December 21, 2017

Gay Dodson, RPh, Executive Director/Secretary
Texas State Board of Pharmacy
William P. Hobby Building, Suite 3-500
333 Guadalupe Street
Austin, Texas 78701

CMS #542930

RE: FDA Inspection of Healix Infusion Therapy, Inc.

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, Healix Infusion Therapy, Inc., now located at 1330 Industrial Blvd., Suite 100, Sugar Land, Texas 77478-2576 (Community Sterile Pharmacy License #20668).

FDA inspected the firm from September 1, 2016, to September 14, 2016, at its former location at 1075 W. Park One Dr., Suite 200, Sugar Land, Texas 77478. The Texas 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/UCM521750.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 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 Healix 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 firm's response to the Form FDA

483,[1] dated September 28, 2016, the firm stated that it "[provides] only patient-specific prescriptions in accordance with federal guidelines for operation of 503A pharmacies."

During the inspection, the FDA investigator observed a deviation from appropriate sterile practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Specifically, the firm used two non-sterile disinfectants in the ISO 5 aseptic processing areas. However, Healix committed to FDA in its above noted written response to correct the deviation in the Form FDA 483. In addition, the deviation identified appears 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 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 Thao Ta, Compliance Officer, at 214-253-5217, or by email at Thao.Ta@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: 2017.12.21 15:28:04 -06'00'

John W. Diehl
Acting Director, Compliance Branch
Office of Pharmaceutical Quality Operations, Division II

Enclosure:
Healix's 483 response, dated September 28, 2016
Establishment Inspection Report (EIR)

[1] See attached the firm's response to the Form FDA 483, dated September 28, 2016, from Lucinda J. Van Anglen, B.S., Pharm.D., Vice President of Pharmacy.