DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718)340-7000; Fax: (718)662-5661 Industry Information: www.fda.gov/oc/industry	04/04/2016 - 04/22/2016* FEI NUMBER 3007174596

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Ronald DelGaudio, President & CEO

FIRM NAME	STREET ADDRESS
Kings Park Slope, Inc.	357 Flatbush Ave
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Brooklyn, NY 11238	503B Outsourcing Facility

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

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

(a) Positive pressure differential was lost in the ISO 7(b) (4) cleanroom on 1/5/2016, 1/6/2016, 1/7/2016, 1/10/2016, 1/11/2016, and 1/31/2016 and in the ISO 8 anteroom on 12/6/2015, 1/2/2016, 1/5/2016, 1/9/2016, and 1/10/2016. Since the firm does not have continuous monitoring of pressure differential in place and only records the pressure differential (b) (4) , it is unknown whether the loss of positive pressure occurred during sterile processing.

(b) The firm failed to conduct passive viable air sampling using settling plates when compounding operations are occurring as per SOP 03-18.01, entitled, (b) (4) Passive Viable Air Sampling." On 4/5/2016, we observed the compounding/filling of Glycopyrrolate 0.6 mg/3 mL in 6 mL syringe (Lot #G0405161; Used By 05/20/2016). We were informed by the firm that viable air sampling is performed only (b) (4) by an outside contractor (b) (4)

(c) The firm does not conduct personnel monitoring after each compounding session. On 4/5/2016, we observed the compounding/filling of Glycopyrrolate 0.6 mg/3 mL in 6 mL syringe (Lot #G0405161; Used By 05/20/2016), which took more than (b) (4) to complete that morning. No personnel monitoring was conducted for the production. We were informed by the firm that personnel monitoring (fingertip (b) (4) is performed (b) (4)

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OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process. Specifically,

(a) Media fill simulation has not been performed for all aseptic processing. Management stated media fill was only performed (b) (4)

(b) Per SOP 05-04.01, entitled, "Hand Hygiene and Sterile Garbing Procedure," "Protective eye wear will be (b) (4) Management indicated goggles may be (b) (4) . There is no assurance that sterility of the goggle can be maintained during de-gowning.

(c) The firm failed to perform adequate unidirectional airflow studies under dynamic conditions to show that its aseptic operations are designed to prevent microbiological contamination of products or provide adequate assurance of product sterility.

(d) The firm has not conducted any verification of the uniformity of the (b) (4) sterilization throughout the lot of Progesterone in Olive Oil 50 mg/mL filled containers.

(e) The firm has not verified container closure integrity for compounded products.

OBSERVATION 3

Written records are not made of investigations into unexplained discrepancies. Specifically,

(a) No investigation was initiated for loss of positive pressure differential in the ISO 7 (b) (4) cleanroom on 1/5/2016, 1/6/2016, 1/7/2016, 1/10/2016, 1/11/2016, and 1/31/2016 and in the ISO 8 anteroom on 12/6/2015, 1/2/2016, 1/5/2016, 1/9/2016, and 1/10/2016.

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(b) The firm has no written procedure which addresses actions to be taken in the event of action or alert limit excursions for environmental and personnel monitoring. On the first day of the inspection, the FDA inspection team observed the reading of (b) (4) plates and it was found a plate from the monitoring of a component tote employed in the anteroom exhibited a visual result of too numerous to count. In response to our query, management stated that the (b) (4)

OBSERVATION 4

The separate or defined areas necessary to prevent contamination or mix-ups are deficient. Specifically,

On 04/05/2016, during our observation of the technician gowning in the ante room, we saw (b) (6), (b) (7)(C) sleeve touched a cart and the top of (b) (6), (b) (7)(C) hood touched shelving on the other side. The placement of a cart in the ante room appeared to reduce the space for (b) (6), (b) (7)(C) to conduct gowning.

