DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA 404 BNA Drive, Building 200, Suite 500 Nashville, TN 37217-2597 (615) 366-7801 FAX: (615) 366-7802 Industry Information: www.fda.gov/oc/industry	6/25/18-7/2/18
	FEI NUMBER 3003780900

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Christopher S. Gilbert, PharmD., Owner/Phamacist in Charge

FIRM NAME	STREET ADDRESS
People's Custom Rx and Clinical Care, LLC	785 Brookhaven Circle East
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Memphis, TN 38117-4501	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

On 6/25/18, during the aseptic processing of Dexamethasone NAPO4 24mg/ml Injectable, lot #06252018@1, an operator was observed placing her gloved hands outside the ISO 5 area and not re-sanitizing prior to placing her gloved hands under the ISO 5 hood. The same operator was observed wearing a face mask and hairnet which left the skin of her forehead partially exposed. The operator was observed to introduce the exposed skin of her forehead inside the ISO 5 hood.

OBSERVATION #2

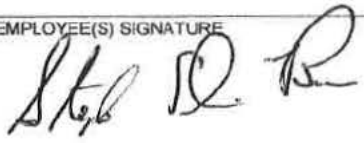
You have no assurance that the endotoxin level of your intrathecal drug products are safe, since you do not have any endotoxin data and your firm doesn't perform endotoxin testing for the finished product. These preparations are made using non-sterile starting material. Furthermore, there is no endotoxin testing data for your API.

In addition, the stock solution for Baclofen (Baclofen USP Powder and Sodium Chloride) is (b) (4) (b) (4) and never tested for sterility or endotoxin after repeated use. The stock solution of Papaverine/Phentolamine is also (b) (4) which are initially tested for sterility only and then not re-tested after repeated use.

Your firm produced (b) (4) lots of intrathecal drug products between 3/25/18-6/26/18 which were not tested for endotoxin prior to being dispensed to patients. For example, Baclofen Intrathecal 1000mcg/ml Injectable, lot #05072018@71 was produced on 5/7/18 under Rx (b) (6) for patient (b) (6)

OBSERVATION #3

On 6/27/18, I observed that the magnahelic gauge monitoring differential pressure between the ISO 8 anteroom

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Stephen D. Brown, Investigator	07/02/2018

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and unclassified area was at "0". In addition, the gauge used to monitor the pressure between the ISO 7 cleanroom and ISO 8 anteroom was not working. During this time, an operator was preparing the following two lots of intrathecal drug product under the ISO 5 hood which were dispensed to patients:

A. Morphine/Baclofen Intrathecal 35mg-100mcg/ml Injectable, lot #06272018@14 (Rx (b) (6) for patient (b) (6) (b) (6)

B. Morphine/Bupivacaine Intrathecal 40mg-20mg/ml Injectable, lot #06272018@3 (Rx (b) (6) for patient (b) (6) (b) (6)

OBSERVATION #4

SOP # 3.300.303 entitled, "Disinfectant Solution and (b) (4) " (Effective date: 9/1/17) does not identify the contact time used for the (b) (4) and (b) (4) disinfectants. In addition, there is no documentation to substantiate the (b) (4) minute contact time currently in use.

OBSERVATION #5

Your firm uses a (b) (4) for the depyrogenation of glassware used in the production of sterile, injectable drug products. The (b) (4) used for depyrogenation for (b) (4) minutes has never been verified.

In addition, the (b) (4) is located in an area which is not in close proximity to the ISO 5 hood. In this case, the (b) (4) is located in the ISO 8 anteroom which requires that depyrogenated glassware be transferred through a door leading into the ISO 7 cleanroom for subsequent storage.

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	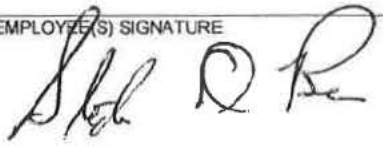	Stephen D. Brown, Investigator	07/02/2018