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

VIA SIGNATURE CONFIRMED DELIVERY

April 9, 2020

Dr. Kamlesh Gandhi, PharmD
Executive Director
Arizona State Board of Pharmacy
1616 W. Adams Street, Ste 120
Phoenix, AZ 85007

Dear Dr. Kamlesh Gandhi:

The purpose of this letter is to refer to the Arizona State Board of Pharmacy (BOP), for appropriate follow up, the U.S. Food and Drug Administration's (FDA) concerns about poor sterile practices observed during an FDA inspection at a pharmacy licensed by the Arizona BOP, Banner Pharmacy Services, LLC located at 7300 W. Detroit Street, Chandler, AZ 85226-2410, (Pharmacy licenses: #Y005621; expires 10/31/21; #Y005958 expires 10/31/2020).

FDA inspected the firm from October 2, 2019 to October 8, 2019. Arizona BOP was informed of the inspection but did not accompany the FDA investigator during the inspection. 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/133246/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 reviewed a small sample of records for products compounded by Banner Pharmacy Services and determined, based on this sample, that this firm appears to obtain valid prescriptions for individually-identified patients for the drug products that it compounds and distributes.

Additionally, during the inspection, the FDA investigators observed deviations from appropriate sterile practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. The deviation observed during our inspection includes:

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1. Disinfecting agents used in the ISO 5 classified aseptic processing areas were not sterile.

Banner Pharmacy Services committed to FDA in its response to the Form FDA 483, dated October 29, 2019, to correct the deviation in the Form FDA 483 and provided documentation in support of the corrective actions. In addition, the deviation identified appears 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. This firm apparently obtains prescriptions for identified individual patients before distributing its compounded drugs, as required by section 503A(a) of the Federal Food, Drug and Cosmetic Act, and FDA believes that the corrective actions can be appropriately overseen by the State. 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 Maria Kelly-Doggett, Compliance Officer at 425-302-0427, or by email at maria.kelly-doggett@fda.hhs.gov.

Sincerely,

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

SP: mpk

Cc:
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Mr. Kevin T. Roche,
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