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	11/1/2016-12/6/2016* FEI NUMBER 3007942369

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Peter L. Fallon , Owner

FIRM NAME	STREET ADDRESS
Fallon Wellness Pharmacy, L.L.C.	1057 Troy Schenectady Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Latham, NY 12110-1002	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 WE OBSERVED:

OBSERVATION 1

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically, Out-of-Specification results were obtained during environmental monitoring during sterile processing on September 13, 2016, September 20, 2016 and October 6, 2016.

a. On September 13, 2016 a result of 1 CFU/m^3 was recorded for the Viable particle air sampling within your Anteroom Clean Room (ISO 7 environment) and the fingertips of the left hand of the sterile processing pharmacist working within your ISO 5 LAFW exceeded the limit of (b) (4) CFU/m^3 and CFU/plate, respectively, for fungus. The fungal contamination was identified as *Penicillium spp.* The sterile processing pharmacist can move between LAFW Buffer Room (ISO 7), Anteroom (ISO 7) and Hazardous Materials Room (ISO 7). On this day various sterile products were produced including Methylcobalamin 5,000 mcg/0.2 mL Injection, Lot #09132016@18.

b. On September 20, 2016 the limit of (b) (4) CFU/plate for fungus was exceeded as 1 CFU/plate was observed on the surface of the ISO 5 LAFW where the pharmacist conducts sterile drug production/repackaging operations within the ISO 7 Buffer Room. The growth was identified as a non-sporulating hyaline fungus. Additionally, 1 CFU/plate was observed on the sterile processing pharmacist's left hand that was identified as *Penicillium spp.* On this day various sterile products were produced including Tri-Mix (Papaverine/Phentolamine/Prostaglandin) 40/4/0.04 mg/mL, Lot #09202016@8, which was recalled on 11/01/2016.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Chad N Thompson, Investigator Rajiv R Srivastava, Inspector 12/6/2016 X Chad N Thompson Chad N Thompson Investigator Signed by: Chad N. Thompson -S	12/6/2016

c. Environmental Monitoring sampling on October 6, 2016, completed during room re-certification by a third party, showed an OOS result of "UTQ" (Unable To Quantitate), which is equivalent to a result of Too Numerous To Count, for quantity inside the ISO 7 Hazardous Materials Room, on the (b) (4) . This (b) (4) is used to stage materials, container closures, etc. by the pharmacist that is working in the ISO 5 (b) (4) Identification showed that the bacteria was *Bacillus* with no speciation.

This is a repeat observation from the previous, March 2015, inspection.

OBSERVATION 2

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

Specifically,

a. The non-viable air particle counter is out of calibration. The most recent date of calibration was in (b) (4) ; the particle counter was to be re-calibrated by the end of April 2016.

b. The pressure gauge used to conduct (b) (4) testing of (b) (4) , (b) (4) (b) (4) , has never been calibrated.

c. The (b) (4) used for (b) (4) sterilization of utensils, equipment and for the (b) (4) sterilization of Epinephrine/Lidocaine/Tetracaine sterile gel; Medroxyprogesterone Acetate 1% Ophthalmic Suspension; Biotin 10 mg/mL Suspension for Injection was last qualified and calibrated in (b) (4) . The (b) (4) has been out of qualification/calibration since (b) (4) . Since that time one lot of Medroxyprogesterone Acetate 1% Ophthalmic Suspension and one batch of Biotin 10 mg/mL were (b) (4) sterilized and dispensed to patients using the (b) (4) .

d. Your clean rooms are maintained in a manner that could lead to product contamination. We observed the following within the ISO 7 environments for your Buffer Room and Hazardous Material Room, garbage cans lined with non-sterile garbage bags and red sharps containers.

This is a repeat observation from the previous, March 2015, inspection.

OBSERVATION 3

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

Specifically,

a. Sterile solutions of high-risk drug products for intrathecal injections are prepared where the non-sterile active ingredient is (b) (4) Your firm has not conducted any studies to support the stability or sterility, for the following products, over the time periods from when the (b) (4) is prepared until the sterile drug product are used:
   1. Bupivacaine HCl/Morphine Sulfate (10/50 mg/mL; 10/10 mg/mL; 9/50 mg/mL)
   2. Hydromorphone HCl 10 mg/mL
   3. Baclofen 2.5 mg/mL
   4. Morphine Sulfate (25 mg/mL; 50 mg/mL)

b. (b) (4) are prepared for various high-risk products, drug products where the active ingredient is received as a non-sterile ingredient and then (b) (4) to produce a sterile injectable solution. Your firm has not conducted any studies to support the stability and/or sterility over the time periods that the (b) (4) is prepared until the sterile drug products are used, for the following products:

