FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

DELIVERY VIA ELECTRONIC MAIL

May 16, 2022

Kamlesh Gandhi, PharmD, RPh
Executive Director
Arizona State Board of Pharmacy
1616 W. Adams St., STE 120
Phoenix, AZ 85007
kgandhi@azpharmacy.gov

Dear Dr. Gandhi:

The purpose of this letter is to refer to the Arizona State Board of Pharmacy for appropriate follow up, the U.S. Food and Drug Administration's concerns about poor sterile practices observed during an FDA inspection at a pharmacy licensed by the Arizona State BOP, Potter's House Apothecary Inc., located at 21585 N. 77th Ave., STE 1500, Peoria, Arizona 85382 (Pharmacy Permit # Y008443, expiration: 10/31/23).

FDA inspected the firm from September 2, 2020, to September 16, 2020. An FDA investigator was accompanied by an Arizona state investigator for six days. A copy of a Form FDA 483 that documents our investigator's observations from the inspection can be found at https://www.fda.gov/media/144846/download, with any nonpublic information redacted. In addition, on September 15, 2021, an Untitled Letter was issued to the firm as a result of this inspection. A copy of this Untitled Letter can be found at https://www.fda.gov/media/158298/download, with any nonpublic information redacted. Because we consider this inspection to be "closed" under 21 CFR 20.64(d)(3), you may request a copy of the Establishment Inspection Report (EIR) that FDA will provide to the firm, which contains additional information about our inspection. If you are a commissioned official or if your state agency has entered into a 21 CFR 20.88 information sharing agreement, you may be able to receive a copy of the Form FDA 483 or the EIR that includes certain nonpublic information. Alternatively, you may also choose to request a copy of the EIR directly from the firm.

During the inspection, the FDA investigator observed deviations from appropriate sterile practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Examples of deviations observed during our inspection include:

1. Visible cracks in acrylic panels of ISO 5 laminar airflow workstation.
2. Unknown residue staining on metal grate of ISO 5 lanimar airflow workstation.
3. Smoke studies for ISO 5 laminar airflow workstation were not preformed under dynamic conditions.
4. Media fills were not performed to simulate actual aseptic operations.

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Potter's House Apothecary Inc. committed to FDA in its responses to the Form FDA 483, dated October 2, 2020, and October 7, 2020, to correct the deviations in the Form FDA 483 and provided documentation in support of those corrective actions. Furthermore, the firm committed to further corrections in their October 18, 2021, response to the Untitled Letter, which also included documentation in support of these corrective actions. In addition, the deviations identified appear to be readily correctable.

After review of the record, FDA does not intend to take further action at this time with regard to the findings of this inspection. Therefore, FDA is referring this matter to the Arizona State BOP for follow up to ensure appropriate corrective action is taken. Please notify us if you become aware of any adverse events or product quality concerns associated with drugs made at this facility, or if you observe any practices at this facility that concern you or that could be violations of federal law.

We look forward to continuing to work with you on the oversight of compounding pharmacies. If you have additional questions, please contact William Millar, compliance officer, at 503-671-1130 Ext. 30, or by email at william.millar@fda.hhs.gov.

Sincerely,

CDR Steven E. Porter, Jr.
Division of Pharmaceutical Quality Operations IV

SP:wm

FEI 3011701621

Cc: Kevin M. Borg, owner, president, and chief executive officer

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