DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA Florida District 555 Winderley Place, Suite 200 Maitland FL 32751 (407) 475-4700 Industry Information: www.fda.gov/oc/industry	8/29-9/2/16 & 9/13/16
	FEI NUMBER FEI: 3006228598

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Benjamin H. David, President & CEO

FIRM NAME	STREET ADDRESS
Wells Pharmacy Network, LLC	1210 SW 33rd Ave.
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Ocala, FL 34474	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

Actionable microbial contamination was present in the ISO 5 area or in adjacent areas during aseptic production.

Specifically, from 2/22/16 to 7/7/16 your firm detected high levels of fungal growth during routine Environmental Monitoring (EM) of active viable air within the IV Clean Room which consists of the (b) (4) . This is evident by the following examples:

February: 7 cfus of Penicillium spp. within the (b) (4)
March: 10 cfus of Cladosporium spp. within the (b) (4)
May: 1 cfu of unidentified basidiomycete within the (b) (4), 1 cfu of penicillium spp. within the (b) (4), and 1 cfu of unidentified coelomycete within the (b) (4),
June: 3 cfus of Cladosporium spp. within the (b) (4), 1 cfu of bacillus spp. (b) (4) and 1 cfu of Cladosporium spp. within the (b) (4)
July: 2 cfus of penicillium spp., 1 cfu of Cladosporium spp. and 1 cfu of aspergillus sydowii, 3 cfus of non-sporulating hyaline fungus, 2 cfus of Cladosporium spp., 1 cfu of penicillium spp., 1 cfu of penicillium spp. and 1 cfu of Cladosporium spp. within the (b) (4).

During this time, your firm continued to produce sterile drug products within the IV Clean Room without adequately evaluating the impact of fungal growth detected during the active air sampling. Your firm initiated an investigation (signed on 7/29/16) for EM conducted in the IV Clean Room. Your firm's investigation determined the root cause of the fungal growth to be a ceiling tile showing fungal growth in close proximity to a fire sprinkler. However, you did not cease sterile drug production in the IV Clean Room until 07/15/16.

Concurrent to this finding, the following three (3) batches failed sterility testing: HCG 5,000 iu lyophilized injectable lot # 06202016@137, Titan Ultra lyophilized injectable lot # 06302016@95 and Quad 2 Injectable lot # 07062016@46. Your firm's corrective action was to discard all sterile drug products produced from 6/20-7/12/16,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Jessica L. Pressley	Jessica L. Pressley, Drug Investigator Meredith M. Cobb, Consumer Safety Officer	09/13/2016

but your quality unit failed to evaluate all sterile drug products currently on the market within expiration (i.e. HCG with a 6 month expiration) that were produced since February 2016 in the IV Clean Room.

OBSERVATION 2
Your firm did not conduct smoke studies of the aseptic processing area under dynamic conditions.

Specifically, the aseptic processing environment in your (b) (4) Clean Room is under negative pressure and the smoke studies performed on the (b) (4) located in this area did not demonstrate that the non-hazardous sterile drug products produced are protected from microbial contamination. Your firm has been producing non-hazardous sterile drug products in the (b) (4) Clean Room since 7/19/16.

OBSERVATION 3
Your firm continued producing sterile drug products while construction was ongoing within your facility without establishing adequate controls to prevent contamination of the production environment.

Specifically, during the construction of the (b) (4) Clean Room which began on (b) (4), your firm produced sterile drugs in the IV Clean Room and the (b) (4) Clean Room and did not have adequate controls in place to protect the production environment within these areas. Moreover, when the construction of the (b) (4) began on (b) (4) your firm continued to produce sterile drug products in the (b) (4) Clean Room without adequate controls in place to protect the production environment in this area. In addition, you did not increase your environmental monitoring frequency to verify that the environment remained suitable for aseptic production during construction.

OBSERVATION 4
Your firm produced sterile drug products within the (b) (4) Clean Room during pressure differential failures on 5/25/16, 5/26/16, 5/27/16, 5/31/16, 6/8/16 and 6/9/16. Your firm placed the following note next to the failed readings, "task needs to reflect positive pressure not negative," but the log where all these readings are recorded states (b) (4) Pressure Differential Testing (negative pressure).

In addition, your pressure differential log does not identify which area the pressure readings are taken from (b) (4) and will not provide you with meaningful data about the quality of

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your aseptic processing environment.

OBSERVATION 5
Hazardous and non-hazardous drugs were produced in the same area without providing adequate containment, segregation, and/or cleaning of work surfaces, utensils, and/or personnel to prevent cross-contamination.

Specifically, your firm produces chemotherapy drugs, non-hazardous drugs and hazardous drug products in (b) (4) Clean Room on the same day without evidence to show adequate controls and cleaning were followed between batches to prevent cross contamination. This practice is evident by the following example:

On 7/7/16, your firm produced:
Progesterone in Sesame Oil 150mg/mL inj. (Qty.: (b) (4) lot # 07072016@7 (hazardous drug)
Trimix 30mg/4mg/40mcg inj. (Qty.: (b) (4) lot # 07072016@111 (non-hazardous drug)
Mitomycin, lyophilized 40 mg inj. (Qty.: (b) (4) lot # 07072016@94 (chemotherapy drug)
Alprostadil 10mcg/mL inj. (Qty.: (b) (4) lot # 07072016@112 (non-hazardous drug)

OBSERVATION 6
On 07/12/16, dead insects and fungal growth were found in the ISO 7 annex room during cleaning. This area had been previously cleaned on 07/11/16. The corrections taken by your firm to address this finding did not include an evaluation of your pest control and disinfection programs.

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