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

February 6, 2020

Kamlesh Gandhi
Executive Director
Arizona State Board of Pharmacy
PO Box 18520
Phoenix, AZ 85005-8520

Dear Mr. 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 non-sterile compounding practices observed during an FDA inspection at a pharmacy licensed by the Arizona BOP, Vitalab Pharmacy, Inc. dba Vasco Rx Specialty Pharmacy, located at 4045 E. Bell Road, Suite 163, Phoenix, AZ 85032 (Independent Pharmacy License #Y007977).

FDA inspected the firm from July 22, 2019, to August 2, 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/131274/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 Vitalab Pharmacy, Inc. dba Vasco Rx Specialty Pharmacy 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 investigator observed deviations from appropriate non-sterile compounding practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Specifically, our investigator noted that production personnel used commercial brand diluent to produce all non-sterile oral solutions and suspensions which contained diluent as an ingredient.

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It was unclear if this diluent met the minimum United States Pharmacopoeia (USP) quality standards for use in the production of non-sterile drug products.

Vitalab Pharmacy provided immediate corrections during our inspection by removing all of the specific diluent from inventory and destroying all finished drug products produced with the diluent. They had also purchased USP quality diluent for any further compounding operations. In their August 22, 2019 written response to the Form FDA 483, they reiterated the corrective actions taken and provided a copy of the Certificate of Analysis and invoice corresponding to their current USP diluent component. This deviation appears to have been corrected.

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 CAPT Matthew Dionne, Compliance Officer, at 303-236-3064, or by email at Matthew.Dionne@fda.hhs.gov.

Sincerely,

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

SP:mrd

Cc: Vladimir Lenchitsky, Founder and Chairman of the Board
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