DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Los Angeles District
Pacific Region
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Irvine, CA 92612-2506

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March 30, 2015

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

Dear Mr. Wand:

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, Zion's Rx Formulations Services, LLC, dba Rx Formulations Services, located at 5949 East University Dr, Mesa, AZ 85205 (pharmacy license Y003586).

FDA inspected the firm from November 18, 2014, to December 2, 2014. The Arizona State BOP was informed of the inspection, and FDA investigators were accompanied by Arizona State investigators for the first day of the inspection. A redacted copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM432633.pdf.

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by Rx Formulations 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 dispenses.

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. Specifically, the investigators observed that personnel were gowning in an unclassified area of the facility.

Rx Formulations Services committed to FDA in its response to the Form FDA 483, received December 3, 2014, to correct the above deviation listed in the Form FDA 483.[i] In addition, the deviations identified appear to be readily correctable.

After review of the record, at this time FDA does not intend to take further action with regard to the findings of this inspection. This firm apparently obtains prescriptions for identified

individual patients, consistent with traditional pharmacy practice, 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 David Whitman, Compliance Officer, at 619-941-3769, or by email at david.whitman@fda.hhs.gov.

Sincerely,

for

Alonza E. Cruse, Director
Los Angeles District

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[i] Because you are an FDA commissioned official, you can request an unredacted copy of the Form FDA 483 or the firm's December 3, 2014, response to the Form FDA 483.