DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
New Orleans District Office 404 BNA Drive, Bldg 200, Suite 500 Nashville, TN 37212 615-366-7801 Industry Information: www.fda.gov/oc/industry	09/12/2016-10/20/2016
	FEI NUMBER 3011761321

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Angie C. Andrews, Director of Operations

FIRM NAME	STREET ADDRESS
Wells Pharmacy Network, LLC	450 US Highway 51 BYP N
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Dyersburg, TN 38024	Producer of Sterile 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
Buildings used in the processing of a drug products are not maintained in a good state of repair.

Specifically,

1. Multiple gaps were observed around the light fixture in the ISO 5 room.
2. Water damage was observed in the ceiling of the unclassified area adjacent to the clean room area. In addition, the unclassified area shares a wall with the clean room and multiple gaps were observed in the ceiling tiles directly above this shared wall.

OBSERVATION 2
Non-depyrogenated containers were used in drug production. Your drug product containers were not processed to remove pyrogenic properties to assure that they are suitable for their intended use.

Specifically, the blister packaging used by the firm is not purchased as pyrogen-free and your firm does not depyrogenate this container closure prior to use.

OBSERVATION 3
The flow of drug products through the building is not designed to prevent contamination.

Specifically, there is a potential risk for contamination during the compounding of bulk powdered drugs.

1. Non-dedicated equipment such as the (b) (4) (b) (4), tablet press, and (b) (4) used in the production of your firm's implantable hormonal pellets is not adequately cleaned between each batch to prevent cross-contamination.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Abby L. Mozeke-Baker	June P. Page, Investigator Abby L. Mozeke-Baker, Investigator	10/20/2016

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2. The (b) (4) balance, labeled as (b) (4), located in (b) (4) (b) (4) used in the mixing of your firm's bulk powdered drugs for implantable hormone pellet compounding, was observed to have a crack in the glass that ran diagonally from the top to the bottom of the glass, which has a potential for cross-contamination and foreign objects in your bulk powdered drugs.

3. The (b) (4) used in your firm's (b) (4) (b) (4) and (b) (4) (b) (4) does not meet the manufactures specifications, which has a potential for cross-contamination when mixing your bulk powdered drugs.

OBSERVATION 4
The use of the sporicidal agent in the cleanrooms is inadequate.

Specifically,
Written procedures are not followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product. Your firm fails to use a sporicidal agent in the ISO 5 area on a frequent basis. (b) (4) is not an effective sporicidal agent when a (b) (4) is used.

OBSERVATION 5
Procedures designed to prevent microbiological contamination of drug products are not established, written, and followed.

Specifically, your firm's written procedures, SOP 3.110 - Environmental Monitoring Dyersburg, TN, states in section 8.5, (b) (4)
(b) (4)
(b) (4)
(b) (4) The media fills associated with (b) (4) qualification for sterile product compounding personnel are inadequate. Some deficiencies include but are not limited to:

1. The firm failed to conduct appropriate follow-up investigations and provide documentation identifying the organisms or species for each colony growth for the following (b) (4) plate (Action limit > (b) CFU): (b) (4)

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Plate [D] taken on the (b) (4), was documented to have a CFU of TNTC (too numerous to count). Your firm's management stated no investigation or trending was conducted.

2. On 09/16/2016, your pharmacist failed to accurately read and/or document the environmental monitoring results for samples taken on the following dates and areas:
09/09/2016: (b) (4)
09/07/2016: (b) (4)

OBSERVATION 6
Your firm failed to conduct smoke studies under dynamic conditions.

Specifically, the most recent qualification of the (b) (4) areas completed on (b) (4) by a outside contractor is not accurate in that it states it was performed under dynamic conditions. Your firm stated drug processing was not being conducted during the time of the qualification performance. In addition, the smoke study provided by your firm was not conducted under dynamic conditions.

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