March 5, 2018

VIA UPS EXPRESS

John C. Kirtley, Pharm.D.
Executive Director
Arkansas State Board of Pharmacy
322 South Main Street, Suite 600
Little Rock, Arkansas 72201

Dear Dr. Kirtley:

The purpose of this letter is to refer to the Arkansas 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 Arkansas BOP, Lincare, Inc., dba United Medical Home Infusion, located at 1527 S. Bowman Road, Suite D, Little Rock, AR 72211-4200 (retail pharmacy license #AR20245).

FDA inspected the firm from August 14, 2017, to August 22, 2017. The Arkansas 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/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM575866.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 Lincare, Inc., dba United Medical 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.

During the inspection, the FDA investigator also observed deviations from appropriate

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aseptic practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Specifically, the firm was using a non-sterile disinfecting agent in the ISO 5 areas.

Lincare, Inc., dba United Medical Home Infusion, committed to FDA in its response to the Form FDA 483, received October 27, 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 Arkansas 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 by 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
Date: 2018.03.05 15:29:49 -06'00'

LCDR John W. Diehl, M.S.
Director, Compliance Branch
Office of Pharmaceutical Quality Operations, Division II

Cc: Gregory McCarthy, CEO
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Clearwater, Florida 33764-3102

Chelsey Chandler, Center Manager
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