DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

February 25, 2014

UPS OVERNIGHT MAIL

John A. Foust, Pharm. D., D. Ph., Executive Director
Oklahoma State Board of Pharmacy
2920 N. Lincoln Blvd, Suite A
Oklahoma City, Oklahoma 73105-3488

Dear Dr. Foust:

The purpose of this letter is to inform the Oklahoma State Board of Pharmacy (BOP) that the U.S. Food and Drug Administration (FDA) does not currently intend to take further action with regard to the poor sterile practices observed during an FDA inspection at a pharmacy licensed in Oklahoma, Lowlyn Pharmacies, Inc. d/b/a Red Cross Drug, located at 301 NE 10th Street, Blanchard, Oklahoma 73010. FDA believes that the BOP's actions, described below, have provided effective oversight of the firm and FDA does not need to take further action at this time.

The FDA inspection occurred from March 4, 2013 to March 8, 2013. During the inspection, FDA's investigators were accompanied by BOP inspectors. Attached is a redacted copy of an FDA Form 483 that documents our investigators' observations from the inspection.

During the inspection, the FDA investigator reviewed a small sample of records for products compounded by Lowlyn Pharmacies, Inc. 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. Examples of deviations observed during our inspection include:

1. The facility design did not provide proper separation and protection for the ISO 5 area in the clean room. There were no physical barriers between the clean room where the ISO 5 area is located and the adjacent support rooms. Some of the support rooms were unclassified and not controlled for cleanliness. Materials were transported and personnel moved between areas of lesser quality air into the clean room. This created a significant risk to injectable drugs produced in the ISO 5 area.
2. There was no program for the cleaning and disinfection of the facility. The firm used non-sterile agents to disinfect the ISO 5 area and did not use a sporicidal

agent to clean the facility. Furthermore, the firm did not have an adequate program to monitor the environment and personnel.

3. The firm's program to ensure that each process used was able to produce sterile product without contamination and to evaluate the competency of all personnel who engage in these operations was inadequate. For example, personnel did not perform media fills under conditions that closely simulated the firm's most challenging or stressful conditions encountered during routine aseptic operations.
4. The aseptic practices employed by the operator at the firm were inadequate and increased the risk of microbial contamination of the product. The investigator observed that an operator:
    a. Introduced non-sterile supplies and materials (e.g., non-sterile ingredient containers) into the aseptic processing area without any disinfection.
    b. Entered the clean room without proper gowning and placed ungloved hands into the ISO 5 area to don sterile gloves.
    c. Had bare wrists exposed while performing manual aseptic operations in the critical area.
5. The firm did not adequately verify the effectiveness of the sterilization methods to ensure that injectable products prepared from non-sterile ingredients were sterilized. Furthermore, the firm failed to perform [redacted] (b) (4) tests [redacted] (b) (4) to ensure the [redacted] (b) (4) was integral.
6. The firm failed to use adequate methods to perform sterility testing on finished drug products. Furthermore, the firm did not have data to support the assigned beyond use dates of 180 days on products that were multi-dose and did not contain preservatives.

On May 15, 2013, the BOP took the following prompt actions:

- Suspended the firm's pharmacy license for five years and immediately stayed the order and placed the firm on probation for 5 years;
- Suspended the parenteral permit of the firm indefinitely; prohibited the firm from compounding sterile drug products until the firm petitions the Board and requests that the suspension of its parenteral permit be stayed and that it be allowed to perform sterile compounding upon a showing that the resumption of sterile compounding would not put the public at risk (*i.e.*, a showing that all sterile compounding will be performed in compliance with the BOP's Rules on Good Compounding Practices for Sterile Products); and;
- Respondent was fined a total of $20,000.

Because of the BOP's indefinite suspension of the firm's parenteral permit, these deviations no longer appear to present a risk and FDA does not intend, at this time, to take further action with regard to the findings of this inspection. Therefore, FDA is leaving this matter with the BOP to ensure appropriate corrective action is implemented.

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 further violations of Federal law. In addition, we request that you notify us if you stay the suspension of this firm's parenteral permit, allowing it to resume production of sterile drug products.

We appreciate BOP's swift and effective actions in this matter, and we look forward to continuing to work with you on the oversight of compounding pharmacies. If you have additional questions, please contact Rose M. Ashley, Compliance Officer, at 210-308-1407, or by email at rose.ashley@fda.hhs.gov.

Sincerely,

Reynaldo R. Rodriguez, Jr.
District Director
Dallas District Office

RRR/chm

enc: Redacted Form FDA 483