   1. (b) (4) Stock Injection solution: USP Beyond Use Date (BUD) is 24 hours, currently you are using a BUD of (b) (4), if sterility testing is confirmed per USP <71>

2. (b) (4) Stock Injection solution: USP BUD is 3 days, currently you are using a BUD of (b) (4) if sterility testing is confirmed per USP <71>
3. (b) (4) Stock Injection solution: USP BUD is 24 hours, currently you are using a BUD of (b) (4) if sterility testing is confirmed per USP <71>

c. You have not validated the (b) (4) sterilization (b) (4) cycles used for three of your sterile drug products:
   1. Epinephrine/Lidocaine/Tetracaine sterile gel
   2. Medroxyprogesterone Acetate 1% Ophthalmic Suspension
   3. Biotin 10 mg/mL Suspension for Injection.

This is a repeat observation from the previous, March 2015, inspection.

OBSERVATION 4

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

Specifically,

a. Your firm does not test every sterile drug lot produced for sterility. Sterile drug products are only tested if produced as a (b) (4) .

b. Aseptically processed sterile injectable drug products produced from non-sterile ingredients are released and distributed without having been tested for endotoxins, as reported. For example, you do not anlayze sterile injections of Tri-Mix (Papaverine/Phentolamine/Prostaglandin) for endotoxin.

c. Sterility testing is conducted by a contract testing laboratory that employs a testing method for sterility that is not compliant to USP <71> because the suitability of the method for the

product has not been documented.

This is a repeat observation from the previous, March 2015, inspection.

OBSERVATION 5

Adequate exhaust systems or other systems to control contaminants are lacking in areas where air contamination occurs during production.

Specifically, the ISO 5 (b) (4) within the Hazardous Material Room is not directly (b) (4) . There exists a gap of approximately 12 inches between the top of the (b) (4) and the (b) (4) of the Hazardous Material Room. There is no direct connection from the (b) (4)

OBSERVATION 6

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

Specifically, your (b) (4) ISO 7 clean rooms, the ISO 7 anteroom, and the unclassified surrounding areas are not continuously monitored for air pressure differentials during production. Current practice is to (b) (4) record the air pressure differentials (b) (4)

This is a repeat observation from the previous, March 2015, inspection.

OBSERVATION 7

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

Specifically, there are no separate facilities for processing operations to prevent the contamination from beta-Lactam injectable drugs such as Cefazolin, Ceftazidime, and others. These beta-Lactam powders which are contained in glass vials are processed in the same ISO 5 Laminar Airflow 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 processed in the same hood.

This is a repeat observation from the previous, March 2015, inspection.

OBSERVATION 8

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically, a (b) (4) of (b) (4) with a Beyond Use Date (b) (4) days. Your firm has not conducted any studies to support the stability of (b) (4) over the (b) (4)-day time period from the time that the (b) (4) is prepared until its usage.

OBSERVATION 9

There is a lack of written procedures assigning responsibility, providing cleaning schedules and describing in sufficient detail the methods, equipment and materials to be used for sanitation.

Specifically, your procedure, "1.40 Compounding Area Requirements (Sterile), Version 1.0," does not establish the personnel responsible to review and verify that cleaning/sanitization has been completed as described. The procedure does not describe in sufficient detail the cleaning of surfaces, floors, walls. Your procedure does not establish a time frame for the use of sporicidal agents. The cleaning log provided, as Attachment 1, only includes the (b) (4) activities; it does not provide logs for (b) (4) cleaning.

This is a repeat observation from the previous, March 2015, inspection.

OBSERVATION 10

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

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Specifically, you have not performed disinfectant effectiveness studies to determine if disinfection agents are effective in aseptic areas.

***DATES OF INSPECTION**

11/01/2016(Tue),11/02/2016(Wed),11/03/2016(Thu),11/04/2016(Fri),11/07/2016(Mon),11/08/2016(Tue),11/09/2016(Wed),11/14/2016(Mon),11/22/2016(Tue),11/23/2016(Wed),12/01/2016(Thu),12/05/2016(Mon),12/06/2016(Tue)

12/6/2016

X Rajiv R Srivastava
Rajiv R Srivastava
Inspector
Signed by: Rajiv R. Srivastava -S

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Chad N Thompson, Investigator Rajiv R Srivastava, Inspector 12/6/2016 X Chad N Thompson Chad N Thompson Invest gator Signed by: Chad N. Thompson -S	12/6/2016

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."