DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6000 Metro Drive (Suite 101) Baltimore, MD 21215 (410) 779-5455 Industry Information: www.fda.gov/oc/industry	5/8-12/17; 5/24/17
	FEI NUMBER 3009145318

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Joseph F. McClendon Jr., Owner/CEO/Pharmacist-In-Charge

FIRM NAME	STREET ADDRESS
Pharmacy Associates, Inc.	1308 4th Ave.
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Huntington, WV 25701	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: Non-microbial contamination was observed in your production area.

a.) On 5/9/17, we observed the operator hang (b) (4) bottle onto the side of the trash can while in the ISO 7 clean room during drug product production (aseptic processing) was being performed. The (b) (4) bottle was in direct contact with a non-sterile trash bag in the trash can. The operator continued to use the (b) (4) bottle in the ISO 5 hood while processing Total Parental Nutrition (TPN) (order #050917B) and Hydromorphone Pain Cassette 10 mg/1 ml (Control #1047).

Observation #2: Personnel donned gowning apparel improperly, in a way that may have caused the gowning apparel to become contaminated.

a.) On 5/10/17, the operator touched her ungloved fingers to the finger-tip portions of the sterile gloves while in the ISO 7 gowning room while donning her gloves. We then observed her working in the ISO 5 hood with these gloves while preparing TPN bags (order #050917A).

Observation #3: Personnel failed to disinfect or change gloves frequently enough to prevent contamination.

a.) Specifically, on 5/9/17, while observing the pool for the TPN (order # 050917B) the operator touched his glasses and exposed face with his sterile gloves. He sprayed (b) (4) onto the gloves and then immediately went back to working in the ISO 5 hood without allowing drying of the gloves.

b.) On 5/9/17, we observed the operator in the ISO 7 clean room with his gloved hands below his waist. He then proceeded to work in the ISO 5 hood without first disinfecting his gloves. On 5/10/17, we observed a different operator in the ISO 7 clean room with her gloved hands below her waist. She then proceeded to work in the ISO 5 hood without first disinfecting her gloves.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Nicholas L. Paulin Kenneth E. Felkley	Nicholas L. Paulin - Investigator Kenneth E. Felkley - Investigator	5/24/17

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CITY, STATE AND ZIP CODE Huntington, WV 25701	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile Drug Products

Observation #4: Personnel were observed to be moving rapidly in the vicinity of open sterile units or instruments which disrupted the airflow and increased the risk of bringing lesser quality air into the ISO 5 area.

a.) Specifically, on 5/9/17, the operator working in the ISO 5 hood was observed to exhibit quick and erratic, rather than slow and deliberate movements when performing critical operations such as rapidly moving gloved hands after being sprayed with (b) (4) to rapidly dry them.

b.) On 5/9/17, we observed the operator leaning into the ISO 5 hood thus obstructing unidirectional airflow in the ISO 5 laminar flow hood. On 5/10/17, during drug production, the operator placed her entire upper torso, arms, and head inside the ISO 5 hood while preparing the TPN bags (order #050917A). On 5/10/17, the operator was observed wearing jewelry (ring and necklace) while working in the ISO 5 hood. We observed the operators street clothing to be exposed while working in the ISO 5 hood. The operators were also observed working in the ISO 5 hood without wearing goggles leaving their eyes, eyelashes and eyebrows exposed to the environment. We also observed the operators working in the ISO 5 hood to have exposed skin areas around the eyes, forehead, ears, beard line, and neck. Furthermore, your firm's gowning components worn by operators working in the ISO 5 hood are not sterile (disposable gowns, hairnets, face-masks, shoe cover booties).

Observation #5: Disinfecting agents and cleaning pads or wipes used in the ISO 5 area [aseptic processing areas] are not sterile.

a.) Specifically, the (b) (4) wipes used to clean the clean room and ISO 5 hood are not sterile and non-shedding.

Observation #6: Sporicidal agents are not used in your facility's clean room and/or ISO 5 area.

a.) Specifically, your firm does not use a sporicidal agent for cleaning the ISO 5 hood, ISO 7 clean room and ISO 7 gowning room.

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Observation #7: Environmental monitoring was not performed in your aseptic processing areas.

a.) Personnel Monitoring is not being performed by your firm. Per your firm management, your firm does not have the (b) (4) to perform this testing. Furthermore, the firm does not monitor compounding personnel (i.e. gloved fingers).

Observation #8: 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.

a.) Media fills do not simulate your production process under normal operating conditions. For example, your firm does not include the (b) (4) automated system (used for producing TPNs) during media fills. Your firm also does not include the (b) (4) used for processing the non-sterile powder into a sterile liquid (used for producing the Pain Cassettes) during media fills. Your media fills are not performed under worst case aseptic processing conditions, for example the maximum number of operators in the ISO 7 room and interventions.

Observation #9: Post filtration integrity testing to the sterilizing filter was not performed.

a.) Specifically, no (b) (4) (filter integrity test) has been documented since September 2016. Furthermore, your firm has continued to produce Hydromorphone cassettes which requires a (b) (4) on the (b) (4) filter (non-sterile powder to sterile liquid).

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