DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3128

UPS OVERNIGHT MAIL

March 18, 2014

Gay Dodson, R.Ph.
Executive Director
Texas State Board of Pharmacy
William P. Hobby Building
Tower 3, Suite 600
333 Guadalupe Street
Austin, TX 78701

Dear Ms. Dodson:

The purpose of this letter is to refer to the Texas 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 Texas BOP, Maxor National Pharmacy Services Corporation, d/b/a IV Solutions of Lubbock (IV Solutions), located at 3706-A 20th Street, Lubbock, TX.

FDA inspected the firm from March 18, 2013 to March 20, 2013. FDA's investigators were accompanied by a Texas State BOP inspector for one day of the inspection. Attached is a redacted copy of a Form FDA 483 that documents our investigators' observations from the inspection.

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by IV Solutions 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. In the April 2, 2013 response to the Form FDA 483, the firm advised FDA that "All medications are issued to patients based on a patient-specific prescription, including all compounded medications."[1]

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 firm's program to ensure that each process used is able to produce sterile product without contamination and to evaluate the competency of all personnel who engage in these operations is inadequate. For example, personnel do not perform media fills under conditions that closely simulate the most challenging or stressful conditions encountered during routine aseptic operations.

[1] See attached response letter dated April 2, 2013, from Carl Birdsong, President to Reynaldo R. Rodriguez Jr. Dallas District Director.

2. The firm failed to establish an adequate system for maintaining equipment used to control the aseptic conditions. For example, the firm's "ISO 5" hood rests on a workbench constructed from particleboard with a laminated surface that is exposed. Laminate is difficult to clean so as to maintain a sterile surface. In addition, prolonged contact time with a disinfectant or cleaning agent (i.e., hypochlorite bleach) can damage the surface making it more likely to become contaminated.

3. The firm does not adequately maintain air quality by ensuring a proper air flow from areas of higher cleanliness to adjacent less clean areas by measuring pressure differentials between clean rooms continuously.

IV Solutions committed to FDA in its April 2, 2013 response to the Form FDA 483 to correct some of the deviations. In addition, the deviations identified appear to be readily correctible.

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 Texas 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 Shari Shambaugh, Director, Compliance Branch at 214-253-5215, or by email at shari.shambaugh@fda.hhs.gov.

Sincerely,

Reynaldo R. Rodriguez, Jr.
Dallas District Director

RRR/pbs

enc.
Response letter dated April 2, 2013
Redacted FDA 483