DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Ave. Jamaica, NY 11433-1034 (718) 340-7000 Fax: (718) 662-5661 Industry Information: www.fda.gov/oc/industry	03/04-06 & 14/2014
	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 Avenue
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Brooklyn, NY 11238-4378	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

Your firm failed to establish an adequate system for maintaining equipment used to control the aseptic conditions.

Specifically:

a. Smoke studies were not performed under dynamic conditions to verify that operators and processing equipment do not alter or impede the unidirectional cascade of air from the HEPA filters to the ISO 5 laminar flow benches where sterile drug products are opened and manipulated, and to the rest of the ISO 7 clean room.

b. Adequate exhaust systems or other systems to control contaminants are lacking in that:
1). The (b) (4) wall mounted Magnehelic Pressure Gauges used for measuring the air pressures of the cleanroom and surrounding areas have not been calibrated.
2). One of the recirculating vents in the non-hazardous cleanroom was partially blocked by a printer.

OBSERVATION 2

Clothing of personnel engaged in the processing of drug products is not appropriate for the duties they perform.

Specifically, sterile drug products are aseptically manipulated by the cleanroom operators who wear non-sterile gowns above the knees, non-sterile pants, non-sterile glasses/goggles, non-sterile footwear and non-sterile facial masks. The only apparel that is sterile is the operator's gloves in the non-hazardous ISO 5 area. Non-sterile gloves are used at the hazardous chemo ISO 5 work area. The operator's face and head are not fully covered and allows exposed facial skin and hair over the critical ISO 5 laminar flow areas. Additionally, gowning apparel is composed of particle shedding material.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	James A. Liubicich Charisse K. Green	James A. Liubicich, Investigator Charisse K. Green, Investigator	03/14/2014

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OBSERVATION 3
Your firm failed to establish an adequate system for monitoring environmental conditions in aseptic processing areas.

Specifically,
a. Environmental monitoring for viable air counts in the ISO 5 zones is not performed at least daily during periods of production.
b. Environmental monitoring for non-viable particulates in the ISO 5 zones is not performed under dynamic conditions.
c. The work surfaces, inside the ISO 5 hoods, are not tested for microbial contamination at least daily at the end of operations.
d. Operators' gloves are not tested for microbial contamination at least daily.

OBSERVATION 4
Your firm failed to establish an adequate system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically,

a. Non-sterile wipes are used to disinfect the ISO 5 hoods' sterile processing surfaces.
b. The firm does not use sporicidal disinfectants to disinfect the ISO 5 surfaces.

OBSERVATION 5

Your firm does not have, for each batch of drug product purporting to be sterile and/or pyrogen-free, appropriate laboratory determination of satisfactory conformance to final specifications for the drug product.
Specifically, given the observed inadequate environmental controls, testing is deficient in that:

a. Sterility testing. Your firm only performed sterility testing in limited cases, for one product.
b. Endotoxin testing. Data is not available for any sterile drug products produced.

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OBSERVATION 6

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

No media fills/process simulations have been performed under the most stressful or challenging conditions.

OBSERVATION 7

Containers and closures are not tested for conformance with all appropriate written procedures.

Specifically, the firm does not receive or review certificates of analysis showing sterility for the sterile containers and closures used to process sterile drug products.

OBSERVATION 8

Your firm failed to clean, maintain, and, as appropriate for the nature of the drug, sanitize and/or sterilize equipment and utensils at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements.

Specifically, purchased sterile equipment, such as transfer tubing or ophthalmic drops containers, are accepted into inventory and used for sterile drug processing without reviewing the manufacturer's certificate of analysis to assure sterility.

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