



U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations III
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July 1, 2019

UPS NEXT DAY
SIGNATURE REQUIRED

Lee R. Boyd
General Manager
Infuscience, Inc.
2915 Waters Road, Suite 110
Eagan, MN 55121-1562

Dear Mr. Boyd:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility, Infuscience, Inc., located at 2915 Waters Road, Suite 110, Eagan, MN 55121-1562, from April 17, 2018, to April 25, 2018, 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.

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 Eric Mueller, Compliance Officer, at (402) 331-8536 ext. 101 or by email at: ORAPHARM3_RESPONSES@fda.hhs.gov.

Sincerely,

Nicholas F. Lyons

-S

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

Digitally signed by Nicholas F. Lyons -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA,
ou=People, 0.9.2342.19200300.100.1.1=1300120033,
cn=Nicholas F. Lyons -S
Date: 2019.07.01 14:14:43 -05'00'

Enclosure: EIR, State Referral Letter