DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Pharma Division II 404 BNA Drive, Building 200, Suite 500 Nashville, TN 37217 (615) 366-7801 | Email: orapharm2_responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	07/13/2021-08/05/2021
	FEI NUMBER 3003780900

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Christopher S. Gilbert, Owner/Pharmacist in Charge	
FIRM NAME People's Custom Rx and Clinical Care, LLC	STREET ADDRESS 785 East Brookhaven Circle
CITY, STATE, ZIP CODE, COUNTRY Memphis, TN 38117-4501	TYPE ESTABLISHMENT INSPECTED 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

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.

Specifically, the firm compounds sterile drug products which involves several aseptic manipulation steps. The firm's sterile drug product batch size can range up to (b) (4) for the sterile drug product Cyclosporine 1%. The current media fills are performed only with (b) (4).

OBSERVATION 2

Pressure differentials between areas with different air classifications were not monitored prior or during sterile drug production.

Specifically, there is no verification of the pressure differentials before or during sterile drug production. Pressure differentials are measured with (b) (4) which are not visible from within the cleanroom. The firm has no alarm system that would signal if room pressures were out of specification. Pressure differential values are only recorded (b) (4).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Marvin D. Jones	Marvin D. Jones - Investigator Clinton J. Lott - Investigator	08/05/2021

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OBSERVATION 3

Non-microbial contamination was observed in your non-sterile drug production area.

Specifically, on 07/13/2021, we observed what appeared to be drug product residue on two ceiling light fixtures in the firm's non-sterile compounding area. These light fixtures were directly above the firm's non-sterile benchtop drug product staging areas. The firm was continuously processing non-sterile drug products in this area during this inspection. On 07/16/2021, we observed that this residue was still on the light fixtures.

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	Marvin D. Jones	Marvin D. Jones - Investigator Clinton J. Lott - Investigator	08/05/2021

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."