DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax:(973) 331-4969 Industry Information: www.fda.gov/oc/industry	03/30/2015 - 05/22/2015* FEI NUMBER 3002127548

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Alan R. Brown, President

FIRM NAME	STREET ADDRESS
Liberty Drug & Surgical	195 Main St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Chatham, NJ 07928-2405	Producer of Sterile Drugs

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 WE OBSERVED:

OBSERVATION 1

The flow of components, drug product containers, closures, in-process materials, and drug products though the building is not designed to prevent contamination.

Specifically,

a. The raw materials such as IV bags and containers containing the non-sterile finished drug products are labeled, sprayed with (b) (4), and wiped with non-sterile wipe in the uncontrolled Pharmacy area. The products are brought into the ISO 7 Anteroom and placed on the sink during personnel gowning. The transfer of products from the ISO 7 Anteroom into the ISO 6 clean room is performed without additional sanitization of the containers.

b. The ports of IV bags are wiped with a non-sterile (b) (4) swabs in the ISO 5 laminar flow hood prior to being injected with a drug product.

OBSERVATION 2

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

Specifically, on 3/30/15, during the preparation of spraying IV bags of (b) (4) with (b) (4) one IV bag fell out of the hand of the Pharmacist and landed on the floor of the uncontrolled Pharmacy area. The IV bag was picked up, sprayed with (b) (4), transferred into the clean room and used for a patient specific prescription of Doxycycline 200 mg/ml IV bags.

AMENDMENT 1

	EMPLOYEE(S) SIGNATURE	DATE ISSUED
SEE REVERSE OF THIS PAGE	Barbara J. Wilimczyk-Macri, Investigator Philip F. Istafanos, Microbiologist Susan T. Hadman, Microbiologist Frederick Razzaghi, Investigator Nicholas A. Violand, Investigator	05/26/2015

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OBSERVATION 3

Buildings used in the manufacture, processing, packing, or holding of a drug product do not have the suitable size, construction, and location to facilitate cleaning, maintenance, and proper operations.

Specifically,

a. The ISO 7 Anteroom is approximately (b) (4) inches in width and has a sliding door into the ISO 6 clean room.
b. The ISO 7 Anteroom contains a sink whose water source is (b) (4)

OBSERVATION 4

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically, smoke studies are not performed under dynamic conditions in the ISO 6 clean room or within the ISO 5 laminar flow hood/biological safety cabinet.

OBSERVATION 5

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

Specifically,

a. Environmental monitoring which includes viable air, non-viable air, and surface contact plates are not performed on a routine basis. The monitoring of the ISO 5 laminar flow hoods, ISO 6 clean room, and ISO 7 Anteroom is performed by an outside contract testing laboratory only (b) (4)
b. Viable air and non-viable air environmental monitoring is not conducted within the ISO 5 laminar flow hood.
c. Personnel monitoring, which is performed on the fingertips, is not conducted on a routine basis or each day.

Procedure 03-08.01, Gloved Fingertip Sampling states this testing is to be completed at least (b) (4) The finger tip sampling has only been performed in (b) (4)

OBSERVATION 6

Clothing of personnel engaged in the manufacturing, processing, packing, and holding of drug products is not appropriate for the duties they perform.

Specifically,

a. The gowning for the sterile operations in the ISO 6 clean room consists of a non-sterile disposable laboratory coat,

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shoe covers, a hair cover and a surgical mask.

b. On 03/30/15, the Pharmacist within the ISO 6 clean room was observed donning sterile gloves in a manner that could compromise the sterility of the gloves. In addition, during the gowning process, the non-sterile disposable laboratory coat was observed touching the walls of the ISO 7, Anteroom.

OBSERVATION 7

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

Specifically, the lint free wipes used within the ISO 6 clean room are not sterile and are stored on the supply cart outside its original container.

OBSERVATION 8

The written stability program for drug products does not include reliable, meaningful, and specific test methods.

Specifically, the establishment of beyond use date of 60 days for Doxycycline 100 mg/ml and 132 days for 17-Hydroxyprogesterone 250 mg/ml did not include testing the product for endotoxins and sterility. Potency was the only test used to support the beyond use date.

OBSERVATION 9

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

Specifically,

a. (b) (4) in the production of Doxycycline 100 mg/ml Injection. In addition, (b) (4) in the production of Doxycycline 100 mg/ml Injection is (b) (4) and there are no studies demonstrating (b) (4) is suitable for (b) (4) finished product.

b. (b) (4) used to sterilize product vials for Doxycycline 100 mg/ml and rubber stoppers is not qualified or routinely evaluated to ensure that it is performing as required.

c. Media fills are not routinely performed. Procedure 03-07.01, Personnel Aseptic Media Fill Verification requires

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media fill be performed at least (b) (4) Media fills were last performed in January of 2014.

OBSERVATION 10

Each lot of a component, drug product container, and closure that is liable to microbiological contamination that is objectionable in view of its intended use is not subjected to microbiological tests before use.

Specifically, non-sterile raw materials including Active Pharmaceutical Ingredients are used in the production of sterile injectable drug products. The materials are received with a Certificate of Analysis that does not assure it is suitable for the manufacture of sterile products and does not contain results from microbiological testing performed by the vendor. Not all Active Pharmaceutical Ingredients are tested upon receipt.

OBSERVATION 11

Test procedures relative to appropriate laboratory testing for sterility and pyrogens are not followed.

Specifically,

a. Method suitability as described within the compendial method has not been performed for sterility testing of Doxycycline 100 mg/ml and 17-Hydroxyprogesterone 250 mg/ml.

b. Morphine 50 mg/ml Injection and Methadone 10 mg/ml Injection are made in anticipation of orders for office supply and patient-specific prescriptions. These products are not tested for endotoxin, sterility, or potency.

OBSERVATION 12

Written production and process control procedures are not followed in the execution of production and process control functions and documented at the time of performance.

Specifically, written production and process control procedures are not followed, do not include details pertinent to routine operations or include details that are accurate.

a. Procedures do not include information that is accurate. For example, Procedure 03-06.01, Surface Sampling Procedure, states there are three classifications, ISO 5, ISO 7 and ISO 7/8. The (b) (4) certification of the clean room states the three classifications are ISO 5, ISO 6, and ISO 7.
b. Written procedures are not inclusive of all the details required to carry out operations. Procedure 02-04.01, Sterile Compounding Area Cleaning and Disinfecting does not provide instruction on the cleaning and disinfecting agents to be used and when they are to be used. Currently (b) (4) is used (b) (4) and (b) (4) is used (b) (4)

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c. Procedures are not followed. Procedure 02-05.01, Sterile Pressure Differential Monitoring states pressure differentials will be documented at least (b) (4) Pressure differentials have only been documented for (b) (4) [redacted]

OBSERVATION 13

Procedures describing the handling of written and oral complaints related to drug products are not written or followed.

Specifically, there is no procedure for the receiving and handling of complaints.

*** DATES OF INSPECTION:**
03/30/2015(Mon), 03/31/2015(Tue), 04/01/2015(Wed), 04/07/2015(Tue), 04/08/2015(Wed), 04/09/2015(Thu), 04/30/2015(Thu), 05/04/2015(Mon), 05/07/2015(Thu), 05/22/2015(Fri)

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