



U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations III
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June 13, 2019

UPS NEXT DAY
SIGNATURE REQUIRED

Stanley S. Kent, R.Ph.
Chief Pharmacy Officer
Michigan Medicine
1500 E. Medical Center Drive
Ann Arbor, MI 48109-5008

Dear Mr. Kent:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility, Michigan Medicine, located at 1500 E. Medical Center Drive, Ann Arbor, MI 48109, from December 3, 2018 to December 14, 2018, by the U.S. Food and Drug Administration (FDA). In addition, we are enclosing the letter sent to the Michigan 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 Tina Pawlowski, Compliance Officer, at (313) 393-8217, 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
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: 2019.06.13 13:13:39 -05'00'

Enclosure: EIR, State Referral Letter