DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661	8/21/2018-9/14/2018* FEI NUMBER 3007174596

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dmitry Vagman, Pharmacist in Charge and Vice President

FIRM NAME	STREET ADDRESS
Kings Park Slope Inc	357 Flatbush Ave
CITY, STATE, ZIP CODE, COUNTRY Brooklyn, NY 11238-4378	TYPE ESTABLISHMENT INSPECTED 503A

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 use of sporicidal agents in the ISO 5 classified aseptic processing area was inadequate.

Specifically, aseptic processing areas are deficient regarding the system for cleaning and disinfecting the equipment to produce aseptic conditions. For example,

- On 8/21/18, one of your pharmacy technicians was observed cleaning the top and bottom of the ISO 5 **(b) (4)** laminar flow hood (used to produce non-TPN drug products in the ISO 7 non-hazardous cleanroom), with sporicidal agent, sterile **(b) (4)** from side to side, rather than from back to front.
- On 8/27/18, one of your pharmacy technicians was observed cleaning the front of the **(b) (4)** **(b) (4)** (used to produce TPN drug products in the ISO 5 **(b) (4)** laminar flow hood located in the ISO 7 non-hazardous cleanroom) **(b) (4)** **(b) (4)** in the ISO 5 **(b) (4)** laminar flow hood, with sporicidal agent, sterile **(b) (4)** first, and then sterile **(b) (4)**

OBSERVATION 2

Disinfecting agents and cleaning wipes used in the ISO 5 classified aseptic processing areas were not sterile.

Specifically, the type of wipes your firm currently uses for cleaning/disinfecting the ISO 5 hoods is **(b) (4)** wipes, which are

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Rachael A Moliver, Investigator	X Rachael A Moliver Investigator Signed By: Rachael Moliver -S Date Signed: 09-14-2018 11:27:19	9/14/2018

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(b) (4) for aseptic environments. However, these wipes are not sterilized prior to use in the ISO 5 aseptic processing areas.

OBSERVATION 3

Your facility design allowed the influx of poor quality air into a higher classified area.

Inadequate pressure differentials between higher quality air rooms and lower quality air rooms were observed. Specifically, I observed multiple out-of-specification (OOS) pressure differential readings for pressure differential gauge (b) (4) and no investigation was initiated for the loss of negative pressure differential in the ISO 7 hazardous cleanroom. Electronic pressure differential gaug (b) (4) located in the ISO 7 anteroom, measures the pressure differential between the ISO 7 hazardous cleanroom to the ISO 7 anteroom, with an established negative pressure range from (b) (4)

Yet, on 7/13/18 from 09:44:03 to 09:53:11, all of the (b) (4) pressure differential readings for gauge (b) (4) were out of range for a total of nine minutes and eight seconds. The readings ranged from -0.017 to 0. During this time of inadequate pressure differential between the ISO 7 hazardous cleanroom and the ISO 7 anteroom, one drug product was produced in the ISO 7 hazardous compounding cleanroom, Daratumumab 20mg/mL, Rx (b) (6) filled on 7/13/18 at 9:45AM.

According to you firm's management, your pharmacist in charge or designee reviews the pressure differential logs (b) (4) for all your firm's (b) (4) electronic pressure differential gauges for pressure differentials that are out of range for two minutes or more. However, the (b) (4) reviews of the pressure differential readings are not documented, and your firm does not have any record of these reviews.

This is a repeat observation.

OBSERVATION 4

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.

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Specifically, your firm currently performs media fills for a process using (b) (4) however, your firm does not perform (b) (4) to sterilize any of your compounded drug products. Your firm only performs (b) (4) aseptic filling, as well as (b) (4) terilizes one product, progesterone olive oil 50mg/mL.

This is a repeat observation.

***DATES OF INSPECTION**

8/21/2018(Tue), 8/22/2018(Wed), 8/23/2018(Thu), 8/24/2018(Fri), 8/27/2018(Mon), 8/28/2018(Tue), 8/29/2018(Wed), 9/14/2018(Fri)

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