



U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations I
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March 25, 2020

Ms. Deepa Jacob
Pharmacist In Charge
Keystone Rx LLC
3070 Bristol Pike
Building 2, Suite 216-b
Bensalem, PA 19020

Dear Ms. Jacob:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility, Keystone Rx LLC, located at 3070 Bristol Pike, Building 2, Suite 216-B, Bensalem, PA 19020-5364 from July 8, 2019, to July 12, 2019, by the U.S. Food and Drug Administration (FDA). In addition, we are enclosing the letter sent to the Pennsylvania 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 CDR James Mason, via email at james.mason@fda.hhs.gov or by phone at (570) 262-0519.

Sincerely,
Stephanie
T. Durso -S

Digitally signed by Stephanie T. Durso -S
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People,
0.9.2342.19200300.100.1.1=1300194209,
cn=Stephanie T. Durso -S
Date: 2020.03.25 11:03:58 -04'00'

Stephanie Durso
Compliance Branch Director
Office of Pharmaceutical Quality Operations
Division I/New Jersey District Office

Enclosure: EIR, SRL

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