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	11/6/2019-11/20/2019* FEI NUMBER 3006997792

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Scott Berliner, RPh, President at Life Science Pharmacy Inc.

FIRM NAME	STREET ADDRESS
Life Science Pharmacy Inc	144 Route 17m Ste 4
CITY, STATE, ZIP CODE, COUNTRY Harriman, NY 10926-3321	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-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 OBSERVED:

OBSERVATION 1

Non-pharmaceutical grade components are used in the formulation of non-sterile drug products.

Specifically, your firm uses non-USP grade, (b) (4) (b) (4) (b) (4), to compound the following suspensions and enema from bulk drug substances:

- Rx #(b) (6), CHLORAL HYDRATE(G) SUSP 500MG/5ML, fill date: 10/1/19, Qty: 450mL;
- Rx #(b) (6), NYSTATIN ORAL SUSP(RASPBERRY) 100,000U/ML, fill date: 9/16/19, Qty: 900mL; and,
- Rx #(b) (6), BUTYRATE ENEMAS (100mM/LITER) 100MM/LITER, fill date: 10/25/19, Qty: 3000mL.

OBSERVATION 2

ISO-5 classified areas were not certified under dynamic conditions.

Specifically, uni-directional airflow was not verified under operational conditions. A smoke study was conducted under static conditions by (b) (4) dated July 2019, and was only performed and documented for your firm's ISO 5 (b) (4) flow BSC and not for the ISO 5 (b) (4) LFH. Both the ISO 5 (b) (4) flow BSC and ISO 5 (b) (4) LFH are located in the ISO 7 cleanroom and have both been utilized for processing sterile drug products.

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: 11-20-2019 13:29:36	11/20/2019

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OBSERVATION 3

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.

Specifically, no media fills have been successfully completed and documented in the last year.

OBSERVATION 4

Pressure differentials between areas with different air classifications were not monitored prior or during sterile drug production.

Specifically, your firm does not have any records documenting the monitoring of the pressure differentials. Your firm has (b) (4) gauges that monitor pressure differentials, including (b) (4) that measures the pressure differential between the ISO 7 cleanroom and ISO 8 anteroom and (b) (4) that measures the pressure differential between the ISO 8 anteroom and unclassified general pharmacy area.

OBSERVATION 5

The use of sporicidal agents in the cleanrooms and/or ISO 5 area is inadequate or infrequent.

Specifically,

a) A sporicidal agent is used less than (b) (4) in the ISO 5 areas and ISO 7 cleanroom. Currently, it is your firm's practice to perform a (b) (4) cleaning of the ISO 5 and ISO 7 areas with (b) (4) (b) (4) (b) (4) (minimum of a (b) (4) contact time), and (b) (4) (b) (4) % (b) (4)

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b) The (b) (4) cleaning of the ISO 5 areas and ISO 7 cleanroom with sporicidal agent, (b) (4) (b) (4), was not performed and documented in the (b) (4) cleaning log for July 2019.

***DATES OF INSPECTION**

11/06/2019(Wed), 11/07/2019(Thu), 11/08/2019(Fri), 11/11/2019(Mon), 11/13/2019(Wed), 11/20/2019(Wed)

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Rachael A Moliver, Investigator

X Rachael A Moliver
Investigator
Signed By: Rachael Moliver -S
Date Signed: 11-20-2019 13:29:36

DATE ISSUED
11/20/2019

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 judgment, 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."