



U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations III
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February 23, 2018

UPS NEXT DAY

Stacey Sekutowski
Regional Pharmacy Manager
Heartland I.V. Care
1400 Energy Park Drive, Suite 17
Saint Paul, MN 55108-5272

Dear Ms. Sekutowski:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility, Heartland I.V. Care, located at 1400 Energy Park Drive, Suite 17, Saint Paul, MN 55108-5272, from July 10, 2017 to July 14, 2017, by the U.S. Food and Drug Administration (FDA). In addition, we are enclosing the letter sent to the Minnesota 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 Brian D. Garthwaite, PhD, Compliance Officer, at 612-758-7132 or by email at: ORAPHARM3_RESPONSES@fda.hhs.gov.

Sincerely,

**Nicholas F.
Lyons -S**

Nicholas F. Lyons
Compliance Director
Division of Pharmaceutical Quality Operations III

Digitally signed by Nicholas F. Lyons -S
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ou=FDA, ou=People,
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cn=Nicholas F. Lyons -S
Date: 2018.02.23 12:35:01 -06'00'

Enclosure: EIR and State Referral Letter