



U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations III
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June 14, 2018

UPS NEXT DAY

David J. Miller, R.Ph., Ph.D.
Co-owner
Keystone Pharmacy
4021 Cascade Road SE, Ste.50
Grand Rapids, MI 49546

Dear Dr. Miller:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility, Keystone Pharmacy, located at 4021 Cascade Road SE, Ste. 50 Grand Rapids, MI 49546, from October 17, 2017, to November 3, 2017, 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 CFR 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 CFR 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, Ph. D., 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
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People,
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cn=Nicholas F. Lyons -S
Date: 2018.06.14 12:19:25 -05'00'

Enclosure: EIR and State Referral Letter