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	7/16-24/2019
	FEI NUMBER 3003780900

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: 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

Personnel did not disinfect gloves to prevent contamination.

Specifically, on 7/16/2019, during the aseptic processing of Tri-Mix, lot #07162019@34, an operator was observed placing her gloved hands outside the ISO 5 area and not consistently re-sanitizing prior to placing her gloved hands under the ISO 5 hood.

THIS IS A REPEAT OBSERVATION

OBSERVATION #2

The cleaning wipes used in the ISO 5 classified aseptic processing areas were not sterile.

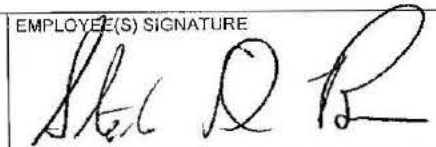
Specifically, on 7/16/2019, an operator was observed using a non-sterile wipe to apply sterile, (b) (4) to the exterior of the HEPA filter inside the ISO 5 hood in the cleanroom.

OBSERVATION #3

Review of the certification report for the cleanrooms dated 3/28/19 revealed that smoke studies in the ISO 5 hood were not performed under dynamic conditions.

OBSERVATION #4

Your firm produced highly potent drugs without providing adequate cleaning of work surfaces to prevent cross-contamination.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Stephen D. Brown, Investigator	07/24/2019

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Specifically,

All hazardous, non-sterile drug products including Progesterone and Estriol are produced under a common (b) (4) hood. Your firm uses (b) (4) to clean the work surface in the hood between preparations. Your firm has no evidence to show that the use of (b) (4) will effectively remove residues which might be present on the hood surface after production.

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		Stephen D. Brown, Investigator	07/24/2019