DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615) 366-7801 Fax:(615) 366-7802 Industry Information: www.fda.gov/oc/industry	07/20/2015 - 07/29/2015 FEI NUMBER 3003780900

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: William C. Johns, Owner

FIRM NAME	STREET ADDRESS
People's Custom Rx and Clinical Care, LLC	785 Brookhaven Circle East
CITY, STATE, ZIP CODE, COUNTRY	TYPE 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 WE OBSERVED:

OBSERVATION 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and followed.

Specifically,

1) Per your firm's SOP No. 3.300.302 "Garbing and Gloving Procedure for Sterile Compounding", when leaving the clean room technicians should replace hair covers, face masks, and gloves before re-entering the clean room. On 07/21/2015 we observed a technician leave the clean room to retrieve supplies from the ante room. This technician did not change their hair net, mask, or gloves before re-entering the clean room to perform aseptic processing.

2) Your firm does not use sterile alcohol to sanitize the technician's gloves or hood surface during aseptic processing. Your firm uses non-sterile 99% Isopropyl Alcohol.

3) The gowning components your firm uses during aseptic processing are not sterile. The hair covers, face masks, and shoe covers are stored in open containers in the ante room. Per your firm's SOP No. 3.300.302 "Garbing and Gloving Procedure for Sterile Compounding", non-sterile gowning can be reused and is to be left hanging in the ante room when not in use. Your firm allows gowns to be re-used throughout a technician's shift.

OBSERVATION 2

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

1) Your firm performs weekly air and surface monitoring in the prep room, ante room, and ISO 5 hoods. This is inadequate as environmental conditions are not monitored every day production occurs.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Zada L. Giles, Investigator Zada L Giles Mary A. Millner, Investigator Mary Millner	07/29/2015

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2) Your procedure for weekly air and surface monitoring is inadequate as you only take 1 surface sample and 1 air sample from each room. Your clean room contains 2 hoods; therefore, each hood is not being monitored when you do perform air and surface sampling.

3) Your compounding technicians' fingertips are monitored every 6 months. Per your firm's SOP 3.300.604 "Environmental Monitoring of the Aseptic Compounding Area: Gloved Fingertip Testing", your aseptic technicians' fingertips should be monitored biweekly. Neither is adequate as technicians are not monitored each time they perform aseptic processes.

OBSERVATION 3

The flow of components, drug product containers, closures, in-process materials, and drug products though the building is not designed to prevent contamination.

Specifically,

1) Per your firm's SOP 3.300.308 "General Aseptic Compounding Procedures when Working within the Secondary Engineering Controls and Primary Engineering Controls", all supplies should be decontaminated in the ante room and transferred into a clean sanitized cart for introduction into the clean room. On 07/21/2015 we observed a technician carry 3 plastic totes containing components (sterile syringes, sterile needles, compounded stock solution) to be used during aseptic processing into the ante room. After gowning, the technician stacked these totes and entered the clean room without decontaminating the totes or components. The technician was processing Myers vitamin injections with Vitamin C.

2) Per your firm's SOP 3.300.308 "General Aseptic Compounding Procedures when Working within the Secondary Engineering Controls and Primary Engineering Controls", decontamination should be performed as supplies are introduced into the aseptic work area. On 07/20/2015 and 07/21/2015 we observed a technician place components under the ISO 5 hood to be used for aseptic processing without any decontamination step. On 07/20/15 the technician was processing HCG/B12 injections and Mitomycin bladder irrigation. On 07/21/15, the technician was processing Myers vitamin injections with Vitamin C.

OBSERVATION 4

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically,

1) Your Cleanroom Certification Report dated 03/27/2015 indicates smoke studies were performed for the ISO 5 hoods; however, these studies were not video recorded or documented. Also these studies were not performed in dynamic conditions.

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2) Your firm does not continuously monitor pressure in the laminar flow hoods, clean room, or ante room. Air pressure is only checked once per day.

OBSERVATION 5

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.

Specifically,

1) Your firm produces stock solutions used to fill individual prescriptions. Your stock solution lot sizes supply the firm with enough product to fill approximately 3 weeks of prescriptions. Each stock solution container can be used for multiple fills. You have not conducted the appropriate tests to validate this process.

2) Your firm has not validated your sterilization process for autoclaving rubber stoppers and finished drug products (suspensions including prednisolone and stanozolol).

3) Your firm has not validated the process of depyrogenating/sterilizing glassware via a dry heat oven. The glassware is used in the mixing and holding of drug products to be aseptically filled or terminally sterilized.

4)Your firm has not validated the process of terminal sterilization for oil based drug products using a dry heat oven.

OBSERVATION 6

Routine calibration of equipment is not performed according to a written program designed to assure proper performance.

Specifically,

1) Your firm uses a Boekel model incubator for sterility samples. The directions for use for the TSB syringes your firm uses state to incubate at 22.5°C +/- 2.5°C. During a review of your firm's temperature logs for this incubator for the last 4 months (April-July 2015), it was found that temperature was out of range for this entire time period. The temperature ranged from 25.2°C to 30.8°C.

2) Your firm uses a Lab-Line model incubator for environmental monitoring. The directions for use for the TSA plates your firm uses state to incubate at 35°C +/- 2°C. During a review of your firm's temperature logs for this incubator for the last 4 months (April-July 2015), it was found that temperature was out of range for 37 days (approximately 30% of the time) during this time period. The temperature range was 39°C to 44°C for the out of range readings.

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OBSERVATION 7

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room to produce aseptic conditions.

Specifically,

Your firm uses sterile isopropyl alcohol, Sporicidin, and Accel TB disinfectant for daily cleaning of the ISO 5 hoods and clean room. Per your firm's SOP 3.300.303 "Disinfectant Selection and Use Rotation", these 3 cleaners are rotated on a quarterly cycle with sterile isopropyl alcohol being used twice. This only allows for a sporacide to be used for 1 quarter of the year for cleaning your ISO 5 hoods and clean room.

OBSERVATION 8

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release.

Specifically,

Your firm does not conduct identity and potency testing of each lot of drug produced.

OBSERVATION 9

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically,

Your firm has not performed stability studies for your sterile products that include ID, potency, degradant, impurity, and other stability indicating parameters. Beyond use dates of greater than 48 hours are given to sterile injectable drugs that do not contain preservatives.

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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 judgement, 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."