



December 21, 2017

Mark G. Winters
Chief Operating Officer and Vice-President of Operations
Healix Infusion Therapy, Inc.
1330 Industrial Blvd., Suite 100
Sugar Land, Texas 77478-2576

CMS #542930

Mr. Winters:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility, Healix Infusion Therapy, Inc., previously located at 1075 W. Park One Dr., Suite 200, Sugar Land, Texas 77478, from September 1, 2016, to September 14, 2016, by the U.S. Food and Drug Administration (FDA). In addition, we are enclosing the letter sent to the Texas State Board of Pharmacy for follow-up.

When the Agency considers an inspection to be "closed" under 21 C.F.R. 20.64(d)(3), it will release a copy of the EIR to the inspected establishment and we have enclosed a copy with this letter. The Agency continually works to make its regulatory process and activities more transparent for regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the Freedom of Information Act (FOIA) and 21 C.F.R. Part 20. This, however, does not preclude you from requesting and possibly obtaining any additional information under FOIA.

If there is any question about the released information, 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
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ou=FDA, ou=People, cn=John W. Diehl -
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Date: 2017.12.21 15:29:57 -06'00'

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

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