DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 214-253-5200 Industry Information: www.fda.gov/oc/industry	06/27/17, 06/28/17, 06/29/17, 07/03/17, 07/07/17, 07/11/17
	FEI NUMBER 3013330273

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Ricque A. Gonder, Branch Manager

FIRM NAME	STREET ADDRESS
Park Infusioncare LP dba Preferred Homecare	13621 Inwood Road, Suite 420
CITY, STATE AND ZIP CODE Dallas, TX 75244	TYPE OF ESTABLISHMENT INSPECTED Sterile Drug Producer

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) (WE) OBSERVED:

OBSERVATION 1

Vermin was observed in your production area.

Specifically,

1. On 06/28/17, one dead insect was observed on top of ISO 5 Hood (b) (4) (Serial # (b) (4) inside the Cleanroom. Additionally, one dead insect was observed on the bottom shelf of the refrigerator used for storing your finished produced sterile products and one dead insect was observed on the bottom shelf of the refrigerator used for storing drug ingredients to be produced.

2. Your ISO 5 Hoods are not constructed for appropriate cleaning and maintenance. Reddish-brown residue was observed under the contact surface grating of ISO 5 Hood (b) (4) (Serial # (b) (4) and ISO 5 (b) (4) (Serial # (b) (4)) where the operator performs sterile production.

3. Ceiling tile of the Anteroom appeared to display reddish-brown discoloration.

4. The Anteroom door was observed to have an approximately one and a half (1 ½) inch gap from the bottom of the door to the floor which exposed the Anteroom to the unclassified area. According to your Pressure Gauge Readings Log from October 20-31, 2016, the pressure readings were documented as (b) (4) for the Anteroom (your firm's specifications for pressure differentials in the Anteroom are to be greater than (b) (4)

6. (b) (4) the Cleanroom and the unclassified area. On 06/27/17, materials were observed being transfered from the unclassified area to the Cleanroom with the use of (b) (4) while producing sterile drug products in the Cleanroom.

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		Anh M. Lac, Consumer Safety Officer	07/11/2017

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Dallas, TX 75244	Sterile Drug Producer

OBSERVATION 2

Personnel were observed touching equipment or other surfaces located outside of the ISO 5 area with gloved hands and then proceeding with aseptic processing without changing or sanitizing gloves.

Specifically,

A. On 06/27/17, an operator was observed opening the door of the Cleanroom to grab supplies in the Anteroom and then re-entered the Cleanroom to proceed with the preparation of 3 in 1 TPN 120gm Protein 1800mL for RX #(b) (6), (b) (7)(C) without changing or sanitizing gloves.

B. On 06/28/17, an operator was observed donning sterile gloves improperly by touching the outside of the sterile gloves with her bare hands.

OBSERVATION 3

Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

Specifically, your media fill consists of (b) (4) and the contents get (b) (4). However, this process does not simulate the most challenging aseptic manipulations performed at your firm such as the processing of your TPN sterile products. According to your Pharmacy Manager, the aseptic process for TPN products requires the following steps which include but are not limited to: setting up the (b) (4) the specified amount of ingredients (i.e., (b) (4) into the (b) (4) operator (b) (4), then the operator (b) (4) (b) (4) (b) (4)

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OBSERVATION 4

Disinfecting agents and cleaning pads or wipes used in the ISO 5 area (aseptic processing areas) are not sterile.

Specifically,

A. Disinfectants, (b) (4) and (b) (4) Wipes, used to clean surfaces and equipment in the ISO 5 Hoods, ISO 7 Cleanroom, and ISO 7 Chemoroom are non-sterile.

B. The low-lint wipes used to clean surfaces and equipment in the ISO 5 Hoods are non-sterile.

OBSERVATION 5

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

Specifically,

A. Your environmental monitoring samples (viable air, surface monitoring plate, and finger touch plate) are not incubated at an adequate temperature and duration to recover the appropriate microorganisms. Per manufacturer's instruction for use of contact sampling plates, "(b) (4) (b) (4) '. However, your environmental air and surface contact plates sampled from ISO 5 Hoods were documented to be incubated only at (b) (4) F (~(b) (4) C) for (b) (4) (b) (4) days. Additionally, finger touch plates were also documented to be incubated only at ~(b) (4) C for (b) (4) (b) (4) days.

B. According to your ISO rooms and hoods certification records, (b) (4) /m³ was recovered from viable air sample collected from your ISO 5 (b) (4) (Serial # (b) (4) on 04/24/17 and on 10/17/16. Your firm has not performed investigation into the source of the contamination.

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