/2015(Thu),7/31/2015(Fri),8/03/2015(Mon),8/04/2015(Tue),8/05/2015(Wed),8/06/2015(Thu)

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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."