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 718-34-7000 Industry Information: www.fda.gov/oc/industry	3/02,03,04,06,10/2015
	FEI NUMBER 3007942369

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: George R. Doherty, Owner & Pharmacist

FIRM NAME	STREET ADDRESS
Fallon Wellness Pharmacy, L.L.C.	1057 Troy Schenectady Road
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Latham, New York 12110-1002	Producer of Sterile Drug Products

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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.

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 ISO 5 laminar flow hoods, nor the ISO 5 (b) (4) where drug products are aseptically processed.

b). The door providing entry to the anteroom (ISO Class 7), from the unclassified non-sterile production room, was observed to be open throughout the inspection. Reportedly, the door is not capable of closing due to the airflow balance between the anteroom and the main non-sterile production room.

c). Your clean room is maintained in a manner that could lead to product contamination. We observed the following clutter within the ISO Class 7 environment including a dispenser of clear adhesive tape, supply bins with various articles, and equipment that were not utilized during filling operations.

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 eyeglasses, a non-sterile hair net, and non-sterile under garments that were worn outdoors prior to entry to the clean room.

b). The clean room operator was observed re-using coveralls that were hanging on a hook in the anteroom.

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c). The operator's forehead was not covered allowing exposed facial skin over the critical ISO 5 laminar flow areas where sterile injectable drug products are processed.

d). We observed the gowning practices of the pharmacist prior to the production of Bevacizumab (0.05 mL) 25 mg/mL Injection (Avastin 25 mg/mL Injection). (b) (6) entered the sterile production area wearing a single pair of non-sterile gloves. Within the clean room (b) (6) donned a second pair of gloves, sterile latex, powder free. When (b) (6) extended (b) (6) arms to ensure that (b) (6) fingers filled the appropriate position, the pharmacist's bare wrist and forearm were exposed to the ISO 7 clean room environment.

OBSERVATION 3
There is a failure to thoroughly review 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.

a). Amphotericin 5mcg/0.1mL ophthalmic injection lot 05232014@5 was recalled on 6/12/14. This was due to a failing sterility test result. The firm did not perform an investigation to determine the cause of contamination nor develop a plan to prevent future occurrences.

b). Bevacizumab (Avastin) injection 25mg/mL lot 06162014@95 failed the (b) (4) test on 6/18/14 where the sample had one confirmed microorganism detected. The firm did not perform an investigation into the failing sterility result.

c). An outside vendor tested for air viables in the hazardous clean room, during the (b) (4) clean room certification, on 9/25/14. The limit of (b) (4) fungal cfu/m3 was exceeded and found to be 12cfu/m3. On 10/29/14, after some room modifications, a retest found the airborne fungal sampling result at 33cfu/m3. On 12/15/14, the hazardous clean room met the limit after additional modifications. The previous clean room certification was on (b) (4) and until 9/25/14 the air viable counts were unknown. The firm's investigation did not assess the impact on non-sterile powders that are all weighed in the hazardous clean room and eventually become part of a sterile finished drug product. Potentially affected non-sterile powders are those weighed after the (b) (4) certification to before the 9/25/14 certification where it is unknown if the clean room was contaminated and from 9/25/14 until 12/15/14 where there was known contamination.

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OBSERVATION 4
Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

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 (b) (4) cleanroom certification by an outside vendor; lastly on 9/25/14.

b). Environmental monitoring for non-viable particulates in the ISO 5 zones is not performed under dynamic conditions. The firm only monitors non-viable air counts during the (b) (4) cleanroom certification by an outside vendor; lastly on 9/25/14.

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 (b) (4).

d). The (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.

OBSERVATION 5
Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

a). Your firm uses a non-sterile disinfectant agent, (b) (4) to disinfect the ISO 5 surfaces.

b). Sporicidal agents are not used to disinfect the ISO 5 surfaces.

c). No disinfectant effectiveness studies have been performed to determine if disinfection agents are effective in aseptic processing areas.

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OBSERVATION 6
Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written, and followed.

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

b). (b) (4) are prepared for various products from non-sterile ingredients. These (b) (4) can be held for up to (b) (4) days as for Methylcobalamin injection. Your firm has not conducted any studies to support the stability/sterility over the time periods that (b) (4) are prepared until usage.

c). You have not validated the (b) (4) sterilization used for seven of your sterile drug products, such as Triamcinolone Acetonide 1mg/0.05 ml Injection, within your (b) (4)

OBSERVATION 7
Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.

a). Your firm does not test every sterile drug lot produced for sterility or endotoxins. Sterile drugs produced from non-sterile components are only tested for sterility (b) (4) and endotoxins (b) (4), on a (b) (4) basis.

b). Sterility testing is conducted by a contract laboratory employing testing methods that have not been validated or shown to be equivalent to USP <71>. "(b) (4)" is used in testing sterility of Avastin syringes.

OBSERVATION 8
The separate or defined areas necessary to prevent contamination or mix-ups are deficient.

There are no separate facilities, for processing operations, to prevent 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 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 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.

a). Your firm has not tested for sterility or potency over the assigned Beyond Use Date (BUD) for any sterile injectables or sterile ophthalmics. For example, your firm has not conducted any testing to support the BUDs such as 90 days refrigerated for Epinephrine 1:1000 injection or 180 days room temperature for Glycerin/Lidocaine 50/0.3% injection. You have no data to assure that the sterility and potency will be maintained over the time period of the BUD.

b). There is no antimicrobial effectiveness testing data for any sterile drug products containing preservatives, such as Glycerin/Lidocaine Injection or Papaverine/Phentolamine Mesylate/Prostaglandin Injection in various strengths.

OBSERVATION 10
Containers and closures are not reviewed for conformance with all appropriate written procedures.

a). Your firm does not receive or review certificates of analysis showing sterility for the sterile containers, such as vials used for sterile drug products.

b). Purchased sterile equipment, such as transfer tubing, syringes, etc. 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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