U.S. FOOD & DRUG ADMINISTRATION

May 14, 2018

UPS Overnight

Malcolm J. Boussard, Executive Director
Louisiana State Board of Pharmacy
388 Brentwood Drive
Baton Rouge, LA 70809-1700

Dear Mr. Boussard:

The purpose of this letter is to refer to the Louisiana 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 Louisiana BOP, First Call IV Pharmacy LLC, located at 1500 Veterans Memorial Blvd, Kenner, Louisiana 70062 (Pharmacy License #PHY.004950-IR; expires 12/31/18).

FDA inspected the firm from July 25, 2017, to August 2, 2017. Louisiana 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/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm573915.pdf, 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 First Call IV Pharmacy, LLC 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. In the response to the Form FDA 483, received on October 19, 2017, the firm advised FDA that it "engages in the compounding of patient-specific sterile preparations per physician's prescriptions using only FDA approved ingredients." The firm also stated that " No bulk compounding, manufacturing or 503B activities are engaged in."

During the inspection, the FDA investigator observed deviations from appropriate sterile practice standards that, if not corrected, could lead to contamination of drugs,

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potentially putting patients at risk. Examples of deviations observed during our inspection include:

1. An operator's bare hands being exposed within the ISO 5 work area while donning gloves in preparation for sterile drug production. In addition, operators were observed leaning into the ISO 5 work area, exposing hair and skin, as they performed aseptic production.

2. Failure to sanitize materials prior to transferring them into the ISO 7 sterile production room.

3. Materials flowed into the ISO 7 sterile production room from an unclassified area via a pass-through window.

4. Failure to disinfect the aseptic processing areas with a sporicidal agent at an adequate frequency.

First Call IV Pharmacy, LLC committed to FDA in its responses received on October 19, 2017, and December 20, 2017, to correct the deviations in the Form FDA 483 and provided documentation in support of those corrective actions. In addition, the deviations identified appear to be readily correctable.

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 Louisiana 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 Rebecca Asente, Compliance Officer, at 504-846-6104, or via email at Rebecca.Asente@fda.hhs.gov.

Sincerely,

John W. Diehl -S

Digitally signed by John W. Diehl -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=John W. Diehl -S, 0.9.2342.19200300.100.1.1=2000099727
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LCDR John W. Diehl, M.S.
Director, Compliance Branch
Office of Pharmaceutical Quality Operations, Division II