OBSERVATION 5

Control procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product. Specifically,

Preservative content (relative concentration) have not been tested and confirmed for the following lots of Progesterone in Olive Oil 50 mg/mL IM: P01141550 (prepared on 01/14/2015), P05271550 (prepared on 05/27/2015), P09081550 (prepared on 09/08/2015), and P12171550 (prepared on 12/17/2015).

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OBSERVATION 6

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

Sporicidal disinfection of aseptic manufacturing areas is only performed (b) (4)

OBSERVATION 7

Employees are not given training in written procedures required by current good manufacturing practice regulations. Specifically,

The firm has a written procedure which addresses good documentation practices including the proper manner to handle correction of errors; however, in the course of reviewing monitoring logs for equipment employed in the laboratory, it was observed that there were a number entries which had been either crossed out and re-written without initials and date or were covered by white-out and rewritten without initials and date. Management stated that this is a new employee who had not been trained yet regarding good documentation practices and, in fact, had not received any CGMP training despite the fact that he was given documentation responsibilities.

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OBSERVATION 8

The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A) and (B). Specifically,

- The statements, "This is a compounded drug," and "Not for Resale," as well as the lot or batch number; storage and handling instructions; and information to facilitate adverse event reporting www.fda.gov/medwatch and 1-800-FDA-1088, are not on your outsourcing facility's drug product labels. Examples of drug product labels that do not contain this information:
  - o 20 Progesterone/Olive Oil 50 mg/mL
  - o 30 Progesterone/Olive Oil 50 mg/mL
  - o Total Parenteral Nutrition Solution Formula (b) (4) 1100 mL, Dextrose 70% 297 mL, Sterile Water for Injection 150 mL, with Additives: Sodium Chloride 25 mEq, Calcium Gluconate 5 mEq, Magnesium Sulfate 5 mEq, Potassium Chloride 37.6 mEq, Potassium Phosphate 12 mMol, Sodium Acetate 40 mEq, and (b) (4) 10 mL
- In addition to the above, the name, address, and phone number of your outsourcing facility is also not on your outsourcing facility's drug product labels. Examples of drug product labels that do not contain this information:
  - o Decitabine 40 mg/8 mL, Sodium Chloride 0.9% 105 mL IV Piggyback
  - o Fluorouracil 4300 mg/86 mL, Sodium Chloride 0.9% 14 mL Intravenous
- Further, the expiration date and the quantity or proportion of each inactive ingredient are not on your outsourcing facility's drug product labels. Examples of drug product labels that do not contain this information:
  - o 20 Progesterone/Olive Oil 50 mg/mL
  - o 30 Progesterone/Olive Oil 50 mg/mL
- Furthermore, the following information is not found on the container labels for the drug products you produce:
  - o The route of administration.

An example of a label that does not contain this information:

- o Progesterone Olive Oil Inj Solution 50 mg/mL Volume 10 mL Vial

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OBSERVATION 9

Your outsourcing facility did not submit a report to FDA identifying a product(s) compounded during the previous six months for the December 2015 reporting period as required by section 503B(b)(2)(A). Specifically, the following are examples of products that were compounded between June 1, 2015, and November 30, 2015, but were not identified on your report dated December 21, 2015:

- Irinotecan 250 mg/12.5 mL, Dextrose 5% 262 mL compounded on 6/15/2015 for patient (b) (6)
- Fludarabine Phosphate 57 mg/2.28 mL, Sodium Chloride 0.9% 105 mL compounded on 7/8/2015 for patient (b) (6)
- Doxorubicin 108 mg/54 mL repackaged on 10/13/2015 for patient (b) (6)
- 1 Leuprolide Microdose compounded on 6/19/2015 for Rx #(b) (6)
- 15 Diazepam Vag Cream 2 mg/gm compounded on 11/28/2015 for Rx #(b) (6)

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*DATES OF INSPECTION: 04/04/2016 (Mon), 04/05/2016 (Tue), 04/07/2016 (Thu), 04/12/2016 (Tue), 4/14/2016 (Thu), 4/19/2016 (Tue), 4/22/2016 (Fri)

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