



Dallas District Office  
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Dallas, Texas 75204-3128

**May 5, 2016**

**VIA UPS Express**

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

Dear Ms. Dodson:

The purpose of this letter is to refer to the Texas 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 Texas BOP, Home Intensive Care Pharmacy, Inc., located at 7220 Louis Pasteur Drive, San Antonio, TX 78229 (Community Sterile Compounding Pharmacy #11247).

FDA inspected the firm from April 20, 2015, to May 5, 2015. The Texas State BOP was informed of the inspection but did not accompany FDA investigators during the inspection. A redacted copy of a Form FDA 483 (FDA 483) that documents our investigators' observations from the inspection can be found at:  
<http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORAElectronicReadingRoom/UCM454888.pdf>

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by Home Intensive Care Pharmacy, 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 firm used non-sterile wipes to clean and disinfect the ISO 5 hoods where drug products are prepared.
2. The operators did not sanitize components and materials prior to introducing them into the ISO 5 hoods.

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Re: Home Intensive Care Pharmacy, Inc.  
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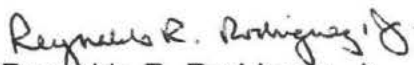
3. An operator was observed resting <sup>(b) (6)</sup><sub>(b) (7)</sub><sub>(c)</sub> arms on the work bench inside the ISO 5 area during sterile production. At the time of the inspection, the firm's general gowning requirements left exposed skin around the eyes, forehead and neck of the operator. The firm did not exercise proper gowning technique and operators did not wear goggles to ensure safety and sterility of the sterile drug product.

Home Intensive Care Pharmacy, Inc. committed to FDA in its response to the FDA 483 to correct the deviations in the FDA 483. In addition, the deviations identified appear to be readily correctable. However, in response to the use of non-sterile wipes, the firm stated they "will review its current policies and ascertain whether changes are needed concerning the use and type of sterile wipes."

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 John W. Diehl, Compliance Officer, at (214) 253-5288.

Sincerely,

  
Reynaldo R. Rodriguez, Jr.  
Dallas District Director

CC:

Carol Fisher, R.Ph., M.P.A.  
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