People's Custom Rx
785 Brookhaven Circle East
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901-682-2273
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peoplescustomrx.com

People's Custom Rx

"Custom Compounding for People and Pets"

To Whom It May Concern:

On behalf of People's Custom Rx, I authorize the United States Food and Drug Administration (FDA) to publicly disclose the information described below on FDA's web site. I understand that the information that is disclosed may contain confidential commercial or financial information or trade secrets within the meaning of 18 U.S.C. § 1905, 21 U.S.C. § 331 0), and 5 U.S.C. § 552(b)(4) that is exempt from public disclosure under those statutory provisions and/or relevant FDA regulations. I agree to hold FDA harmless for any injury caused by FDA's sharing the information with the public.

Information to be disclosed: People's Custom Rx's letter dated 08/23/2021 excluding attachments/exhibits, which responds to FDA's Form 483 dated 08/05/2021.

Authorization is given to FDA to disclose the above-mentioned information which may include confidential commercial or financial or trade secret information. As indicated by my signature, I am authorized to provide this consent on behalf of People's Custom Rx and my full name, title, address, telephone number, and facsimile number is set out below for verification.

Chris Gilbert PharmD.
Owner
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August 23, 2021

Department of Health and Human Services
Food and Drug Administration
Pharma Division II
404 BNA Drive, Building 200, Suite 500
Nashville, TN 37217

Via Email orapharm2_responses@fda.hhs.gov

Attn: Ruth Dixon, District Director
Marvin D. Jones, Investigator
Clinton J. Lott, Investigator

Re: Response to FDA Form 483

Dear Director Dixon and Investigators Jones and Lott:

The Food and Drug Administration ("FDA") conducted an inspection of People's Custom Rx and Clinical Care Center, LLC ("PCCCR"), a pharmacy located at 785 Brookhaven Circle East, Memphis, Tennessee, during the period of July 13- August 5, 2021. Upon the conclusion of its inspection, the FDA provided PCCCR with a FDA Form 483, a copy of which is enclosed. This letter is PCCCR's response to the FDA Form 483 observations. We respectfully request that this response, excluding the attachments, be posted on the FDA's website with the Form 483 and be included every time the FDA provides a copy of PCCCR's FDA Form 483 to anyone outside the FDA.

PCCCR engages in the practice of pharmacy by compounding and dispensing patient specific prescriptions for patients located in and around Tennessee. As a licensed pharmacy, PCCCR is required to comply with applicable state laws and regulations governing pharmacy compounding, and with the applicable United States Pharmacopoeia ("USP") chapters 795, 797, and 800 regarding pharmacy compounding. 21 U.S.C. § 353a specifically exempts a compounding pharmacy from the FDA's Current Good Manufacturing Practices ("cGMP") requirements imposed on drug manufacturers.

Our pharmacy is dedicated to doing things right, and more importantly, one of our upmost goals is to ensure that our drugs are prepared in a safe and effective manner. The following are our responses to each of the observations made in the FDA 483.

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 40/10ml plastic eye drop bottles for the drug product Cyclosporine 1%. The current media fills are performed only with 9/10ml glass vials.

Response: PCCCR has ordered the appropriate media and containers to simulate the most challenging conditions that an aseptic operator would encounter in our operations. PCCCR aseptic operators will be required to perform media fills with this more challenging technique no later than October 31, 2021.

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 wall-mounted manometers 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 once per day.

Response: Per USP Chapter 797, "A pressure gauge or velocity meter shall be installed to monitor the pressure differential or airflow between the buffer area and the ante-area and between the ante-area and the general environment outside the compounding area. The results shall be reviewed and documented on a log at least every work shift (minimum frequency shall be at least daily) or by a continuous recording device. The pressure between the ISO Class 7 (see Table 1) and the general pharmacy area shall not be less than 5 Pa (0.02 inch water column)." In addition to the once a day logging of the pressure for each ISO-7 room in the PCCCR sterile suite, effective August 6, 2021, aseptic operators are required to log the room pressure when they enter the ISO-7 room to compound a preparation and when they exit the ISO-7 room. This information is recorded on the formula worksheet for the preparations that were compounded during the time that the aseptic operator was in the ISO-7 room. Attached is an example of a formula worksheet that has the logged ISO-7 room pressures highlighted.

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 fixture.

Response: PCCCR staff went through the pharmacy compounding areas on 07/19/2021 and cleaned light fixtures and other areas subject to drug residue or other potential contaminants, in and around drug processing areas. PCCCR realizes that insanitary conditions have the potential to contaminate compounded drug preparations.

PCCCR operators will be retrained by August 31th, 2021, to clean more effectively, especially when there is a spill or other incident that could result in potential contamination of a drug product in the compounding area.

Conclusion

With this written response, PCCCR has sought to address all of the FDA's observations and concerns. If the FDA desires additional information from, or communication with, PCCCR, please contact me at 901-682-2273.

Sincerely,

Chris Gilbert
Owner and Pharmacist in Charge
People's Custom Rx and Clinical Care Center, LLC