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	02/13/17, 02/14/17. 02/17/17
	FEI NUMBER 3012669716

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Michael P. McDonald, Regional Vice President of Infusion

FIRM NAME	STREET ADDRESS
Park Infusioncare, LP dba Preferred Homecare	4007 Bellaire Blvd Ste G
CITY, STATE, ZIP CODE, COUNTRY Houston, TX 77025-1165	TYPE ESTABLISHMENT INSPECTED Aseptic Drug Processor

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

The facility design and maintenance was observed to allow the influx of poor quality air into a higher classified area.

1) Your firm has a number of structural and maintenance deficiencies in classified areas. These are summarized below:

a. One of the (b) (4) ISO 5 hoods ("HOOD (b) (4)") in the ISO 7 cleanrooms has a work surface made of wood covered with what appears to be formica, with visible residues and abrasions on the surface. The Nurse Manager acknowledged that this surface is not amenable to suitable cleaning.
b. One of the (b) (4) ISO 5 hoods ("HOOD (b) (4)") exhibited a crack in the plexi-glass like side panel. This same ISO 5 hood exhibited an accumulation on dust above the hood.
c. One of the (b) (4) ISO 5 hoods ("HOOD (b) (4)") displayed reddish-brown discoloration consistent with rust along the right and left corners of the interior of the hood. The majority of the HEPA filter for ISO 5 hood exhibited an orange-red discoloration.
d. In the ISO 7 cleanroom there are observable gaps between the HEPA filters and the ceilings. Some gaps were mended with tape. Four of nine tiles above were observed displaced in the ISO 7 cleanroom such that there was a continuous space between the ISO 7 cleanroom and the unclassified area above the ceiling.
e. The wall in the ISO 7 cleanroom has a distorted/ damaged wall with a brownish tinge.
f. The ISO 7 anteroom has a ceiling made of ceiling tiles like found in an office space. Gaps were observed around ceiling tile and the HEPA filter in the ceiling of the ISO7 anteroom such that there was a continuous space between the ISO 7 anteroom and the unclassified area above the ceiling. Additionally, the HEPA filter appeared distorted at the edge of the filter.
g. The sink in the ISO 7 anteroom has a work surface made of wood covered either with what appears to be formica and in an apparent rough, unfinished state. The Nurse Manager acknowledged that this surface is not amenable to suitable cleaning.
h. Wooden doors separate the anteroom and cleanroom. This surface is not amenable to cleaning.

2) The firm is lacks the following items to assess the acceptability of the air quality
a. Pressured differential between the ISO 7 and ISO 5 areas and the unclassified and ISO 7 areas are not actively monitored or recorded to ensure positive pressure is maintained during sterile drug manipulation activities. Furthermore, the pressure gauges between the ISO 7 cleanroom and ISO 7 anteroom areas and the ISO 7 anteroom

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Massoud Motamed, Investigator	DATE ISSUED 02/17/2017

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and unclassified areas had not calibrated to ensure accurate pressure readings. As such during the months of September, October and November of 2016 pressures in the anteroom appeared negative relative to the cleanroom. During this time, your firm continued aseptic processing of drug products. You firm purported that there are not accurate pressure readings prior to identifying this negative pressure in the anteroom after an extended period of time. During the months of September, October and November of 2016, (b) (4) aseptically processed units had been dispensed.

b. Documented pressure differentials could not be explained. From August 2016 to February 2017, pressure differentials (highest and lowest recorded values) of the classified areas can be found in the table below:

Value Represented	Cleanroom	Anteroom	Chemo Room
Highest pressure recorded (inWC)	(b) (4)	(b) (4)	(b) (4)
Lowest pressure recorded (inWC)	(b) (4)	(b) (4)	(b) (4)

It was observed that aire pressure in the ISO 7 cleanroom forced ceiling tiles to become displaced, exposing the ISO 7 cleanroom to the unclassified area above the ceiling.

2) The firm contracts (b) (4) to perform room certification. During the certification dated (b) (4) (b) (4) (the latest certification) and discussion with the associated technician the following deficiencies were documented:

a. Dynamic smoke studies were not conducted. Furthermore, there is no evidence that smoke studies have been conducted in the ISO 7, and ISO 5 areas.

b. The entire certification report was conducted under static conditions, and is silent with regards to applicability under normal operating conditions.

c. HEPA integrity was not assessed.

d. On 02/14/2017, the technician stated "Rooms [are] not designed to pass smoke tests" when I asked about the lack of assessment of smoke patterns outside the ISO 5 hood.

OBSERVATION 2

The use of sporicidal agents in the cleanrooms and/or ISO 5 area is inadequate or infrequent.

On 02/14/2017, your Pharmacist-in-Charge stated that a sporicidal agent is not utilized to disinfect the ISO 5 hoods. Specifically, your firm stated only (b) (4) is used to clean ISO 5 hoods used for aseptic processing.

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