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, New York 11433-1034 718-340-7000 Industry Information: www.fda.gov/oc/industry	9/10, 11, 12, 19/2014
	FEI NUMBER 3011022663

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Billy Kim, Vice President, Operations

FIRM NAME	STREET ADDRESS
BioScrip Pharmacy (NY), Inc.	1 Vermont Drive
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Lake Success, New York 11042	Producer of Sterile Drug Products

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 systems for maintaining any equipment used to control the aseptic conditions.

Specifically:

a). Smoke studies were not performed under dynamic conditions to verify that operators, processing equipment or activities of the ISO 7 clean rooms do not alter or impede the unidirectionality of air from the HEPA filters in the two ISO 5 laminar flow hoods, nor the one operational ISO 5 biological safety cabinet where drug products are aseptically processed.

b). The two ISO 7 clean rooms, the ISO 7 anteroom, and the unclassified surrounding areas are not continuously monitored for air pressure differentials during production.

c). During the semi-annual clean room certification performed by an outside vendor on 1/06/14, the differential pressure in the non-hazardous (IV mix room) was found to not meet the required firm's limit. The measurement was at negative 0.007 below the limits of 0.02-0.05, yet no investigation was performed to determine the cause of the recorded value.

d). An operator was observed opening a package of sterile gloves by placing the outer non-sterile outer wrapping onto an ISO 5 working surface where sterile drugs were being processed. Additionally, during sterile drug processing the operator was observed placing a non-sterile cloth wipe onto the same ISO 5 working surface.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	James A. Liubicich	James A. Liubicich - Investigator	09/19/2014

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OBSERVATION 2

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

a). Sterile drug products are aseptically manipulated by the clean room operators who were observed wearing non-sterile gowns, non-sterile glasses/goggles, non-sterile footwear, non-sterile facial masks, and non-sterile bonnets.

b). The operator's face and neck are not fully covered allowing exposed facial skin and hair over the critical ISO 5 laminar flow areas where sterile injectable drug products are processed.

OBSERVATION 3

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

Specifically,
a. Environmental monitoring for viable air counts in the ISO 5 zones is not performed at least daily during periods of production. The firm only monitors viable air counts during the semi-annual cleanroom certification by an outside vendor; lastly on 7/01/14.

b. Environmental monitoring for non-viable particulates in the ISO 5 zones is not performed under dynamic conditions. This was last performed on 07/01/14.

c. The work surfaces, inside the ISO 5 hoods, are not tested for microbial contamination at least daily during periods of production and at the end of operations. This monitoring is only performed monthly.

d. Operators' gloves are not tested for microbial contamination at least daily during periods of production. Glove fingertips are only monitored annually.

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OBSERVATION 4

Aseptic processing areas are deficient regarding the 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 and they are composed of particle shedding material.

b. The firm does not use sporicidal agents to disinfect the ISO 5 surfaces.

c. A non-sterile liquid, AccelTB, is used in disinfecting ISO 5 surfaces.

d. No disinfectant effectiveness study has been performed to determine if disinfection procedures and disinfectants that are used can maintain the ISO 5 environment in the hoods.

OBSERVATION 5

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written, and followed.

No media fills/process simulations have been performed under the most stressful or challenging conditions. Instead, the firm uses an aseptic technique validation kit which doesn't utilize equipment and containers used in normal processing.

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OBSERVATION 6

Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.

Your firm has not conducted any sterility testing for any products.

OBSERVATION 7

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

Specifically,

a). Your firm is processing Penicillin-type injectable drugs, such as Penicillin, Nafcillin, and Oxacillin, in the same ISO 5 hood with your non-penicillin products. The absence of a structurally isolated area creates the potential that accidental breakage of vials of penicillin powders could contaminate your other sterile drug products.

b). There is no separate air handling system for penicillin drugs.

c).There are no separate facilities, for processing operations, to prevent contamination from beta-Lactam non-penicillin injectable drugs, such as Cefazolin, Ceftazidime, Aztreonam, and others. These beta-Lactam powders, which are contained in glass vials, are processed in the same ISO 5 hood as are sterile injectable non beta-Lactam drugs. There is no assurance that a potential breakage of the glass vial and consequent powder spill would not contaminate other sterile drug products.

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OBSERVATION 8

For each batch of drug product, there shall be appropriate laboratory determination of satisfactory conformance to final specifications for the drug product.

Specifically, visual checks of sterile injectable drugs for clarity/discoloration or particulates/contaminants are not performed against contrasting backgrounds.

OBSERVATION 9

There shall be a written testing program designed to assess the stability characteristics of drug products. The results of such stability testing shall be used in determining appropriate storage conditions and expiration dates.

Your firm has not tested for sterility or potency over the assigned Beyond Use Date (BUD) for any sterile injectable, all of which are preservative free. For example, your firm has not conducted any testing to support the BUDs such as 14 days refrigerated for Vancomycin or 7 days room temperature for Fluorouracil. You have no data to show that the sterility and potency will be maintained over the time period of the BUD.

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."